BOARD OF REGENTS
UNIVERSITY OF MINNESOTA

Audit Committee

June 2015

June 11, 2015

10:00 a.m. - 12:00 p.m.

East Committee Room, McNamara Alumni Center

AUD - JUN 2015

BOARD OF REGENTS
DOCKET ITEM SUMMARY

Audit **June 11, 2015**

Agenda Item: Internal Audit Plan

☐ **Review** ☐ **Review + Action** ☐ **Action** ☒ **Discussion**

☒ *This is a report required by Board policy.*

Presenters: Gail Klatt, Associate Vice President, Internal Audit

Purpose & Key Points

The recommended Internal Audit plan for FY 2016 is risk-based and continues to reflect the principles of the Integrated Framework of Internal Control. The plan includes 25 audits of University processes and units, and the review of several significant business processes that have been directly impacted by the Enterprise System Upgrade. Additionally, significant audit attention is planned for units involved with human subject research to assist in informing the Audit Committee as it carries out its monitoring responsibilities of the administration's Implementation Plan.

Selection of activities for inclusion in the annual audit plan also considered alignment with the Institutional Risk Profile and well-balanced coverage across the University. Audit resources have also been reserved for administrative/special requests and investigative audit needs.

Background Information

The Audit Committee is delegated the responsibility to review the annual internal audit plan on behalf of the Board of Regents in conformance with Board of Regents Policy: *Audit Committee Charter* and Board of Regents Policy: *Board Operations and Agenda Guidelines.*

FISCAL YEAR 2016
INTERNAL AUDIT ANNUAL PLAN

PURPOSE OF THE ANNUAL PLAN

The annual internal audit plan is intended to demonstrate:

- the breadth and depth of audit activities addressing financial, operational, compliance, strategic, and reputational risks of the University;
- accountability for our resources; and
- the progress in our efforts to continually improve the University's Internal Audit program.

It is our intent to convey a current sense of the University's internal control environment and the extent to which institutional risk mitigation is being assessed by regular audit activities, addressed proactively through advisory services, or investigated as a result of issues raised.

DEVELOPMENT OF THE ANNUAL PLAN

The development of the annual audit plan is based on information gathered through broad consultation across the University and a formal assessment of existing and emerging risks. We also do a scan to identify areas of emphasis at relevant federal agencies and use a survey of other research universities regarding the assessment of risks within their institutions.

External Risk Assessment / Scan of the National Landscape of Higher Education

Regulatory Agencies: The federal regulatory agencies that have significant involvement with University activities continue to be highly focused on the implementation of the **Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards** issued in December 2014, both internally within the agencies themselves, as well as by their grantees.

Research Universities: Our survey of other research universities identified four consistently cited areas of risks being overseen by the governing boards: leadership succession planning and transition, IT security, reputational risks, and student/campus safety.

Internal Risk Assessment

As part of the planning process, we held individual discussions with each member of the Board of Regents to identify areas of risks/ concerns at the governance level for audit consideration. The risks most often identified in these discussions were:

- Human subject research
- Board governance practices
- MN Health
- Succession planning for institutional leadership positions
- Autonomy
- Public relations and communications

We also held discussions with 86 institutional officials from 40 units to solicit input on the University's institutional risks and any specific areas of concern. Themes which emerged from these discussions included the risks associated with 1) developing a field shaping workforce in light of the University's demographics, including succession planning for key employee turnover, faculty recruitment and retention commitments, etc., 2) the impact of continued administrative cost re-allocations and reductions and rising cost pool charges on collegiate/unit finances, and 3) regulatory compliance concerns associated with Title IX and human subject research.

Operational Risk Assessment

Finally, our annual planning process includes re-examining the audit universe to ensure that all university activities are considered when determining how audit resources will be allocated. We also consider new regulatory developments, new business processes, and institutional priorities and strategic initiatives.

The Office of Internal Audit continues to utilize a formalized risk assessment methodology in selecting processes/units/systems for inclusion in the annual audit plan. Relative risk assessment is necessary to provide a basis for the rational deployment of our limited resources across the institution. The risk factors that we considered in prioritizing institutional activities are:

- Impact on the University's mission
- Impact on University finances
- Assessment of the activity's control environment
- Level of compliance concerns
- Impact of information technology
- Complexity and/or diversity of the activity
- Changes in the organization or leadership

Our operational risk assessment resulted in a risk ranking of 175 individual auditable activities, of which 19 are considered to be high risk, 103 moderate risk, and 53 low risk. A rating of "high-risk" does not mean that the activity is perceived to have control problems, but rather reflects the criticality or centrality of the activity to the University's mission.

OVERALL RISK ASSESSMENT AND IMPACT ON THE FY2016 AUDIT PLAN

The primary focus of the FY2016 audit plan is two-fold. First, carrying out the requisite audit work to appropriately inform the Audit Committee's monitoring of the Human Subject Research Implementation Plan. This work will be conducted as both targeted reviews as well as by testing of human subject research activities within individual unit audits. Second, the audit plan includes audits of several

significant business processes now that the Enterprise Upgrade is complete. This will allow us to evaluate the impact of the Upgrade on the efficiency and effectiveness of these processes and their related controls.

Additionally, the FY 2016 audit plan includes continued attention on activities within the Academic Health Center.

ALLOCATION OF AUDIT RESOURCES

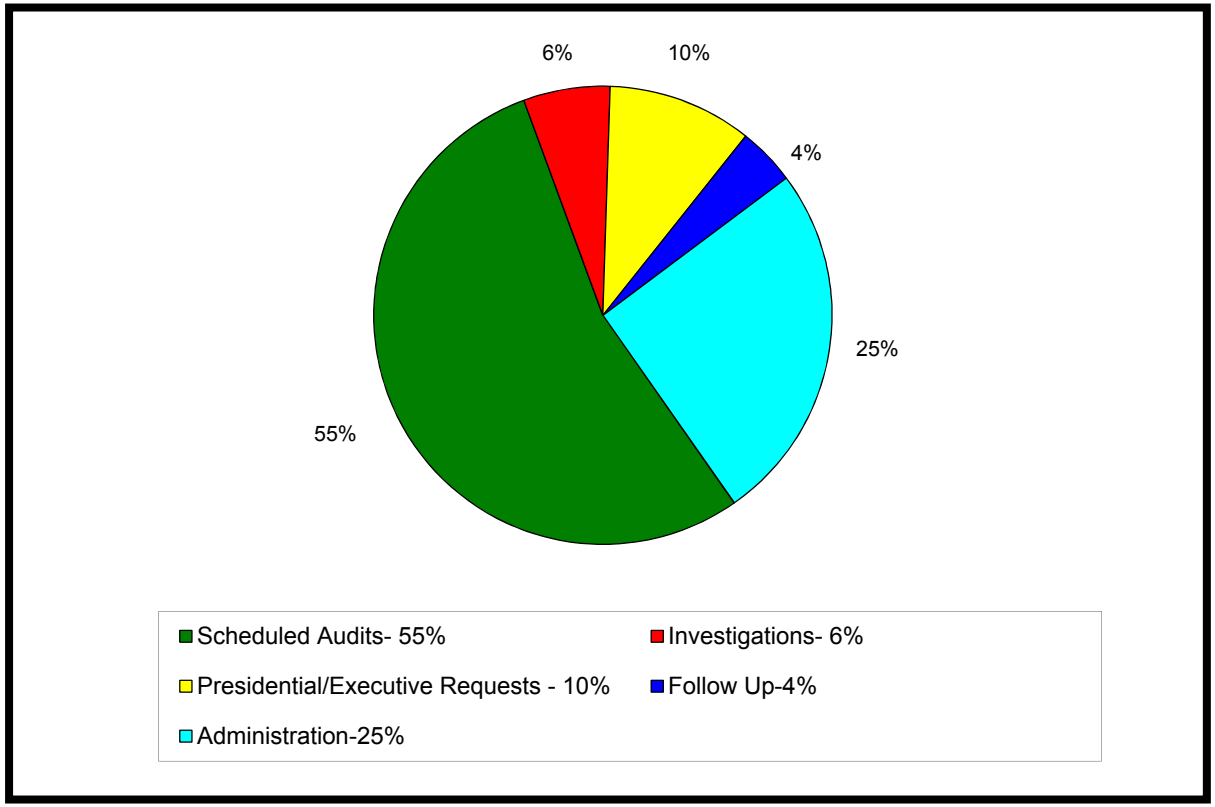
The audit plan is based on a planned staffing complement of 15.5 FTE professionals, which is our full complement.

Approximately 55% of the Office of Internal Audit's resources are committed to the completion of planned audit projects. This year 4% of those resources will be needed to complete carry-over work from our FY 2015 audit plan. Seven audit projects are currently in process and will be completed in FY 2016.

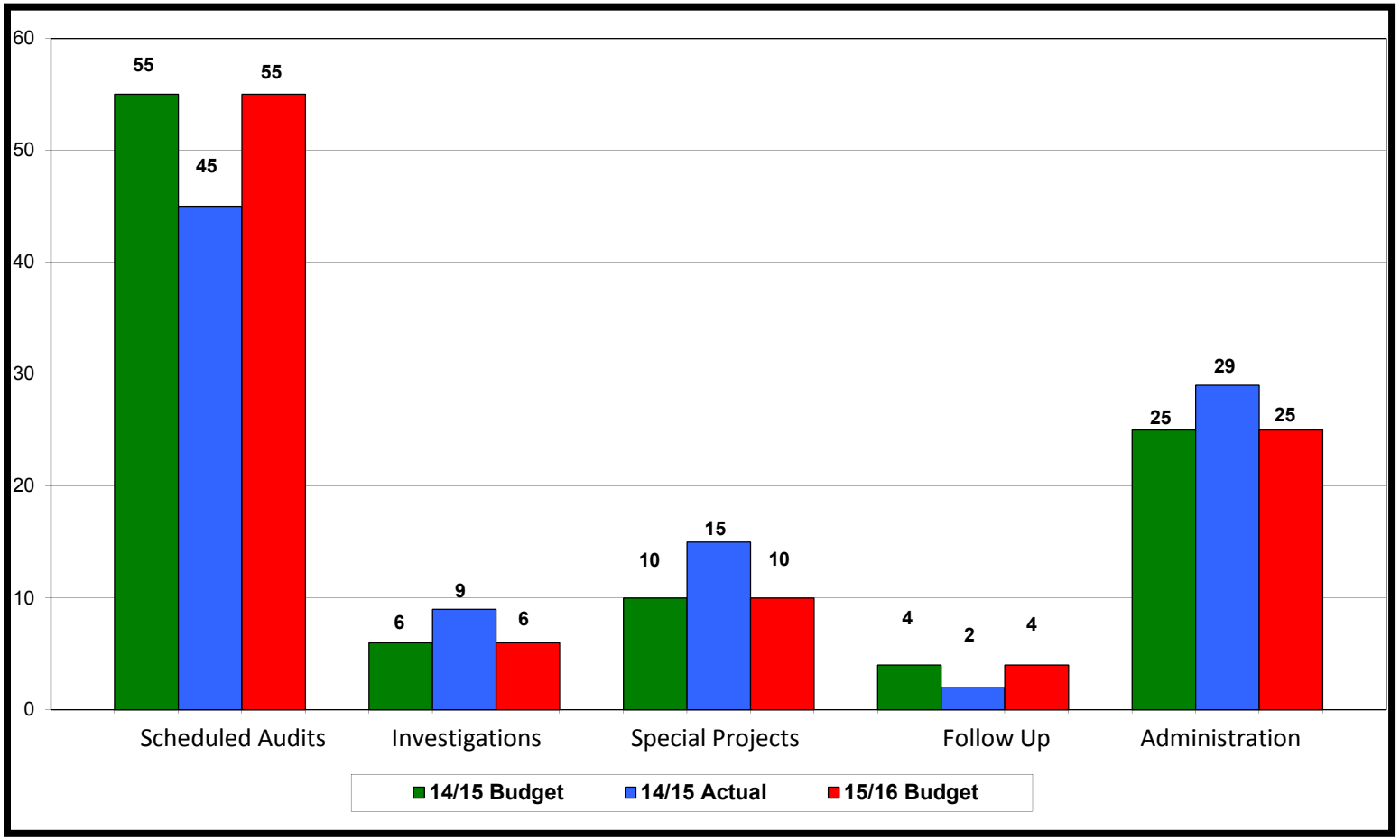
The remainder of our FY 2016 audit resources is reserved as follows:

- 10% has been reserved to accommodate requests from the President, the Board, or members of the senior leadership team. This has been supported by the Audit Committee. The number of hours remains consistent from previous years.
- 6% has been reserved for investigations. The number of hours remains consistent from previous years.
- 4% has been reserved for follow-up procedures performed on behalf of the Audit Committee. The number of hours remains consistent from previous years.
- 25% has been set aside for internal administrative functions, including our continuous improvement efforts. This remains consistent with the previous year.

FY 2016 PLANNED ALLOCATION OF AUDIT RESOURCES



COMPARSION OF AUDIT RESOURCES FOR FY 2015 AND FY 2016
Percent of Available Time



RELIANCE ON OTHER PROVIDERS

To avoid duplication of work and additional burden on University staff, we continue to place reliance on audit related work performed by other service providers. We rely on the external audit work performed by Deloitte and Touche, LLP in the areas of investments, annual external financial reporting, and RUMINCO, the University's captive insurance company. We also rely on the audit work performed by external construction audit firms engaged by the University's Capital Planning and Project Management (CPPM) unit for construction projects that are delivered using the Design/Build or the Construction Manager at Risk delivery methods. We are in agreement with the scope of this audit work and receive and review copies of their reports.

FY 2016 AUDIT PLAN

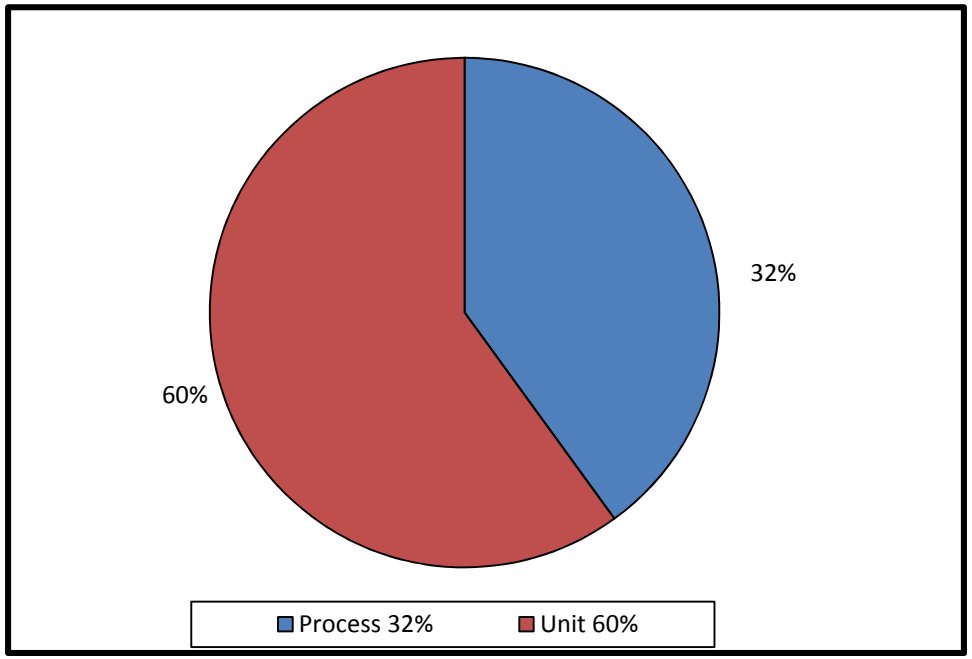
Taking into consideration the risks identified externally as well as internally, and balancing all of the above with our available resources, the audit plan recommended for FY 2016 includes the following:

Audits Planned for FY 16	Process/Unit	Risk Area(s) Covered
High Risk Audits:		
Purchasing Card Process	Process (1)	Higher Education Operating Model*, Financial Management, Technology, Compliance
Non-Sponsored Accounts Receivable	Process (1)	Higher Education Operating Model*, Financial Management, Technology, Compliance
Vendor Payment Process	Process (1)	Higher Education Operating Model*, Financial Management, Technology, Compliance
PCI	Process (1)	Data Privacy/Security*, Higher Ed Operating Model*, Financial Management, Technology, Compliance
Boynton Health Services	Unit	Technology, Student Experience, Financial Management, Compliance
School of Dentistry	Unit	Research, AHC, Financial Management, Compliance, Private Practice, Technology
Human Subjects (TBD)	Process (1)	Human Subject Research*, Research, AHC, Compliance, Technology
Athletics (TC) Financial	Unit	Athletics*, Financial Management, Student Experience, Technology
Athletics (TC) Sport Compliance	Unit	Athletics*, Compliance, Student Experience, Student-Athlete Health and Safety
Human Resource Processes	Process (1)	Technology, Compliance, Financial Management
Student System Processes	Process (1)	Technology, Student Experience, Financial Management
PeopleSoft IT: General Controls, Infrastructure & Governance	Process	IT Infrastructure*, Technology
Moderate Risk Audits:		
College of Design	Unit	Financial Management, Research, Compliance, Leadership Transition, Technology
CSE – Electrical & Computer Engineering	Unit	Financial Management, Research, Compliance, Technology
Law School	Unit	Financial Management, Research, Compliance, Technology
CUHCC	Unit	Financial Management, Compliance, Technology, AHC
Cancer Center	Unit	Federal Research Funding*, Financial Management, Research, Compliance, AHC, Technology
Epidemiology	Unit	Federal Research Funding*, Financial Management, Research, Compliance, AHC, Technology

Audits Planned for FY 16	Process/Unit	Risk Area(s) Covered
UMD Housing	Unit	Campus Safety, Financial Management, Student Experience, Technology
UMD CEHSP	Unit	Financial Management, Research, Compliance, Technology
UMD NRRI	Unit	Federal Research Funding* Financial Management, Research, Technology
OIT Database Administration	Unit	IT Infrastructure*, Research, Technology
Auxiliary Services IT	Unit	IT Infrastructure*, Technology
MN Drive	Process (1)	State Funding*, Research, Financial Management, Compliance, Technology
Review of Faculty Retention/Set-Up/Award	Process (1)	Attracting and Retaining Talent*, Financial Management
Low Risk Audits:		
None		

* This risk is included on the Institutional Risk Profile (Appendix A)
(1) Testing in individual units is planned during this process audit

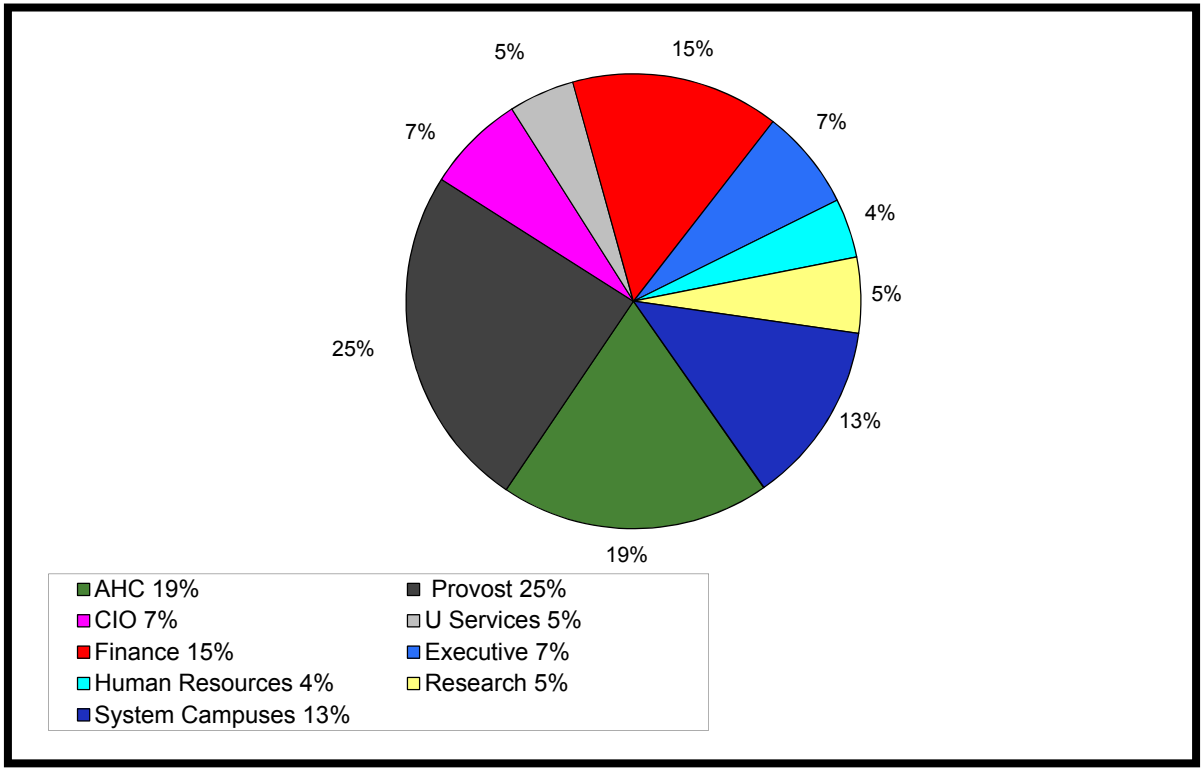
FY 2016 AUDITS BY TYPE OF AUDIT



The proposed audit plan is comprised of 10 process audits (40%) and 15 unit-based audits (60%). Nine (90%) of the process audits will involve unit-level audit testing. Six of the process audits are considered high risk. The proposed audit plan also includes significant coverage of selected risks included on the Institutional Risk Profile (see Appendix A).

The FY 2016 plan continues to provide well-balanced coverage across the University. The following chart shows the distribution of audit coverage by University component for FY 2016, based on the number of hours allocated to each component.

FY 2016 AUDIT COVERAGE BY UNIVERSITY COMPONENTS



FY 2015 RESULTS

For FY 2015, we will have issued 20 audit reports which were the result of planned reviews and requests from management (See Appendix B).

In addition,

- Eight audits are currently in the planning or fieldwork stages and will be completed in FY 2016.
- Three audits were deferred to FY 2016.
- Five audits were not completed due to limited audit resources

During the past fiscal year we conducted 18 investigations into financial or operational misconduct. Where appropriate, we have partnered with the University Police or the Office of the General Counsel to complete these reviews.

We had 1500 fewer hours of audit resources than was planned as a consequence of turnover and the elapsed time required to recruit and onboard new employees.

INDEPENDENCE

There were no incidences during the year in which the independence or scope of internal audit work was restricted in any way.

COORDINATION WITH EXTERNAL AUDITORS

The Office of Internal Audit continues to coordinate its audit plan with the University's external auditors to ensure appropriate coverage is achieved through the internal and external audit plans and to leverage the collective efforts of both organizations. The Office of Internal Audit meets the professional standards required by external auditors to place reliance on internal audit work. We also rely on the work performed by Deloitte and Touche, LLP in the areas of investments, annual external financial reporting, and RUMINCO, the University's captive insurance company.

COORDINATION WITH OTHER INTERNAL RESOURCES

The Office of Internal Audit coordinates its work with other internal units to maximize the quality of audit coverage provided as well as to promote prompt attention when University-wide trends are identified. We have established strong working relationships with the University's Compliance Officer, the Office of Research Education and Oversight, the Human Research Protection Program, the Department of Environmental Health and Safety, and the Office of the General Counsel, each of which work closely with us during audits involving complex regulatory issues.

The Office of Internal Audit interfaces regularly with the Institutional Compliance Officer and we serve on the Executive Compliance Oversight Committee. Input from the Compliance Officer is solicited during our annual audit planning. In addition, throughout the year we report to and collaborate with the Compliance Officer on issues identified during our audits. We also share the results of employee surveys with the Compliance Officer. During fiscal year 2015, a total of 1134 employee surveys were sent out as part of our audit process, with a 70% response rate. Along with the Office of Institutional Compliance, we serve as a triage office for managing U Report, the University's confidential reporting line.

Audit results are also shared with central support units such as the Office of Information Technology, Sponsored Projects Administration, Payroll, Controller's Office, Training Services, and Human Resources when policy non-compliance or when the need for process enhancements are identified. Best practices identified in local unit audits are also shared with these central unit process owners for consideration of broader adoption.

STAFF DEVELOPMENT, QUALIFICATIONS AND PROFESSIONAL INVOLVEMENT

The Office of Internal Audit is committed to providing educational opportunities to our staff in order to enhance our audit knowledge and abilities and to achieve our professional best. Ever-changing government regulations, new technologies, and new developments in auditing principles and methods dramatically affect not only what we audit, but also how we audit. We constantly strive to stay abreast of new developments and improve our audit proficiency in order to enhance the overall quality of our audits. To accomplish this, we pursue a variety of methods to continue our staff's professional education.

Our departmental memberships with the Institute of Internal Auditors (IIA), the Association of College and University Auditors (ACUA), the Association of Certified Fraud Examiners (ACFE), the American Institute of Certified Public Accountants (AICPA), and the Information Systems Audit and Control Association (ISACA) provided staff members the opportunity to attend seminars and conferences that specifically address current issues and techniques in internal auditing. The interaction of our staff members with their peers through these professional organizations helps to keep us up-to-date on the latest auditing trends and issues affecting higher education.

All but one of the professional internal audit staff are professionally credentialed or hold advanced degrees. Specifically,

- Eleven have professional certifications of Certified Internal Auditors, Certified Public Accountants, Certified Information Systems Auditors and/or Certified Fraud Examiners;
- Two are certified in Risk Management Assurance;
- Three have Master of Business Administration degrees;
- One has a Master of Education degree;
- One has a Juris Doctor (law degree);
- Two have a Master of Public Policy degree; and
- Three are pursuing a professional certification.

In the first 10 months of FY 2015, the Office of Internal Audit provided almost 1200 hours of formal and informal training (an average of 103 hours for each employee). These hours do not include the time associated with completing coursework funded by the University's Regents Scholarship Program. We continue to provide the continuing professional development required to maintain the staff's professional credentials. For FY 2016, 1840 hours have been budgeted for formal staff training, an average of 115 hours per employee; this increase is to accommodate training needed for the planned implementation of a new data analytics platform.

PROFESSIONAL STANDARDS

The Office of Internal Audit conducts its work in accordance with the Institute of Internal Auditors' ***Standards for the Professional Practice of Internal Auditing.*** All of the audit staff is also required to comply with the Institute's ***Code of Conduct for Internal Auditors.***

INTERNAL QUALITY ASSURANCE PROGRAM

We have established an internal quality assurance program within the Office of Internal Audit. This program is structured around the robust supervision of audit staff and their work products. In addition, internal practices and tools are routinely evaluated for their

effectiveness and efficiency and changes are made when potential improvements are identified. Our quality assurance measures throughout the year confirmed our practices met the requirements of our professional ***Standards***.

EXTERNAL QUALITY ASSURANCE REVIEW

Our professional standards require that our audit practice undergo an external quality assurance review every five years. Our most current external review was conducted in February 2015 and determined that 1) our work was in full compliance with the ***Standards,*** and 2) University management and the Board of Regents can appropriately rely on the assurance provided by the work performed by the Office. The review team also opined that they had seldom been as impressed with an internal audit activity as they were with the Office of Internal Audit and the quality and level of performance they observed over all aspects of our practice.

OFFICE OF INTERNAL AUDIT FY 2016 STAFFING

We experienced 16% turnover (three positions) in FY 2015. This is consistent with our normal turnover rate of 13%. Two of the departures involved retirements. We have successfully filled all of the positions and will begin FY 2016 at a full staff complement.

OFFICE OF INTERNAL AUDIT BUDGET STATUS

The Office of Internal Audit received additional funding for a 2.0% compensation increase, consistent with the administration's pay plans. The Office's overall budget was reduced by $17,000 (.8%).

We appreciate the continued financial and operational support we receive from the administration.

University of Minnesota Institutional Risk Profile

The institutional risk profile is used to identify those risks of greatest import to the Board of Regents at a governance level. This profile is a synthesis of the committee's work in reviewing a broad range of risks identified by the administration over the last two years.

Likelihood	Low Impact	Moderate Impact	High Impact
High	G • Campus Safety & Security	D • Athletics: Program Integrity & Success of Business Model • IT Infrastructure & Costs • Managing Brand & Reputation	A • Autonomy • Attracting & Retaining Talent • Data Privacy/Security • Student Demographics & Enrollment Strategies
Moderate	H	E • Maximizing Value of Multiple Campuses • Meeting Expectations on Workforce Development • Preparedness of Students • Public Perception of the Value of Higher Education	B • Facilities: Strategic Needs & Aging Infrastructure • Federal Research Funding • Higher Education Operating Model • Human Subjects Research • Implementation of Strategic Plans • Prioritization: Balancing Breadth & Quality of Offerings • State Funding • UM Health Success
Low	I	F • Commercialization of Intellectual Property	C • Effective Communication

Audit Coverage

	FY 16			FY 16
Autonomy			Balancing Offerings	
Attracting and Retaining Talent	x		State Funding	x
Data Privacy/Security	x		UM Health	
Student Demographics/ Enrollment Strategies			Athletics	x
Federal Research Funding	x		IT Infrastructure & Costs	x
Higher Education Operating Model	x		Brand and Reputation	
Human Subject Research	x		Maximizing Multiple Campuses	
Strategic Plan Implementation			Perception of HE Value	
Student Preparedness			Effective Communication	
Workforce Development Expectations			Commercialization of Intellectual Property	
Campus Safety and Security	x			

The following addresses audit coverage based on the previous institutional risk profile:

Unit	FY 15	FY 14	FY 13	FY 12		Unit	FY 15	FY 14	FY 13	FY 12
Research- Infrastructure	x	x	x	x		Investments				
Individual Sponsored Projects	x	x	x	x		Leadership/Succession	x		x	
AHC	x	x	x	x		Student Experience	x	x	x	x
Athletics	x	x	x	x		Associated Organizations	x	x	x	x
Financial Management	x	x	x	x		Tech Transfer			x	
Technology	x	x	x	x		Campus Safety	x	x	x	x
Academic Quality			x	x		Strategic Decisions	x	x	x	x
Quality of Faculty/Staff	x	x	x	x		Asset Optimization	x	x	x	

Audits Completed

Moderate Risk

SAFL NSF Renovation Grant
Recreation & Wellness
Carlson School of Management
Executive Officer and Regent Expenses
Athletics ASPIRE Contract
Server Room Security
OIT Server Administration
Medical School Dept. Head Expense Review
Medical School Duluth
SimPORTAL & CREST
Technology Vendor Due Diligence
Ophthalmology and Visual Neurosciences
Review of Incentive Compensation

Low Risk

UMD Sea Grant
UMD University for Seniors
Baseline Tennis Center
Hormel Institute

System-Wide Audits/Reviews

A Review of Top University Researchers
Executive Officer and Regent Expenses
Environment and Natural Resources Trust Fund

Audit Effort Not Resulting in Audit Report

Monitoring of Enterprise Upgrade Project

Audits Started in FY15 but will be Completed in FY16

High Risk

Department of Medicine

Moderate Risk

College of Pharmacy
21st Century Fund Scholarships
CSE Deans Office
CFANS Deans Office
Clinical Translational Sciences Institute
UMD Athletics

System-Wide Audits/Reviews

Testing of UMF Transactions FY 15

Audits Deferred and in 2016 Audit Plan

Law School (1)
PCI Compliance (2)
OIT Database Administration (2)

Audits Not Completed

Facilities Management – Districts (1)
Review of Large Contract Negotiation (1)
Sponsored Projects Administration (2)
Athletics NCAA Compliance (3)
IT Security Risk Evaluation and Risk Mitigation (4)

(1)Insufficient audit resources available to complete the audit.
(2)Delayed due to ESUP impacts
(3)The four-year requirement for this review was eliminated by the NCAA this year. The University's NCAA Compliance Office intends to have an external peer review conducted. It was decided to wait until that review was performed and then re-evaluate the need for additional audit coverage.
(4)This audit was intentionally dropped from the audit plan as we determined that we could obtain sufficient audit evidence through other means.

2016 Internal Audit Plan

Office of Internal Audit

Board of Regents Audit Committee
June 11, 2015

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Topics

- Risk Assessment and Plan Development
- FY 2016 Audit Plan
- FY 2015 Audit Results

Office of Internal Audit Portfolio

- Audits
- Investigations/Special Projects
- Audit Advisory Services

Developing the Annual Plan

- External Risk Assessment
  - Survey of research-intensive universities
  - Review of regulatory agencies, externally conducted surveys, professional discussion groups, etc.
- Internal Risk Assessment
  - Discussions with administrative leadership
  - Discussions with Board members

Developing the Annual Plan

Operational Risk Assessment

- Assuring that all University activities have been accounted for, and included in a defined auditable activity
- Assessing each auditable activity against a set of defined risk factors

Operational Risk Factors

- Impact of activity on the University mission
- Impact of information technology
- Regulatory compliance issues
- Organizational change/turnover
- Complexity/diversity of operations
- Known or perceived control concerns
- Audit history
- Impact on University finances
- Assessment of activity's control environment

Operational Risk Assessment

175 auditable activities

- 19 high-risk activities
- 103 moderate-risk activities
- 53 low-risk activities

Overall Risk Assessment

Risks relevant for 2016

- Human subject research
- Review of business processes directly impacted by the Enterprise Upgrade
- Continued attention on AHC activities

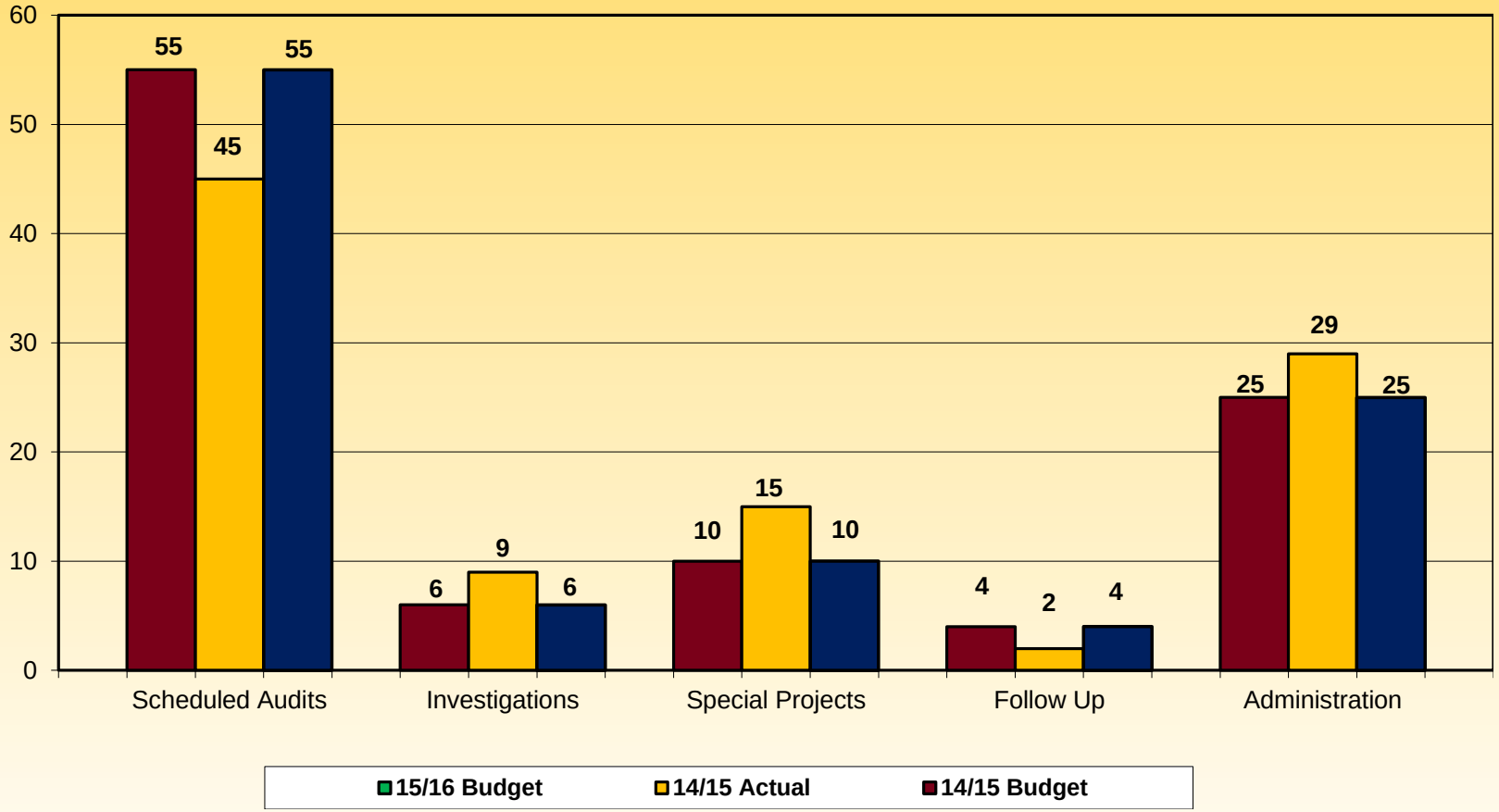
FY 2016 Allocation of Resources

- Scheduled Audits- 55%
- Investigations- 6%
- Presidential/Executive Requests - 10%
- Follow Up-4%
- Administration-25%

FY 2016 Allocation of Resources

COMPARSION OF AUDIT RESOURCES FOR FY 2015 AND FY 2016

Percent of Available Time

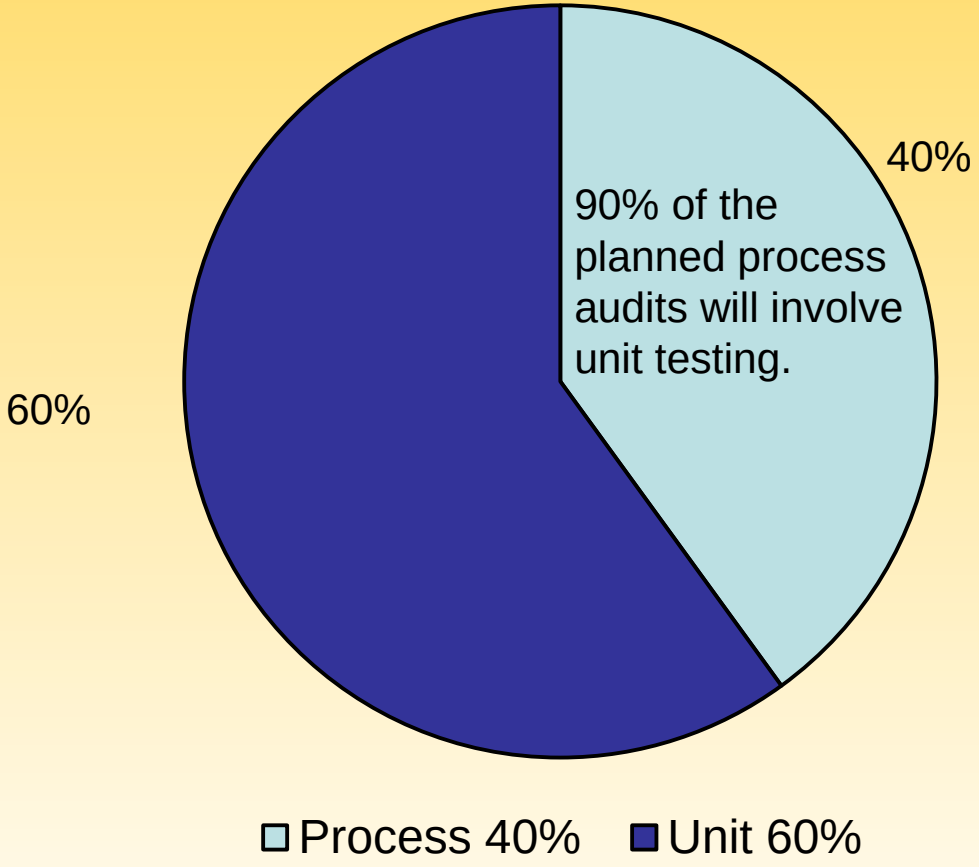


Deploying Audit Resources

We select activities for inclusion in the plan by considering and placing priority on coverage of:

- High-risk activities
- Major organizational components
- Institutional Risk Profile/ Risk Assessments
- Areas of strategic priority
- Management requests

FY 2016 Breakdown by Type of Audit



FY 2016 Audit Coverage by Major Component

- AHC 19%
- Provost 25%
- CIO 7%
- U Services 5%
- Finance 15%
- Executive 7%
- Human Resources 4%
- Research 5%
- System Campuses 13%

FY 2016 Audit Coverage by Major Component

U Services
Auxiliary Services IT

CIO
PeopleSoft Controls, Governance
OIT Database

Provost
Electrical/Computer Engineering
Law School
Boynton
ESUP Student System

Human Resources
ESUP HRMS

System Campuses
UMD CEHSP
UMD Housing
UMD NRRI

Finance
Vendor Payment Process
Pcard Process
Non-sponsored AR
PCI Compliance

Executive
Athletics Financial
Athletics Sport Compliance

Research
Human Subjects
MN Drive

AHC
CUHCC
Cancer Center
Dentistry
Epidemiology

FY 2016 Audit Coverage by Major Component

<u>U Services</u>
Auxiliary Services IT

<u>CIO</u>
PeopleSoft Controls, Governance
OIT Database

<u>Provost</u>
Electrical/Computer Engineering
Law School
Boynton
ESUP Student System

<u>Human Resources</u>
ESUP HRMS

<u>System Campuses</u>
UMD CEHSP
UMD Housing
UMD NRRI

<u>Finance</u>
Vendor Payment Process
Pcard Process
Non-sponsored AR
PCI Compliance

<u>Executive</u>
Athletics Financial
Athletics Sport Compliance

<u>Research</u>
Human Subjects
MN Drive

<u>AHC</u>
CUHCC
Cancer Center
Dentistry
Epidemiology

Institutional Risk Profile

The institutional risk profile is used to identify those risks of greatest import to the Board of Regents at a governance level. This profile is a synthesis of the committee's work in reviewing a broad range of risks identified by the administration over the last two years.

Likelihood	Low	Moderate	High
High	**G** • Campus Safety & Security	**D** • Athletics: Program Integrity & Success of Business Model • IT Infrastructure & Costs • Managing Brand & Reputation	**A** • Autonomy • Attracting & Retaining Talent • Data Privacy/Security • Student Demographics & Enrollment Strategies
Moderate	**H**	**E** • Maximizing Value of Multiple Campuses • Meeting Expectations on Workforce Development • Preparedness of Students • Public Perception of the Value of Higher Education	**B** • Facilities: Strategic Needs & Aging Infrastructure • Federal Research Funding • Higher Education Operating Model • Human Subjects Research • Implementation of Strategic Plans • Prioritization: Balancing Breadth & Quality of Offerings • State Funding • UM Health Success
Low	**I**	**F** • Commercialization of Intellectual Property	**C** • Effective Communication

Impact

Audit Coverage of Institutional Risks

Risk	FY 16		Risk	FY 16
Autonomy			Balancing Offerings	
Attracting and Retaining Talent	x		State Funding	x
Data Privacy/Security	x		UM Health	
Student Demographics/ Enrollment Strategies			Athletics	x
Federal Research Funding	x		IT Infrastructure & Costs	x
Higher Education Operating Model	x		Brand and Reputation	
Human Subject Research	x		Maximizing Multiple Campuses	
Strategic Plan Implementation			Perception of HE Value	
Student Preparedness			Effective Communication	
Workforce Development Expectations			Commercialization of Intellectual Property	
Campus Safety and Security	x			

The 2016 Audit Plan

- Provides reasonable audit coverage across all of the major components of the University.
- Addresses risks currently impacting the University.
- Addresses selective risk areas identified by the Audit Committee as important.

FY 2015 Audit Results

Our Commitment to Accountability

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Our Commitment to Accountability

The Office of Internal Audit is committed to its accountability for the professional conduct of its work.

- We conduct our work in accordance with the ***Standards for the Professional Practice of Internal Auditing*** and abide by our profession's ***Code of Conduct.***
- There were no restrictions on audit scope or interference with our independence during the year.

Quality Assurance Review Conclusions

We underwent a quality assurance review in February 2015

- *"University Management and the Board of Regents can appropriately rely on the assurance provided by the work performed by the Office of Internal Audit.*
- "*Our team, which collectively has extensive experience performing quality assessments, has seldom been as impressed with an internal audit activity as we were with the Office of Internal Audit."*

Our Commitment to Accountability

The Office of Internal Audit is committed to its accountability for the productive use of the resources provided by the University.

In FY 2015:

- ✓ 20 audits completed
- ✓ 8 audits currently in process
- ✓ 3 audits were deferred to FY 2016
- ✓ 5 audits were not completed due to lack of resources
- ✓ 18 investigations conducted

Our Commitment to Accountability

The Office of Internal Audit is committed to its accountability for the professional competence of its staff.

All but one professional staff are professionally certified or hold advanced degrees.

- Eleven are professionally certified as a CPA, CIA, CFE, or CISA
- Seven have master's or JD degrees
- Three are pursuing professional certification
- The audit staff has on average 15 years of audit experience

Our Commitment to Accountability

The Office of Internal Audit is committed to its accountability for the quality of the audit services we provide.

- We routinely benchmark our practices/ performance against other audit functions.
- We request a post-audit evaluation of our services after each audit.
- We have rigorous internal quality assurance processes in place.

Questions?

BOARD OF REGENTS
DOCKET ITEM SUMMARY

Audit **June 11, 2015**

Agenda Item: Internal Audit Update

☐ **Review** ☐ **Review + Action** ☐ **Action** ☒ **Discussion**

☒ *This is a report required by Board policy.*

Presenter: Gail Klatt, Associate Vice President, Internal Audit

Purpose & Key Points

The purpose of this item is to update the Audit Committee on Internal Audit activities, results, and observations to help the committee fulfill its fiduciary responsibilities under its reserved authority for oversight of the internal audit function, as outlined in Board of Regents Policy: *Audit Committee Charter*.

- Since the last follow-up (February 2015 meeting), University departments implemented 13 percent of the outstanding recommendations rated as "essential." This is significantly less than the expected implementation rate of 40 percent. Much of this low rate can be attributed to more than one-half of the recommendations being in audits receiving their first follow-up. Also, 50 percent of the remaining recommendations were not past their target implementation date. Three units fully implemented all their remaining "essential" recommendations.
- An updated control evaluation chart is included for each audit to show progress made on the "essential" items.
- Six audit reports containing 46 recommendations rated as "essential" were issued in the last four months.

Background Information

This report is prepared three times per year and is presented to the Audit Committee in conformance with Board of Regents Policy: *Audit Committee Charter* and Board of Regents Policy: *Board Operations and Agenda Guidelines.*

Internal Audit Update

University of Minnesota Regents Audit Committee
June 11, 2015

This report includes:

- Audit Observations/Information/Status of Critical Measures/Other Items
- Status of "Essential" Recommendations & Bar Charts Showing Progress Made
- Audit Activity Report
- Audit Reports Issued Since February 2015

Details for any of the items in this report are available on request. Individual reports were sent to the President, Provost, Vice Presidents, and Chancellors about these internal audit issues.

Audit Observations/Information

Status of Critical Measures

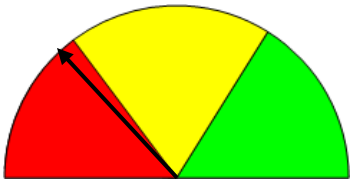
As part of our on-going efforts to provide the Audit Committee with critical information in as concise a format as possible, we have developed the following three charts to present a "snap-shot" status report on work performed by the Office of Internal Audit.

The first chart, "Essential Recommendation Implementation", provides our overall assessment of the success University departments had during the last quarter in implementing our essential recommendations. Readings in the yellow or red indicate implementation percentages less than, or significantly less than, our expected University-wide rate of 40%. Detailed information on this topic, both institution-wide and for each individual unit, is contained in the next section of this Update Report.

The second chart, entitled "Progress Towards Annual Audit Plan Completion", is our assessment of how we are progressing towards completion of the FY 2015 Annual Audit Plan. Readings less than green could be influenced by a variety of factors (i.e. insufficient staff resources; increased time spent on non-scheduled audits or investigations).

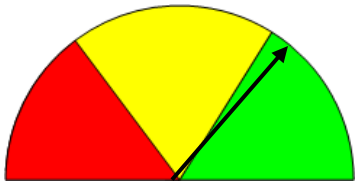
The final chart, "Time Spent on Investigative Activities", provides a status report on the amount of time consumed by investigative activities. Our annual plan provided an estimated budget for this type of work, and the chart will indicate if we expect that budget to be sufficient. Continued readings in the yellow or red may result in seeking Audit Committee approval for modifying the Annual Audit Plan.

Essential Recommendation Implementation



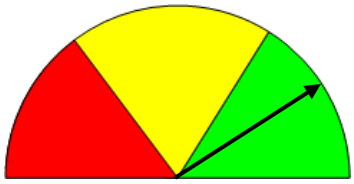
Implementation rates were 13% for the period, significantly less than our expected rate of 40%. 50% of the recommendations remaining have not yet reached their targeted implementation dates.

Progress Towards Annual Audit Plan Completion



Time spent to date on the FY 2015 audit plan is about what was expected and budgeted for the year to date.

Time Spent on Investigative Activities



Time spent on investigative activities and special projects is about what was expected and budgeted for the year to date.

<u>Other Items</u>

- We recently filled a vacant Senior Auditor position through the hiring of an auditor from the Mayo Clinic. A second vacant position has also been filled recently through the hiring of a May 2015 Carlson School of Management graduate student, who starts employment in mid-July.

- At the request of Vice President Brooks Jackson we conducted a joint project with the internal auditor for University of Minnesota Physicians (UMP). This work has provided us with a solid foundation for future joint work involving UMP, and perhaps Fairview.

- We will be completing a review of the conversion of data associated with the Enterprise Upgrade, which will assist Deloitte in completing this year's annual external audit.

- We are again performing non-scheduled audit work at the request of the Office of the Legislative Auditor. The current audit focus is the University's use of funds received from the Environment & Natural Resource Trust Fund. This work is expected to be completed by 6/30/15.

- We completed the last two audits (Incentive Compensation Programs and Executive and Regent Expenses) in a series of audits focused on governance activities. Other audits completed in previous periods included Legal Review of Contracts, Conflict of Interest Process, Code of Conduct, and compliance with Board of Regents Required Reporting.

- The Office of Internal Audit held three sessions, facilitated by the Office of Organizational Effectiveness, to discuss the University's strategic plan and how we can best align our work with the plan's objectives, strategies, and initiatives.

Status of "Essential" Recommendations as of May 29, 2015

Report Date	Audit **(P)** ***Indicates a University process audit***	Original Report Control Rating	# of Essential Recommendations in the Report	# of Essential Recommendations Remaining From Prior Quarter	Current Quarter Results					Overall Progress Towards Implementation*
					Implemented	Partially Implemented		Not Implemented		
						Not Past Target Date	Past Target Date	Not Past Target Date	Past Target Date	
Audits > 2 years old (see the following report for details on unresolved issues)										
Oct-11	UMD School of Fine Arts	Adequate	10	2			1		1	Satisfactory(1)
Feb-12	**Dentistry - axiUm System (P)**	**Adequate**	**14**	**1**	**1**					**Completed (2)**
May-13	Travel & Employee Reimbursements (P)	Good	1	1			1			Satisfactory
Audits < 2 years old; have received prior follow-up										
Dec-13	UMD Information Tech. Systems & Services	Good	6	3			3			Satisfactory
Feb-14	University-wide Purchasing Process (P)	Good	2	2			1		1	Satisfactory
Apr-14	UM - Crookston Campus	Good	6	1			1			Satisfactory
May-14	**UMD Parking Services**	**Good**	**1**	**1**	**1**					**Completed**
Jun-14	Identity Management	Needs Improvement	11	6		3	3			Satisfactory
Jun-14	Parking & Transportation Services	Adequate	10	10		1	9			Satisfactory
Jul-14	UMD University for Seniors	Good	2	1			1			Satisfactory
Audits receiving first-time follow-up										
Oct-14	University Recreation and Wellness	Needs Improvement	6	6	5				1	Satisfactory
Nov-14	Baseline Tennis Center	Good	2	2		2				Satisfactory
Dec-14	A Review of Top Researchers (P)	Good	1	1		1				Satisfactory
Dec-14	Carlson School of Management	Good	3	3		1	2			Satisfactory
Jan-15	Athletics Aspire Contract	Adequate	1	1		1				Satisfactory
Jan-15	Server Room Security	Needs Improvement	17	17		8		9		Satisfactory
Jan-15	Medical School Department Head Expense	Adequate	1	1			1			Satisfactory
Jan-15	**Hormel Institute**	**Good**	**1**	**1**	**1**					**Completed**
	Total:		**95**	**60**	**8**	**17**	**23**	**9**	**3**	

* The following bar charts provide details on progress made towards implementation

(1): UMD School of Fine Arts continues to make significant progress as over 5,000 objects have now been entered into the online object database. However, the entire inventory may encompass over 10,000 items.
(2): Dentistry has made substantial progress towards fully implementing this recommendation, and while some work remains, risks have been reduced to more acceptable levels.

"Essential" Recommendation Implementation Trends

Month / Year of Follow-up Report

	June 2015	Feb. 2015	Sept. 2014	June 2014	Feb. 2014	Sept. 2013	June 2013	Feb. 2013	Sept. 2012	Average
# of Essential Recommendations Receiving Follow-up	60	44	53	34	36	64	56	67	72	54
# of Recommendations Considered Fully Implemented	8	16	12	10	13	30	13	26	16	16
Implementation Percentage	13%	36%	23%	29%	36%	47%	23%	39%	22%	30%

Current Status of Recommendations Rated as "Essential" That Are Over Two Years Old and Are Not Fully Implemented

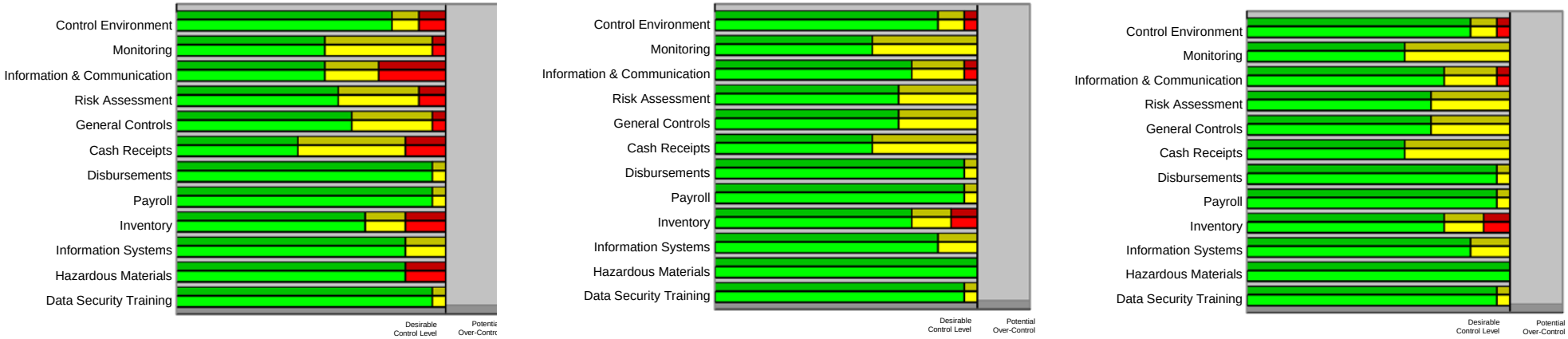
Audit/ Report Date	***Status- Partially Implemented (P) or Not Implemented (N)***	***Senior Management Contact***	***Summary of the Issue/Risk Involved***	***Current Comments From Management***
UMD School of Fine Arts Oct-11	P	William Payne Bilin Tsai	Glensheen should update and expand its inventory records with the ultimate goal of having a complete record of the entire collection. Periodically, the presence and location of inventory items should be verified on at least a sample basis.	According to the director of Glensheen, impressive progress has been made. Nearly 5000 objects have now been entered into the online object database. However, the entire inventory may encompass more than 10,000 items, so considerable time will be required to complete the physical inventory. Current estimated completion date is June 2016.
	N	William Payne Bilin Tsai	Glensheen management should work with Accounting Services to develop procedures for reporting the value of its collection.	Efforts to appraise the collection will commence after the inventory has been completed. These efforts are expected to take approximately six months.
# of Items 2				
Travel & Employee Reimbursements May-13	P	LaCretia Bell Michael Volna	Disbursement Services should continue their efforts to carefully review all cash advance requests to ensure that alternative methods of payment are not more viable before issuing the cash advance. This might include purchases made via vendor invoice or PCard. The corporate travel card is also an alternative for those travelers who do not have other means of paying for travel. In addition, the Controller's Office, in conjunction with OIB, should explore other options for better accommodating the need for compensating University human subjects.	A committee of key stakeholders has been assembled and are in the process of developing and finalizing the RFP. The RFP will be issued as soon as this work is completed, which is expected to be within the next 30 days. As anticipated, due to resource demands, ESUP caused a delay in this project. Additionally, the Controllers Office leadership responsible for this project has been out on medical leave since early February. The Controller recently assigned additional resources to this project to ensure its continued progress.
# of Items 1				

Total: 3

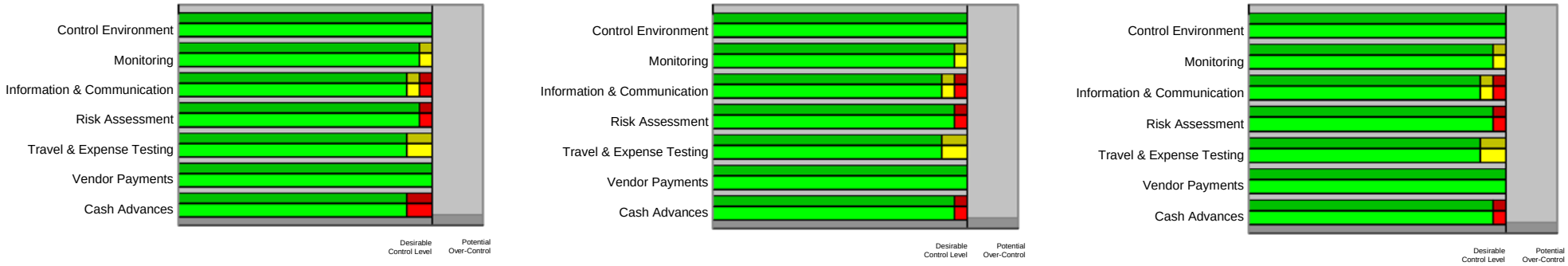
The bar charts shown below are presented to provide pictorial displays of the progress units are making on implementing audit recommendations rated as "essential". The bar chart included in the original report is shown in the left column, along with updated bar charts showing the previous quarter and the current status of the "essential" recommendations only (those bars that have red segments). The chart in the center column displays the status as of February 2015, while the chart on the right represents the current status. Charts are not presented for investigations. Charts for those units having implemented all "essential" recommendations during the current quarter are shown at the end of this report.

U of MN Duluth - School of Fine Arts (October 2011)

Original Report Evaluation | Previous Quarter Evaluation | Current Quarter Evaluation



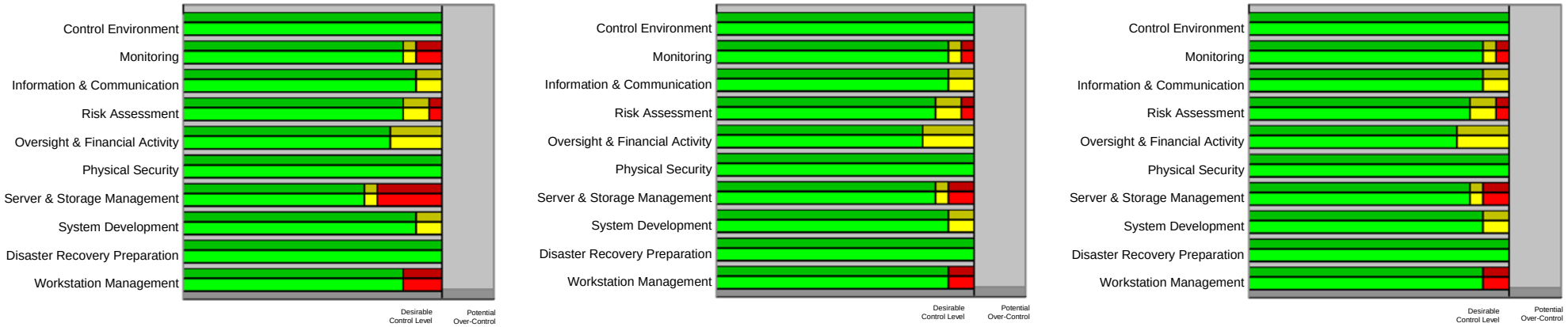
Travel & Employee Expense Reimbursement Process (May 2013)



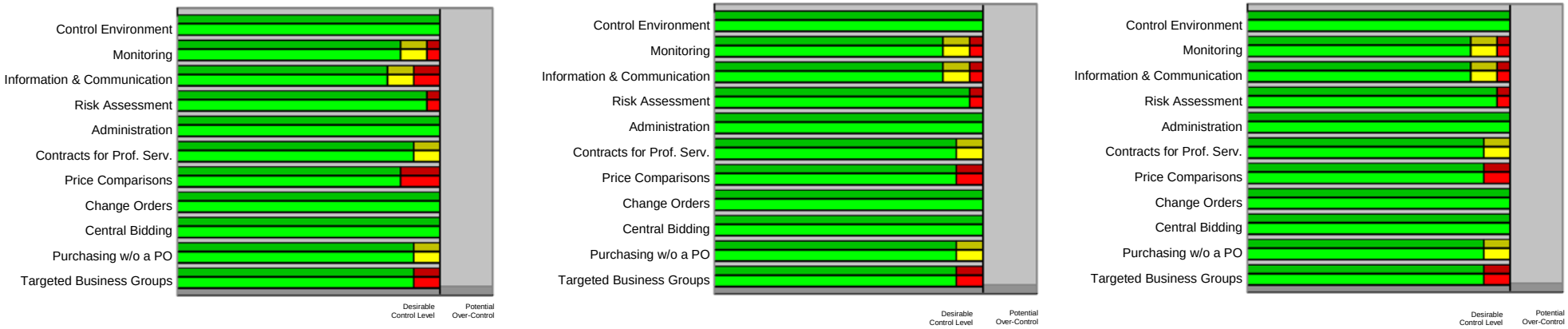
Adequate Control | Significant Control Level | Critical Control Level | Potential Over-Control

Original Report Evaluation | Previous Quarter Evaluation | Current Quarter Evaluation

U of MN Duluth - Information Technology Systems and Services (December 2013)



University-wide Purchasing Process (February 2014)



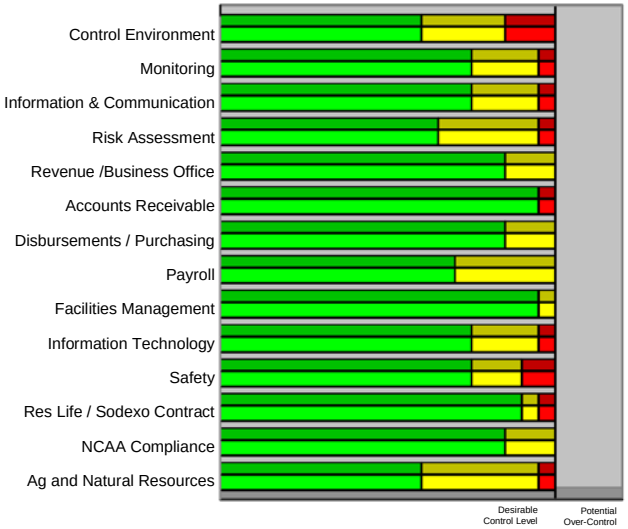
Adequate Control | Significant Control Level | Critical Control Level | Potential Over-Control

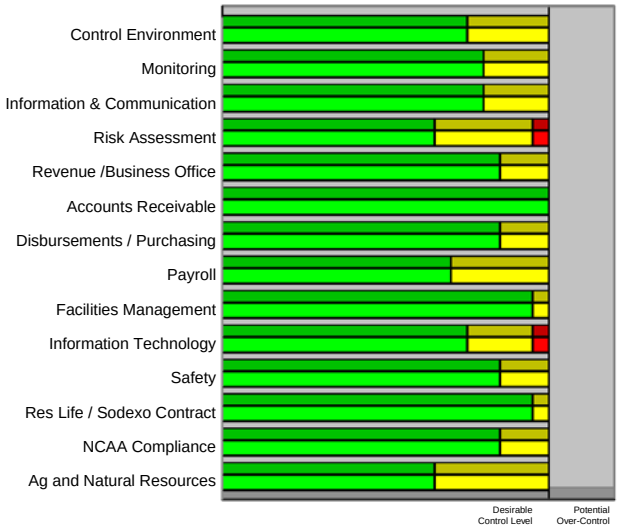
Original Report Evaluation

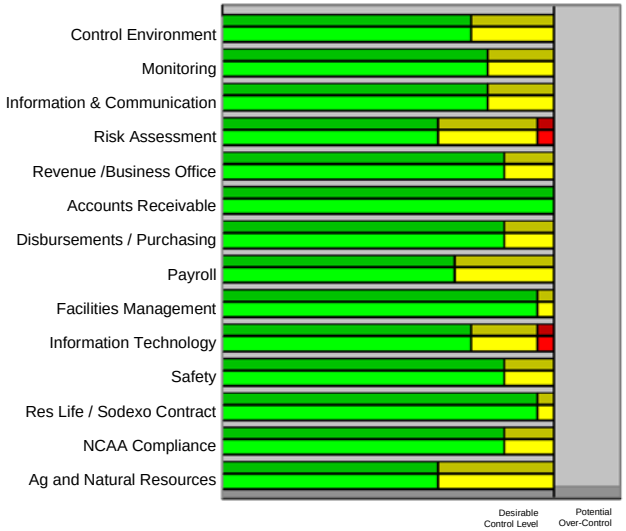
Previous Quarter Evaluation

Current Quarter Evaluation

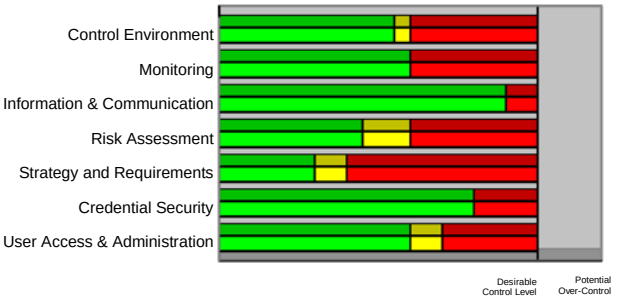
UM - Crookston Campus (April 2014)

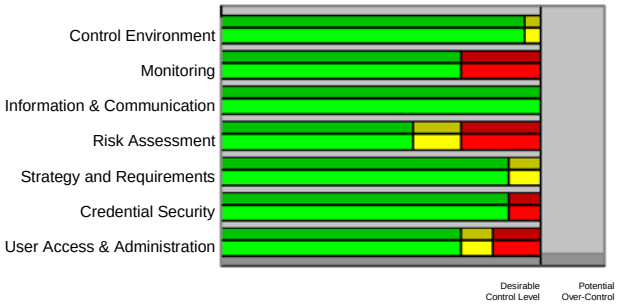






Identity Management (June 2014)





🟩 Adequate Control

🟨 Significant Control Level

🟥 Critical Control Level

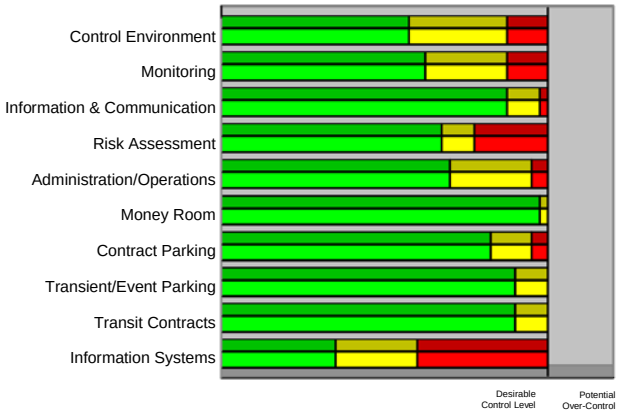
🟦 Potential Over-Control

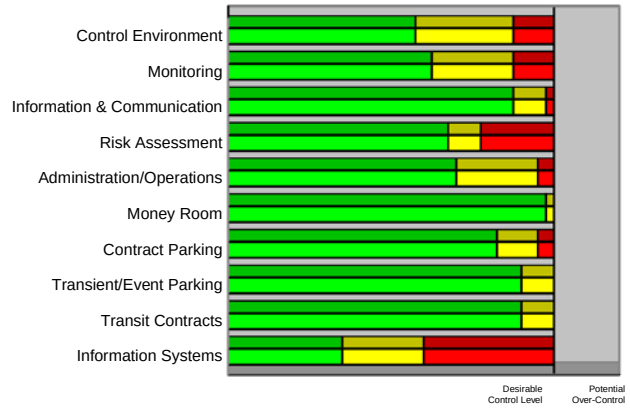
Original Report Evaluation

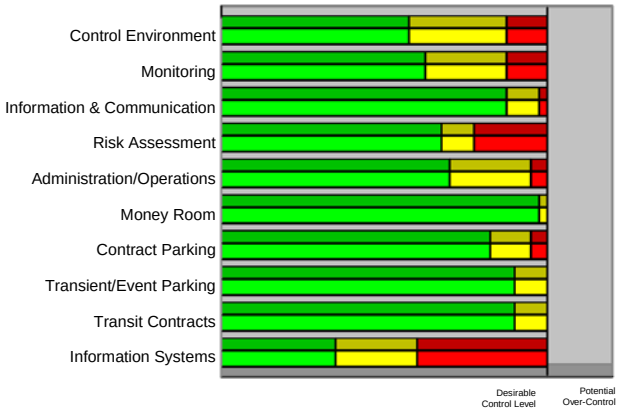
Previous Quarter Evaluation

Current Quarter Evaluation

Parking and Transportation Services (June 2014)

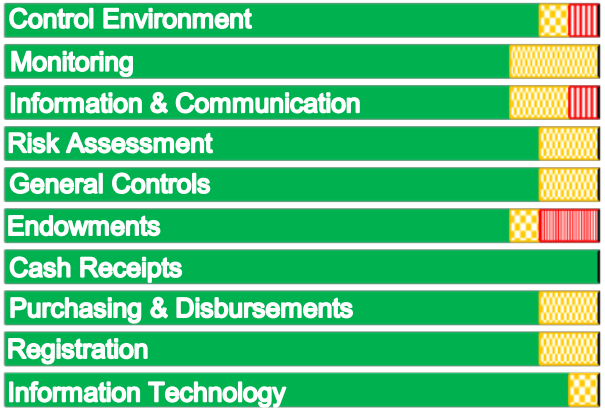


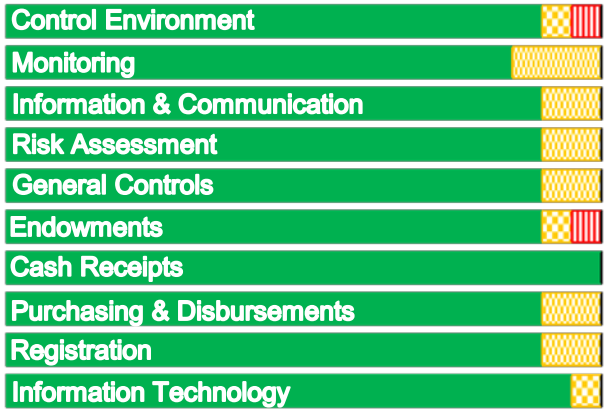


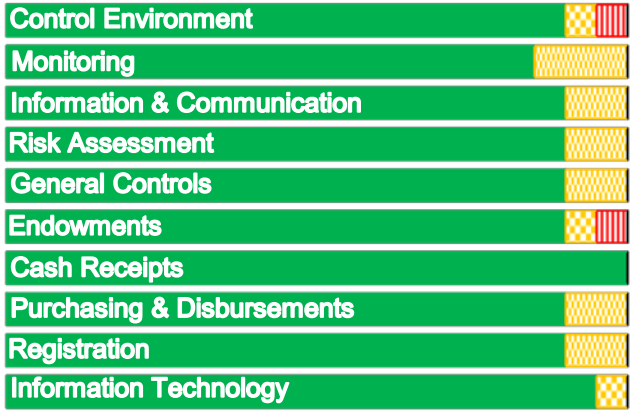


🟩 Adequate Control 🟨 Significant Control Level 🟥 Critical Control Level 🟦 Potential Over-Control

UMD University for Seniors (July 2014)



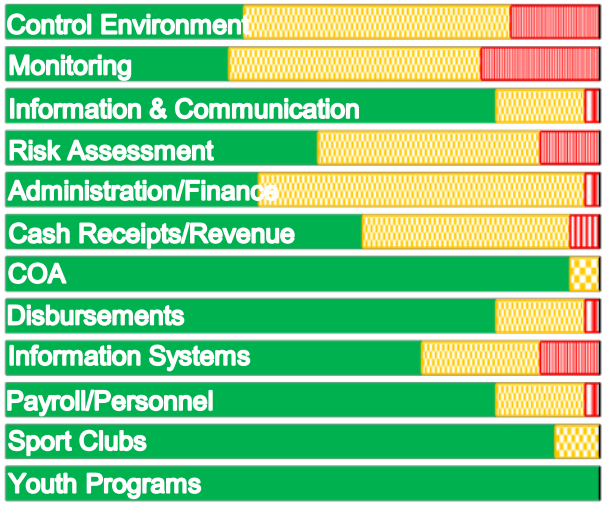




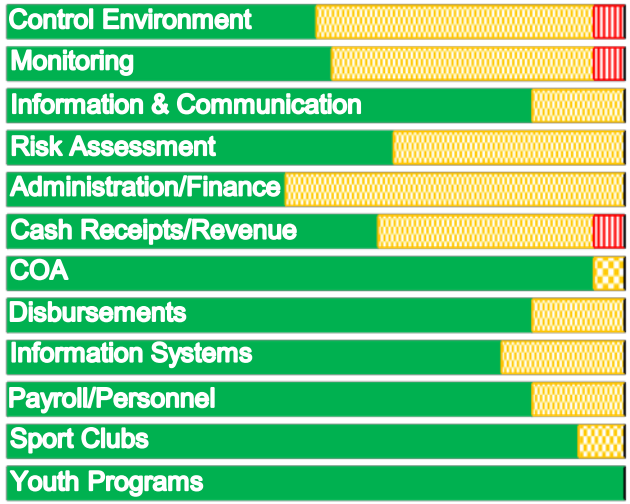
🟩 Adequate Control 🟨 Significant Control Issue(s) 🟥 Critical Control Issue(s)

Original Report Evaluation | Previous Quarter Evaluation | Current Quarter Evaluation

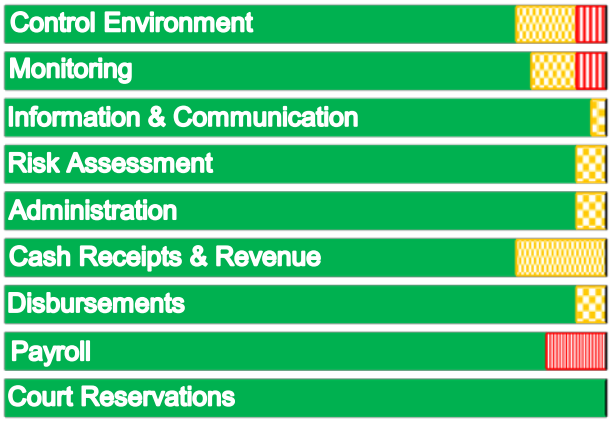
University Recreation & Wellness (October 2014)



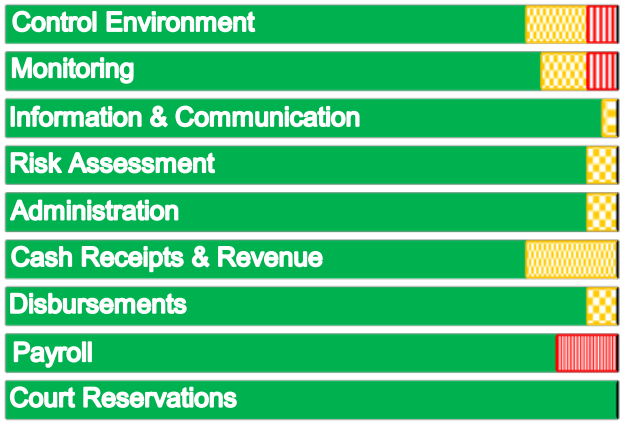
NO PREVIOUS CONTROL EVALUATION CHART



Baseline Tennis Center (November 2014)



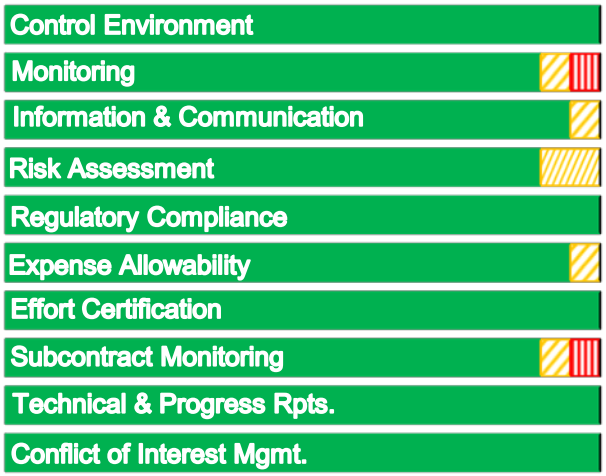
NO PREVIOUS CONTROL EVALUATION CHART



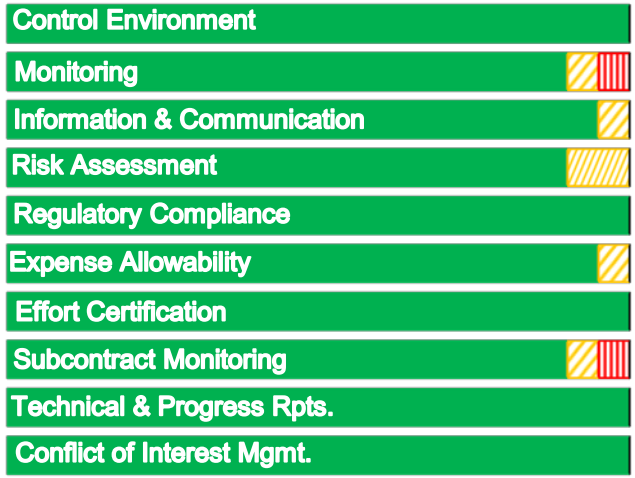
Adequate Control | Significant Control Issue(s) | Critical Control Issue(s)

Original Report Evaluation | Previous Quarter Evaluation | Current Quarter Evaluation

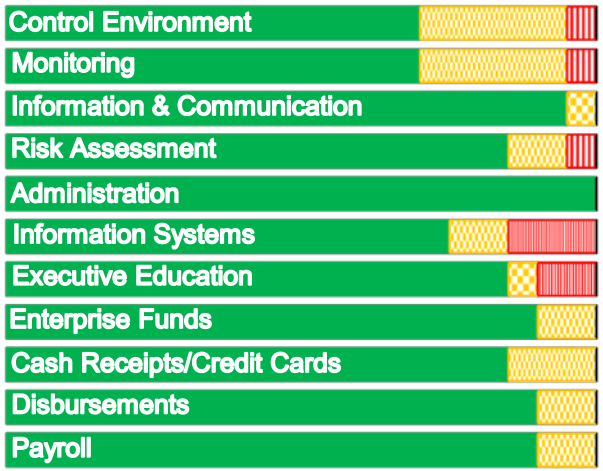
A Review of Top University Researchers (December 2014)



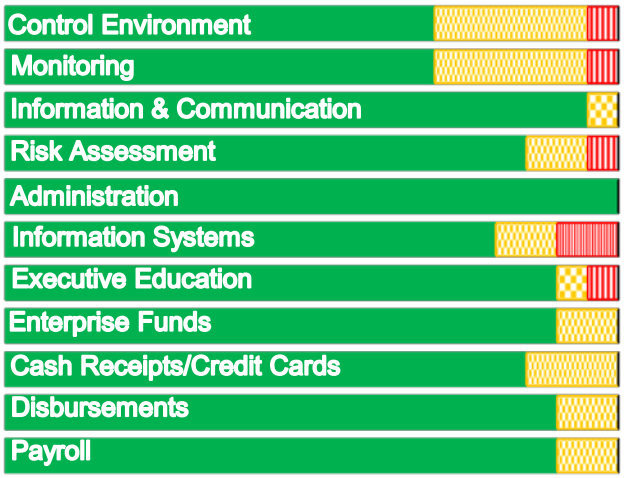
NO PREVIOUS CONTROL EVALUATION CHART



Carlson School of Management (December 2014)



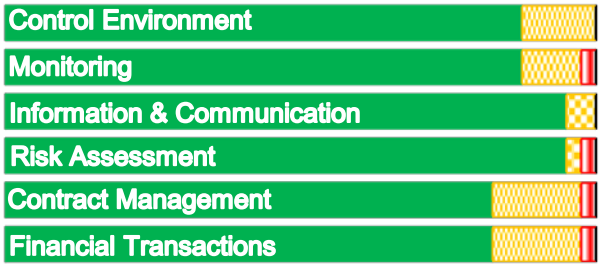
NO PREVIOUS CONTROL EVALUATION CHART



Adequate Control | Significant Control Issue(s) | Critical Control Issue(s)

Original Report Evaluation | Previous Quarter Evaluation | Current Quarter Evaluation

Athletics Aspire Contract (January 2015)



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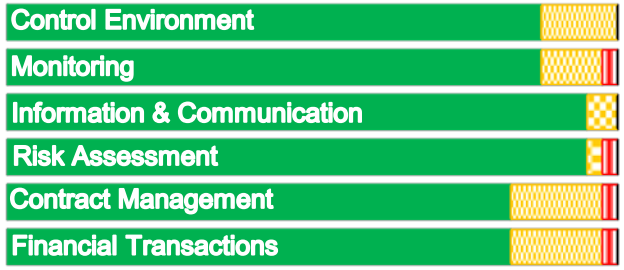
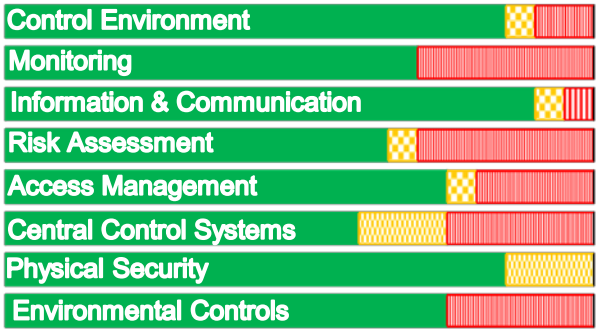
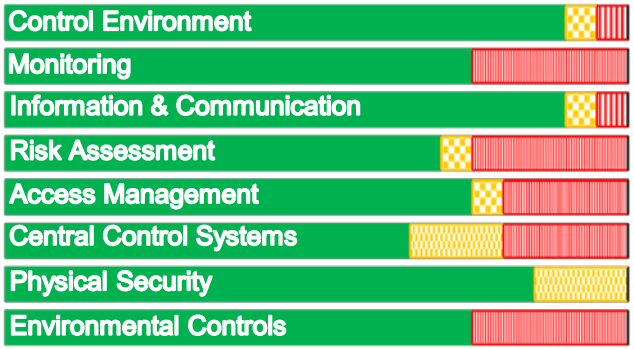


Server Room Security (January 2015)



NO PREVIOUS CONTROL EVALUATION CHART



Adequate Control | Significant Control Issue(s) | Critical Control Issue(s)

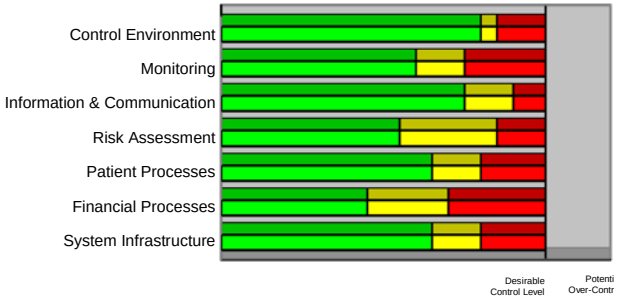
Units with Charts that Fully Implemented their "Essential" Recommendations During the Past Quarter

Original Report Evaluation

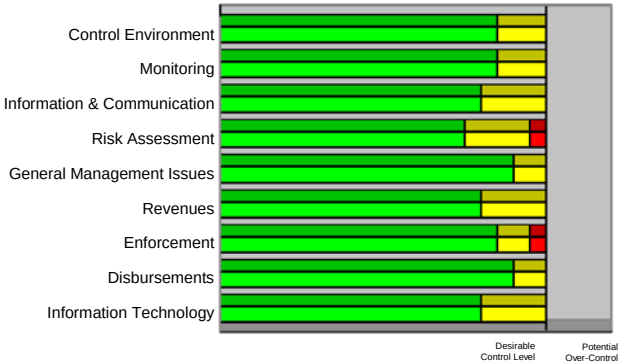
Previous Quarter Evaluation

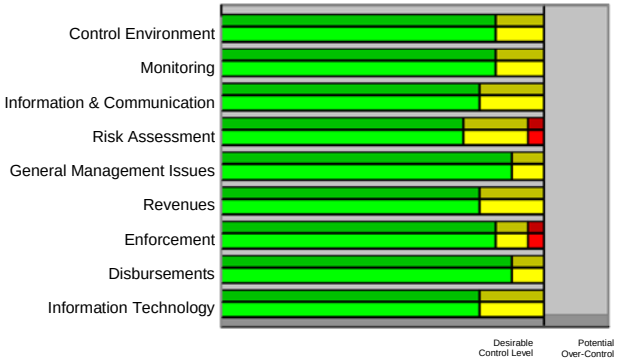
Current Quarter Evaluation

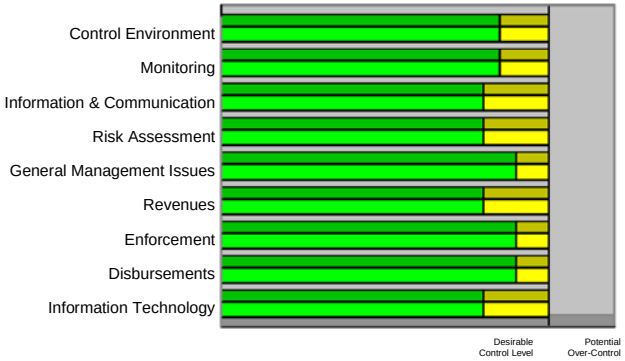
Dentistry - axiUm (February 2012)



UMD Parking Services (May 2014)







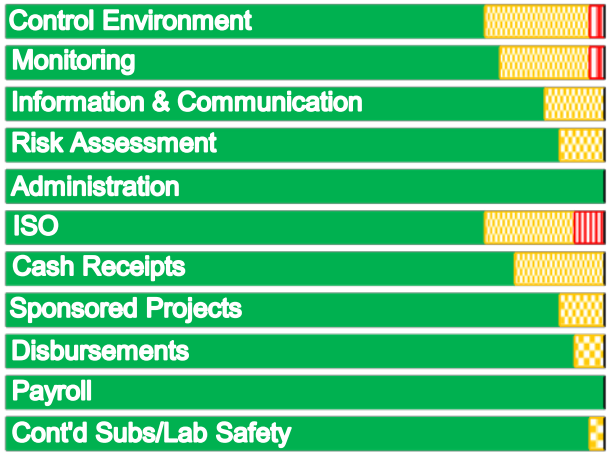
🟩 Adequate Control

🟨 Significant Control Level

🟥 Critical Control Level

🟦 Potential Over-Control

Original Report Evaluation

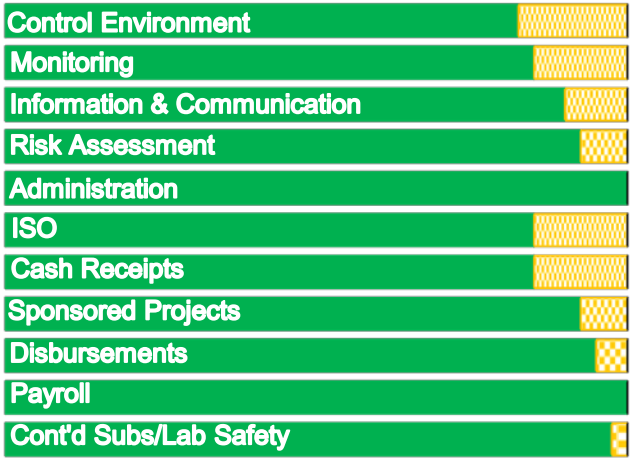


Previous Quarter Evaluation

The Hormel Institute (February 2015)

NO PREVIOUS
CONTROL EVALUATION
CHART

Current Quarter Evaluation



Adequate Control Significant Control Issue(s) Critical Control Issue(s)

Audit Activity Report

Scheduled Audits

- Completed audits of Ophthalmology and Visual Neurosciences, technology vendor due diligence, OIT server administration, the Medical School Duluth campus and a review of incentive compensation. Details are shown on the following charts.
- Began/continued audits of: the Clinical Translational Sciences Institute (CTSI), 21st Century Development Funds, the College of Science and Engineering Dean's Office and related centers, the College of Food, Agricultural and Natural Resource Sciences Dean's Office and related centers, UMD Athletics, the College of Pharmacy, the Department of Medicine and Boynton Health Service.
- Continued to monitor the PeopleSoft upgrade prior to and post the go-live date for readiness and data integrity.

Non-Scheduled Audits

- Completed a requested audit of SimPORTAL & CREST (a unit within the Department of Urology). Details are shown on the following chart.
- Began an audit of selected University projects funded by state appropriations from the Environment and Natural Resources Trust Fund. This work was requested by the Office of the Legislative Auditor and is part of their statewide audit of this fund.

Investigations

- Performed investigative work on nine issues in accordance with the University Policy on Reporting and Addressing Concerns of Misconduct.

Special Projects

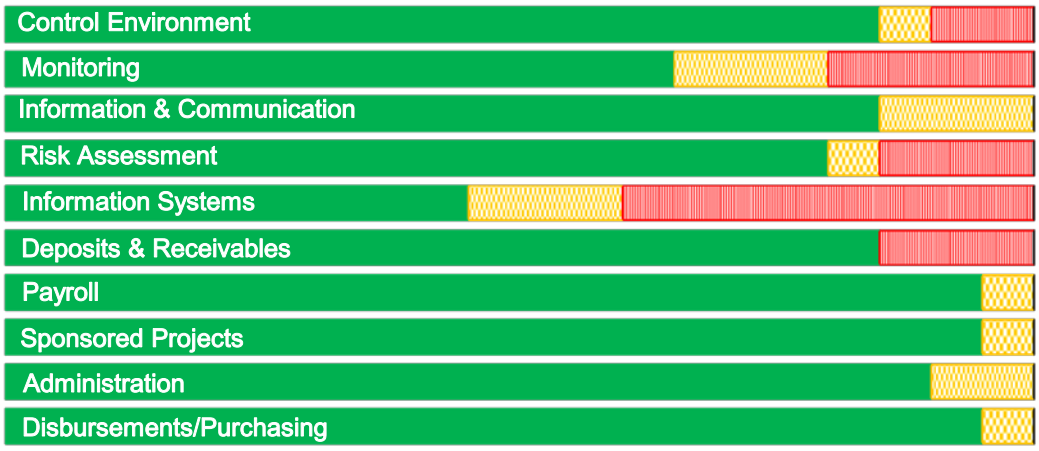
- Provided consulting services related to University payroll exception testing, performed work for the Law School related to external commitments, and completed a project to review Medical School department head salary and reimbursement expenses paid by University of Minnesota Physicians.
- Developed a query to be used to assess institution-wide compliance by faculty and P&A employees for reporting vacation absences.
- Provided technology consulting in several areas including the University's IT security framework, HIPAA security and the University's IT strategic plan.
- Received and reviewed an external consultant's construction audit report related to their review of the recently replaced Williams Arena roof.
- At the request of University Services, we are coordinating with their units to examine the potential of hiring an external consultant to assess current UM policies and procedures used for large energy-based construction projects such as the Combined Heating and Power Plant Project.

Other Audit Activities

- Participated in the following:
  - Senior Leadership Group
  - Operational Excellence Leadership Team
  - President's Policy Committee
  - Board of Regents Policy Committee
  - Executive Compliance Oversight Committee
  - Institutional Conflict of Interest Committee
  - University of Minnesota Foundation Audit Committee
  - Fairview Health Systems Audit Committee
  - Enterprise System Upgrade - Human Resource Functional Steering Committee
  - Uniform Guidance Steering Committee
  - IT Leadership Community of Practice & Advance Leadership Program
  - Human Subject Research Implementation Team

Audit Reports Issued Since February 2015

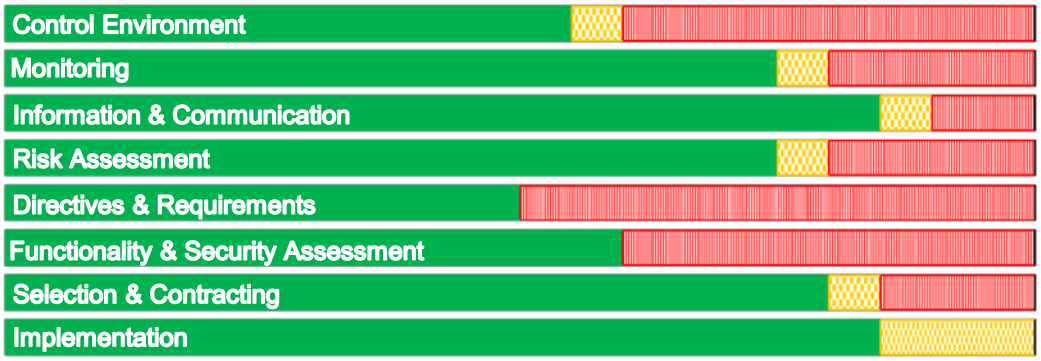
Department of Ophthalmology and Visual Neurosciences



Report #	1518	Issue Date	Apr-15
# of Essential Recs.	9	Total # of Recs.	16
Overall Assessment	Adequate	Adequacy of MAP	Satisfactory

The audit of the Department of Ophthalmology and Visual Neurosciences (OVNS) included the Minnesota Lions Eye Bank (MLEB), a unit operated by OVNS staff but funded by payments received from the Minnesota Lions Vision Foundation, Inc. We believe OVNS has developed a control environment and a system of internal control that addresses most major business and compliance risks. However, the MLEB's oversight of the vendor managing its cloud application iTransplant and its own internal technology control processes need to be enhanced to ensure the confidentiality, integrity, and availability of data. This risk is heightened for iTransplant as it stores sensitive patient and donor data and is required to comply with the Health Insurance Portability and Accountability Act (HIPAA).

Technology Vendor Due Diligence

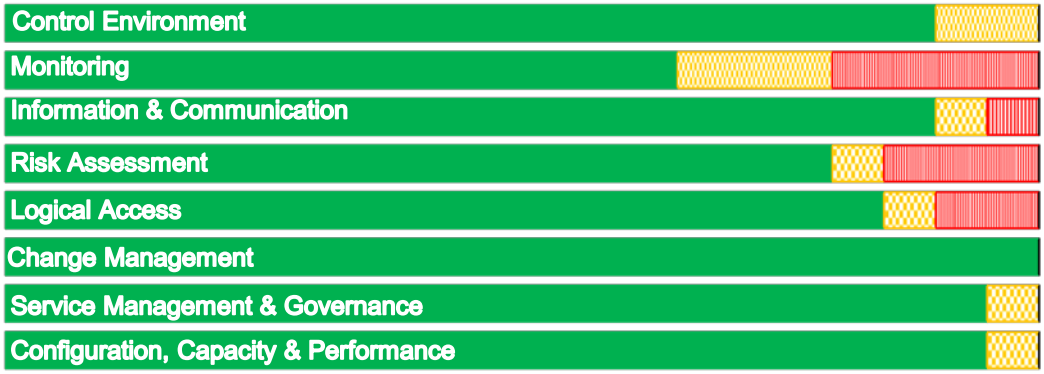


Report #	1519	Issue Date	May-15
# of Essential Recs.	4	Total # of Recs.	8
Overall Assessment	Needs Improvement	Adequacy of MAP	Satisfactory

The University is using an increasing number of vendors to provide technology services where the vendors are responsible for managing systems and/or have access to University data. Despite increased use of these services, controls and processes for performing due diligence of these vendors is inadequate. The University has insufficient directives and oversight for technology vendor management. Units are responsible for determining due diligence processes independently, leading to varied and often inadequate processes.

Adequate Control Significant Control Issue(s) Critical Control Issue(s)

OIT Server Administration



Report #	1520	Issue Date	May-15
# of Essential Recs.	5	Total # of Recs.	8
Overall Assessment	Good	Adequacy of MAP	Satisfactory

OIT server and virtual infrastructure environments are securely configured and meet the majority of vendor and industry configuration recommendations. Furthermore, OIT's server and virtual infrastructure services provide significant benefit to the University and align with University goals by supporting core operations at reduced costs. OIT Servers and Storage manages these services professionally, and has established a system of controls that are generally effective and in alignment with the recently-issued University Information Security Policy. However, a few processes are still not in compliance with the Information Security Policy, including logging and monitoring processes, and require further improvements to minimize risk to data confidentiality, integrity and availability.

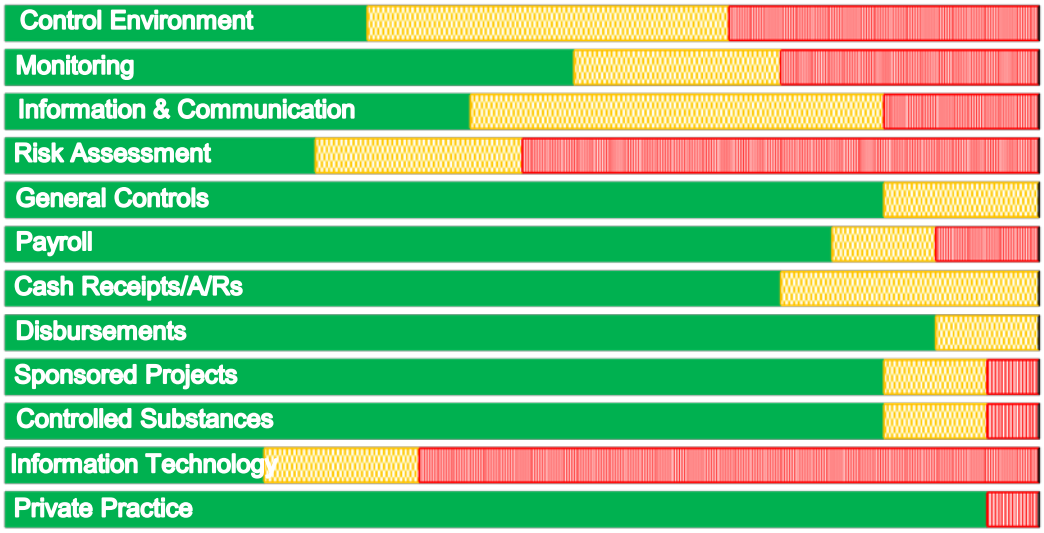
SimPORTAL & CREST

Report #	1521	Issue Date	May-15
# of Essential Recs.	3	Total # of Recs.	7
Overall Assessment	Adequate	Adequacy of MAP	Satisfactory

SimPORTAL (Simulation PeriOperative Resource for Training and Learning) is the primary simulation training "portal" for the procedurally oriented departments within the Medical School. It directly provides space, equipment, technical and logistical support for educational activities involving technical skills and team training via simulation. CREST (Center for Research in Education and Simulation Technologies) also supplies research and evaluation capacity to support innovation in simulation equipment, tools, and processes as well as training curricula. While the activities of SimPORTAL & CREST are generally in compliance with University policies and procedures, issues regarding effort certification and human subject consenting would benefit from improved review and oversight.

Adequate Control Significant Control Issue(s) Critical Control Issue(s)

Medical School Duluth



Report #	1522	Issue Date	May-15
# of Essential Recs.	25	Total # of Recs.	46
Overall Assessment	Needs Improvement	Adequacy of MAP	Satisfactory

In our opinion, the operational, financial and information system controls over several functions within Medical School Duluth (MSD) need improvement. The one functional area of greatest concern to us is information technology (IT). There are critical problems with MSD's IT control and management processes which jeopardize the integrity, confidentiality and availability of their critical systems and data. The lack of adequate IT oversight and risk management has likely contributed to these issues and stymied remediation efforts. This risk is heightened for MSD as some of their systems maintain confidential data including electronic protected health information (ePHI), social security numbers and Family Educational Rights and Privacy Act (FERPA) protected student information. Additional improvements concerning absence reporting, human subject consenting and controlled substances licensure are also warranted.

Incentive Compensation Review

Report #	1523	Issue Date	May-15
# of Essential Recs.	0	Total # of Recs.	3
Overall Assessment	Good	Adequacy of MAP	Satisfactory

University employees receive compensation increases through several methods including across-the-board increases, bargaining unit negotiated increases, merit performance plans and incentive compensation plans. Incentive compensation plans are rare at the University and are often tied to established goals/thresholds in employment agreements. Incentive plan measures are both objective and quantifiable. Our audit included an examination of policies, procedures, and controls relating to incentive-based compensation at the University. A sample of incentive compensation payments were tested for accuracy and compliance. From the results of the audit work performed, we believe the controls and processes related to University incentive compensation plans could be improved by providing a central authority to track, monitor, and approve incentive compensation plans across the University.

Adequate Control Significant Control Issue(s) Critical Control Issue(s)

BOARD OF REGENTS
DOCKET ITEM SUMMARY

Audit **June 11, 2015**

Agenda Item: Implementation of Work Plan to Improve Human Research Protection Program

☐ **Review** ☒ **Review + Action** ☐ **Action** ☐ **Discussion**

☐ *This is a report required by Board policy.*

Presenters: William J. Tremaine, Professor of Medicine, Mayo Clinic
Brian Herman, Vice President for Research
Brooks Jackson, Dean, Medical School & Vice President for Health Sciences

Purpose & Key Points

The purpose of this item is to:

- Review and discuss the final work plan's key recommendations related to:
  - Conflict of Interest.
  - Institutional Review Board (IRB) membership and process.
  - Engaging research participants.
  - Community engagement.

- Approve the resolution endorsing the final work plan to strengthen the University's human research protection program and direct the President to implement the action steps outlined therein.

Background Information

In May 2004, Dan Markingson, while enrolled in a clinical trial of an antipsychotic drug study at the University of Minnesota, committed suicide. Since that time, individuals and groups within and outside the University have raised questions about the study, how Markingson was recruited to be a participant, his treatment during the study, the circumstances of his suicide, and the adequacy of the subsequent investigations.

Following a series of discussions that occurred in Fall 2013, on December 5, 2013 the University of Minnesota Faculty Senate passed a resolution calling for an inquiry to examine current policies, practices, and oversight of clinical research on human participants at the University, in particular clinical research involving adult participants with diminished functional abilities, and asked for an independent panel to conduct the review. The reasoning behind the resolution was while investigations had been conducted on the Markingson case, those investigations did not address the broader question of whether the University's current policies, procedures and practices reflected

best practices in clinical research on human participants and the faculty's high ambitions for ethical behavior.

In January 2014, President Kaler endorsed the Senate resolution and charged Vice President for Research Brian Herman to oversee the inquiry. In June 2014, the Association for the Accreditation of Human Research Protection Programs (AAHRPP) was awarded a contract to assemble a review team and logistically manage the review process. A panel of six outside experts selected by AAHRP was contracted to conduct the review. The panel conducted its work from August 2014 to March 2015. This included reviewing hundreds of documents; conducting a two-day site visit during which they interviewed 53 people; and receiving dozens of comments from stakeholders inside and outside the University.

On February 23, 2015, the panel issued a report containing 63 recommendations for improving the human participants protection program at the University. The language of the report was strong in its statement that while the current program is in many respects adequate, the University must make changes if it wishes to have a leading program in human participants protection.

In a separate but related activity, on March 19, 2015 the Office of the Legislative Auditor (OLA) released a report that focused on the events surrounding the death of Dan Markingson. The OLA report determined that it was not possible to know whether Dan Markingson's suicide was connected to his participation in the University clinical research trial, but did state that the Markingson case raised ethical and conflict of interest issues. Further, the OLA report stated that the University was insular and defensive in its response to the Markingson case. The Legislative Auditor recommended that the University fully implement the recommendations in the external panel report.

On March 12, 2015, President Kaler charged Vice President Herman and Vice President for Health Sciences Brooks Jackson with responsibility for overseeing the implementation of the recommendations of the external review panel by establishing an Implementation Team (Team). The Team has 13 members – individuals from inside and outside the University with the qualifications and expertise to review the recommendations and develop a plan to implement them. It is chaired by William Tremaine, Professor of Medicine, Mayo Clinic and Director, Mayo Clinic IRB. In addition, the Board of Regents approved immediate and longer-term action plans to implement the recommendations at its March 2015 meeting.

During the time of the Team's work, two additional reports were made available to all team members: 1) A draft State of Minnesota Office of the Legislative Auditor's report of May 5, 2015 which presented findings from all industry sponsored studies at the University from 2004-2014; and (2) *Final IRB Investigation Report Into Fairview Concerns Regarding Psychiatry Research Studies at the University of Minnesota*, referred to as the "Oakes report." The Team considered the information from these reports in its recommendations.

Additional key documents related to human subjects research can be found on the Advancing Human Subjects Research section of the Office of the Vice President for Research website.

Implementation Team Charge

The Team was specifically charged with the following:

- A work plan to implement the recommendations, produced within 60 days.

- Accountability metrics for the work plan.
- A recommendation regarding necessary resources to implement the recommendation.
- Engagement of appropriate critical stakeholders in assisting with the implementation.
- Engagement of an external advisor with deep knowledge in human research protection programs, regulations, and law to work with the University on implementation.
- A review of best practices regarding conflict of interest for researchers engaged in human participant studies, including a recommendation on organization or structural changes.
- Formation of an oversight committee made up of community leaders and other parties affected by the implementation and the University research program.

Implementation Team Process

The Team met weekly from April 1, 2015 through May 6, 2015 for two-hour sessions. During those meetings, team members presented action plans on each of the 63 recommendations for discussion by the full team. Significant communication by email or phone was held between meetings to develop action plans and the draft report. The Team created a public website, participated in public hearings and other consultative efforts, and created an email address to receive feedback from interested stakeholders.

Implementation Team Report

The Team submitted a draft report to President Kaler on May 15, 2015. This report was available for public comment from May 18 to June 1, 2015.

The report recommends significant and disruptive changes to the University's human participants research protection program. The intent of these changes is to cultivate a culture of ethics, ensuring the primacy of the University and each investigator's duty to keep the wellbeing of patients who become research participants at the center of policies and procedures, while ensuring the University's commitment to clinical research and its faculty.

The key components of the report are:

- Cultivating a culture of ethics.
- Strengthening IRB membership and review process.
- Human Research Protection Program (HRPP) management of scientific review.
- Relocation of for-cause investigation to a new compliance office.
- Improved protections for participants who have impaired or fluctuating capacity to consent.
- Assessment of the climate of psychiatric studies between the Department of Psychiatry and Fairview, and University Clinical and Translational Research Institute (CTSI) management of interventional drug and device trials in the Department of Psychiatry.
- Enhanced engagement of research participants.
- Education and training of investigators.
- Accountability metrics.
- More stringent management of conflicts of interest.
- Support for a new Community Oversight Board.
- Engagement of an external advisor through implementation of this work plan.

The team received over 60 comments to the draft report, many centered on concerns about undue burden and the proposed policy change regarding Conflict of Interest, suggestions for community

engagement, concerns about changes to scientific review, and questions about the applicability to the Social and Behavioral IRB. The final report reflects those submissions.

President's Recommendation

The President recommends adoption of the resolution.

REGENTS OF THE UNIVERSITY OF MINNESOTA
RESOLUTION RELATED TO
IMPLEMENTATION OF WORK PLAN TO IMPROVE
HUMAN RESEARCH PROTECTION PROGRAM

WHEREAS, the University is committed to meeting, upholding and exceeding the highest ethical standards in research practices involving human participants; and

WHEREAS, these ethical standards are critically important, particularly in the context of clinical research involving participants with limited decision-making capacity; and

WHEREAS, recent reports have made recommendations to improve and create a human participant research protection program that serves as a national model; and

WHEREAS, President Kaler charged a highly qualified team of experts to develop a work plan to implement these recommendations; and

WHEREAS, this team, through a rigorous and transparent process, has drafted a work plan that will result in significant improvements to the University's human participant research protection program; and

WHEREAS, protecting research participants and enhancing the University's research programs are critical institutional priorities;

NOW, THEREFORE, BE IT RESOLVED that the Board of Regents endorses the final work plan to strengthen the University's human research protection program and directs the President to implement the action steps outlined therein, including but not limited to:

a) Strengthening membership and processes of the Institutional Review Board;
b) Additional education and training for investigators;
c) Stronger protections for participants with limited or fluctuating capacity to consent;
d) Enhanced engagement with research participants and families;
e) Formation of a Community Oversight Board; and
f) More stringent management of conflicts of interest.

BE IT FURTHER RESOLVED that the Board of Regents will take an active role in providing ongoing oversight and monitoring of these activities by receiving regular progress reports on implementation of this work plan through its Audit Committee.

REVISED

REGENTS OF THE UNIVERSITY OF MINNESOTA
RESOLUTION RELATED TO
IMPLEMENTATION OF WORK PLAN TO IMPROVE
HUMAN RESEARCH PROTECTION PROGRAM

WHEREAS, the University is committed to meeting, upholding and exceeding the highest ethical standards in research practices involving human participants; and

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WHEREAS, President Kaler charged a highly qualified team of experts to develop a work plan to implement these recommendations; and

WHEREAS, this team, through a rigorous and transparent process, has drafted a work plan that will result in significant improvements to the University's human participant research protection program; and

WHEREAS, protecting research participants and enhancing the University's research programs are critical institutional priorities;

NOW, THEREFORE, BE IT RESOLVED that the Board of Regents (Board) endorses the final work plan to strengthen the University's human research protection program and directs the President to implement the action steps outlined therein, including but not limited to:

a) Strengthening membership and processes of the Institutional Review Board;
b) Additional education and training for investigators;
c) Stronger protections for participants with limited or fluctuating capacity to consent;
d) Enhanced engagement with research participants and families;
e) Formation of a Community Oversight Board; and
f) More stringent management of conflicts of interest.

BE IT FURTHER RESOLVED that the Board will take an active role in providing ongoing oversight and monitoring of these activities by receiving regular progress reports through its Audit Committee at each of the committee's meetings until the work plan has been fully implemented; and

BE IT FURTHER RESOLVED that all Regents receive, and the chair of the Board and the chair of the Audit Committee are delegated authority by the Board to review and approve, all reports to be submitted to the Minnesota Legislature relating to implementation of this work plan; and

BE IT FURTHER RESOLVED that the Office of Internal Audit shall monitor and evaluate the progress reported by the President and report those findings to the Audit Committee.

Preface

Advancing Human Participant Research
Public Comment Summary

The University of Minnesota has a long history of exceptional clinical research that has contributed tremendously to the better health and well being of our society. Thus, the institution's commitment to clinical research is unassailable, and we believe strongly in the need to continue excellence in this area.

The implementation team recommends significant and innovative changes to our human research protection program. The intent of these changes is to cultivate a culture that ensures the primacy of the UMN and all of its investigator's duty to keep the well being of patients who become research participants at the center of policies and procedures, while ensuring our commitment to clinical research and our faculty.

Based on these principles and desire for the broadest adoption possible, the team presented a draft work plan to the public for their review and comment on May 18, 2015 through June 1, 2015. The team received over 70 individual and multi-individual (grouped) comments to the draft plan. Many centered on concerns about undue burden and proposed policy changes regarding conflict of interest; suggestions for community engagement; concerns about changes to scientific review; and questions about the applicability of the changes to the Social and Behavioral IRBs. The final work plan submitted to the President and the Board of Regents incorporates those comments. The specific comments received and team response to these comments are published on the team's website: http://research.umn.edu/advancehsr/index.html

Given the time frame available to the team to produce a report in response to the charge from the President, and the scope of the charge, it was not possible to fully work out all the operational aspects of every recommendation. Having said that, the team wants to assure all stakeholders that as the recommendations are adopted, significant input from the clinical research community will continue to be sought to make sure that they are done thoughtfully and appropriately.

The team wishes to thank all those who submitted very thoughtful comments on the draft implementation team's report. Many of the comments led to substantive changes in the report. These comments also underscore the reality that while this work plan represents the roadmap to reenergize the culture of human studies research at the UMN, implementation of these recommendations will require many additional collegial discussions and engagement by the entire University community.

Implementing the Recommendations of the External Review of the University of Minnesota Human Research Protection Program

Work Plan

June 11, 2015

Implementation Team Members:

Joanne Billings, M.D., MPH, Assistant Professor, Department of Medicine
William Durfee, Ph.D., Morse Alumni Distinguished Teaching Professor, Mechanical Engineering
Debra Dykhuis, Executive Director, Human Research Protection Program
Paul F Goering, M.D., Vice President, Allina Mental Health
Brian Herman, Ph.D., Vice President for Research, *Co-Vice Chair*
Brooks Jackson, M.D., M.B.A, Dean, Medical School; Vice President for Health Sciences, *Co-Vice Chair*
Gail Klatt, Associate Vice President, Office of Internal Audit, *Ex Officio*
Steven Miles, M.D., Professor and Maas Family Endowed Chair in Bioethics, Center for Bioethics; Professor, Department of Medicine
Timothy Schacker, M.D., Professor, Department of Medicine
Naomi Scheman, Ph.D., Professor, Department of Philosophy
William J. Tremaine, M.D., Professor of Medicine, Mayo Clinic, *Chair*
Daniel Weisdorf, M.D., Professor, Department of Medicine
Carolyn S Wilson, RN, Executive Vice President and Chief Operating Officer of Fairview; Co-President, University of Minnesota Health
Jean Wyman, Ph.D, RN, GNP-BC, FAAN, FGSA Professor and Cora Meidl Siehl Endowed Chair in Nursing Research

Table of Contents

1. Executive Summary

Introduction

The University of Minnesota rightfully takes pride in the longstanding tradition of excellence in research by the U of M faculty and staff who work diligently to improve the lives of Minnesotans and others around the world.

Following the receipt of two independent assessments (the External Review report and the Office of the Legislative Auditor report) of the University of Minnesota's Human Research Protection Program (that focused on consenting of individuals with diminished mental capacity and the issues surrounding the death of Dan Markingson), President Eric Kaler jointly charged the Vice President for Research and Vice President for Health Sciences with creating an Implementation team. The goal of the team was to review and implement the recommendations of the External Review as well as consider other changes to enhance the current University Human Research Protection Program (HRPP) such that it could serve as a national model for other institutions to emulate.

The Implementation team met weekly to discuss and refine action plans related to recommendations and groups of recommendations, which resulted in the action plan detailed in the body of this report. The plan was put forth by the implementation team for public comment and review by those inside and outside the U of M.

Key Parts of the Work Plan

Below are the key components of the work plan. For the complete details associated with each of these components, see the body of the report.

- *Cultivating a culture of ethics:* The team recognizes the responsibility of the U of M and each individual research investigator to keep the rights and welfare of research participants at the center of all research activities. The U of M must maintain the

highest ethical standards for the conduct of research with research participants. That culture will come from fostering University-wide conversations, better educating research investigators, and setting standards that commit the U of M to an ethical culture of accountability that is a national model for others to emulate.

Recommendations for how to achieve this national model are included throughout this report. Important and central to these goals, we strongly recommend creating a Fairview/University joint senior leadership team with representatives from the Fairview Research Office, Fairview clinical staff, University Academic Health Center, UM Physicians and the University Office of the Vice President for Research (herein after referred to as FUROC, see section 7) to evaluate the success of the changes made as a result of this report and constantly look for opportunities to enhance the culture changes that need to happen. This team will report its findings to U of M and Fairview leadership.

- *Institutional Review Board (IRB) membership:* The team includes in this report a process to reorganize the IRB so that it can effectively provide thorough, efficient, and timely assessments of all aspects of the proposed research. This reorganization includes a significant increase in the number of review panels for evaluation of biomedical research and increasing the number of people who serve on those panels, as well as to set out guidelines to limit the workload and review process so that time can be given for a more careful consideration of each application. Further, we recommend that IRB members be compensated. The team also states that serving on the IRB must be viewed as a valued service activity for promotion and tenure.

- *IRB review process:* IRB meetings must be conducted in a uniform format that includes meaningful and documented discussions that focus on regulatory requirements for approval and ethical norms for human research participant studies. An increase in the IRB administrative staff will be required so that a thorough pre-review process can occur that ensures the full IRB committee is focused on studies involving greater than minimal

risk or those required by federal regulations to be reviewed at a convened meeting. Significant investments in an online IRB review management system will need to be made. The team also recommends that benchmark visits to IRBs at other institutions be made to better inform IRB members.

- *Scientific review:* Conducting a proper scientific review by qualified individuals who have no conflict of interest is paramount and has proven to be difficult when the review is handled by the department hosting the research. We recommend eliminating departmental peer review and creating a process in the HRPP to manage scientific reviews. That process will include defining the qualifications of and conflicts for peer reviewers.

- *Monitoring of studies:* The system to monitor investigators compliance with IRB approved activities needs to be strengthened. We recommend resources be made available to increase the number of PAR's that are completed each year, particularly for research conducted at Fairview. Results of each investigation need to be reported to the FUROC (see section 7) as well as department, center, and college leadership to ensure that everyone who is responsible for the conduct of that research is aware when problems are found.

- *For-cause investigations:* Investigation into allegations of investigator misconduct or ethical violations should also be relocated from the HRPP to a new OVPR Research Compliance Office function. The research misconduct investigation process already resides in the OVPR. Any findings that result from an investigation should be reported to the FUROC (see section 7) as well as department, center, and college leadership. In addition, communication of results should be made to the investigator, complainant (if known), and to the research participant, if applicable.

- *Research participants who have impaired or fluctuating capacity to consent:* The team recognizes that conducting research with participants with impaired capacity is central to the problems identified by the External Review. Included in this report is a detailed discussion of how to define impaired capacity and guidelines for how to identify studies that include a vulnerable population or research participants with impaired capacity. We believe that discussions of capacity should be included at every step of the research design and implementation process. In this report we identify new tools that will be used to assess capacity to consent. We suggest how to qualify investigators and research staff to be responsible for obtaining consent. We mandate the creation and use of a consent capacity monitoring plan that lasts the duration of the study where it is anticipated that capacity to consent may fluctuate, for example, in patients with severe mental or critical illness. We recommend a process of intermittent live consent monitoring by someone appropriately trained and not associated with the research study in those situations where the research participant population is identified as impaired. We identify situations where research participants may be potentially vulnerable to coercion or exploitation and provide a process to ensure coercion or exploitation does not take place. Finally, we state that the definition of who can be a Legally Authorized Representative (LAR) must be standardized and conform to national norms and the laws of the State of Minnesota, and also that a consent advocate should be a regular part of the consent process for vulnerable research participants.

- *Department of Psychiatry:* The Department of Psychiatry routinely engages in research with research participants with impaired consent capacity. However, these studies are not unique to the Department of Psychiatry. We are recommending that appropriate training programs for clinical staff, investigators and IRB members be developed and mandated when research involves a vulnerable population. We also recommend that one of the new IRB panels be dedicated to reviewing studies involving research participants with impaired or fluctuating capacity to consent and that this panel be responsible for all applications that involve this population. To that end we propose the

University of Minnesota Clinical and Translational Research Institute (CTSI) assume management for the conduct of interventional drug and device trials in the Department of Psychiatry. We further recommend that an independent consultant be hired to assess the clinical and research climate concerning psychiatric studies conducted at Fairview to develop a plan that addresses shared concerns and creates a climate where clinical research with psychiatric research participants can occur that meets the highest ethical standards of research possible. We state that an education plan be developed for the two faculty specifically named in the External Review report. Finally it is important to articulate and act on how to improve the process of how research is done, especially in this very important population.

We document in this plan a process in which clinical staff who provide care for psychiatric patients but who are not part of the research team will be able to participate in the early stages of study and protocol development to provide insight on how the study might impact clinical care of the patient and to create an atmosphere of shared responsibility for all aspects of the research study. In addition we recommend a process where engaged community members can have a real voice in how psychiatric research is conducted. We suggest that the FUROC, mentioned above, continuously monitor the research climate and be regularly engaged with groups involved in the clinical research process (CTSI, HRPP, and OVPR) to make suggestions and course corrections.

- *Engaging research participants:* Research participants should be considered part of the research team and their feedback should be an integral part of the process for conducting human research. In addition, a process should exist to deliver information back to the participant on the outcome of the research he or she participated in. Current mechanisms for these activities are insufficient and require considerable strengthening. To that end, we recommend a new staff position in the CTSI Community Engagement Core, a Community Liaison Officer, should be created to provide day-to-day management of the research subject engagement activities and to regularly report

defined metrics to OVPR. We recommend that the CTSI Community Liaison Officer be actively involved in these activities and act as a resource. We recommend a process be adopted to promptly address all reported concerns and that metrics be collected on research participant satisfaction. Finally, we recommend a process to ensure that a plan is in place to share final result with all research participants.

- *Education and training of investigators:* The team strongly believes that appropriate training of investigators is at the core of creating and embracing a culture where research can be conducted that meets the highest ethical standards. We recommend a new position of a Human Research Procedures, Policies and Ethics Education Coordinator within the CTSI or HRPP with coordinated links to the Center for Bioethics. This individual will be responsible for establishing guidelines for minimal expectations for both basic and advanced research compliance and research participant protection training that is reviewed and approved by an oversight process in the HRPP. This individual will ensure that required and optional training modules on appropriate topics are available and kept current. Specific attention should be given to curriculum for advanced training in the use of research participants with limited or fluctuating capacity to consent. Training programs should be developed collaboratively by the HRPP, CTSI, the Center for Bioethics and other U of M resources to address these needs. This process should engage community members, including research participants.

- *Accountability metrics:* As part of implementing the recommendations included in this report, metrics will be collected to assure that the changes made are meeting the expectations of research participants, the University community, and our partners. These metrics also allow for continued quality improvement with the expectation that they will be reviewed at minimum twice each year by the Community Advisory Board and by the new OVPR Research Compliance office.

- *Managing conflicts of interest:* The team recommends that the U of M adopt a more stringent reporting structure than dictated by current policy or Public Health Service (PHS) guidelines. The Implementation team proposes that henceforth, a financial interest, including equity, consulting income, speaker fees, and/or royalties must be disclosed from the first dollar or from contractual rights to receive funds. In addition, the team recommends that in general an investigator may not receive any personal compensation from a company during the time that investigator participates in any new research study funded by that industry sponsor.

- *Community Oversight Board:* The team fully embraces the evolving concept that active participation of the community is integral to the conduct of research involving research participants. We recommend creation of a 12-member board of external academic, professional and community experts. This board will advise the OVPR and the HRPP on best practices for research participant protection. The board will report regularly to OVPR.

- *External advisor:* An international expert with knowledge in research participant protection will be retained and will work with those responsible for implementing the action plan described in this report. The expert will provide input and feedback to the Vice President for Research and Vice President for Health Sciences on progress. The expert will be engaged on a monthly basis until implementation is complete.

- *Required resources:* The current annual budget of the U of M HRPP is $2.2M. The estimated cost for this action plan is a $5.5M one-time cost and an increase to a more extensive HRPP annual budget of $4.4M.

This report, describing how to implement the recommendations, was presented by the Implementation team for a 15-day public comment and review period for those inside and outside the U of M.

2. Introduction

2.1. Reason for the Implementation team

In May 2004, Dan Markingson, while enrolled in a clinical trial of an antipsychotic drug study at the University of Minnesota, committed suicide. Since that time individuals and groups within and outside the U of M have raised questions about the study, how Markingson was recruited to participate as a research participant, his treatment during the study, the circumstances of his suicide, and the adequacy of the subsequent investigations. Following a series of discussions that occurred in Fall 2013, on December 5, 2013 the University of Minnesota Faculty Senate passed a resolution calling for an inquiry to examine current policies, practices, and oversight of clinical research with research participants at the U of M, in particular clinical research involving adult participants with diminished functional abilities, and asked that there be an independent panel to conduct the review. The reasoning behind the resolution was while investigations had been conducted on the Markingson case, those investigations did not address the broader question of whether the U of M's current policies, procedures and practices reflected best practices in clinical research with research participants and the faculty's high ambitions for ethical behavior.

In January 2014, Eric Kaler, President of the U of M, endorsed the Senate resolution and charged Brian Herman, Vice President for Research, to oversee the inquiry. In June 2014, the Association for the Accreditation of Human Research Protection Programs (AAHRPP) was awarded a contract to assemble a review team and logistically manage the review process. A panel of six outside experts, selected by AAHRP, was contracted to conduct the review.

The panel conducted its work from August 2014 to March 2015, this included reviewing hundreds of documents, conducting a 2-day site visit where they interviewed 53 people and receiving dozens of comments from stakeholders inside and outside the U of M.

On February 23, 2015, the panel issued a report containing 63 recommendations for improving the human research protection program at the U of M. The language of the February report was strong in its statement that while our current program is in many respects adequate, the U of M must make changes if it wishes to have a leading program in research participant protection. The External Review's report is available at http://research.umn.edu/advancehsr/keydocs.html.

In a separate but related activity, on March 19, 2015 the Office of the Legislative Auditor released its report that focused on the events surrounding the 2004 death of Dan Markingson. The Auditor's report determined that it was not possible to know whether Dan Markingson's suicide was connected to his participation in the U of M clinical research trial, but did state that the Markingson case raised ethical and conflict of interest issues. Further, the Auditor's report stated that the U of M was insular and defensive in its response to the Markingson case. The Auditor recommended that the U of M fully implement the recommendations in the External Review report. The Auditor's report is also available at http://research.umn.edu/advancehsr/keydocs.html.

On March 12, 2015, President Kaler charged Brian Herman, Vice President for Research, and Brooks Jackson, Vice President for Health Sciences, with the responsibility of overseeing the implementation of the recommendations of the External Review by establishing an Implementation team made up of individuals internal and external to the U of M who had the qualifications and expertise to review the recommendations and develop a plan to implement them. In addition, at its March 27, 2015 meeting, the University of Minnesota Board of Regents approved immediate and longer term action plans to implement the recommendations.

The Implementation team has 13 members, some external to the U of M, and is chaired by Dr. William Tremaine, Professor of Medicine, Mayo Clinic and Director, Mayo Clinic IRB.

During the time of the Implementation team's work, two additional reports were made available to all team members: (1) a draft State of Minnesota Office of the Legislative Auditor's report of May 5, 2015 which presented findings from all industry-sponsored studies at the U of M from 2004-2014; and (2) *Final IRB Investigation Report Into Fairview Concerns Regarding Psychiatry Research Studies at the University of Minnesota*, referred to as the "Oakes report". This team considered the information from these reports in the recommendations contained in this report. Report 2 above is publically available on the Advancing Human Subjects Research website.

2.2. Team Charge

The Implementation team was specifically charged with the following:

- *A work plan to implement the recommendations, to be produced within 60 days*
- *Accountability metrics for the work plan*
- *A recommendation regarding necessary resources to implement the recommendation*
- *Engagement of appropriate critical stakeholders in assisting with the implementation*
- *Engagement of an external advisor with deep knowledge in human research protection programs, regulations, and law to work with the U of M on the implementation*
- *A review of best practices regarding conflict of interest for researchers engaged in human research participant studies, including a recommendation on organization or structural changes*
- *Formation of an oversight committee made up of community leaders and other parties affected by the implementation and the U of M research program*

2.3. Team Process

The Implementation team met weekly from April 1, 2015 through May 6, 2015. During those meetings team members presented action plans on each of the 63 recommendations made by the External Review. Each proposed action plan was co-

authored by two or more Implementation team members and was brought to the full team for discussion and debate. Significant between-meeting email and telephone communications were held among team members to review the recommendations and prepare the final work plan.

In addition, the implementation team created a pubic website, http://research.umn.edu/advancehsr/ that tracked all the activities of the implementation team, provided weekly summaries of the Implementation team meetings, listed relevant documents related to the activities of the Implementation team, and provided information about public hearings and other consultative efforts on this subject held at the U of M. The team also created an email address advancehsr@UMN.edu to receive feedback from interested stakeholders at any time.

2.4. Structure of the Report

Sections 3 through 18 of this plan contain the detailed implementation work plan, which is tied to the specific recommendations of the External Review panel. Each recommendation from the External Review report has been given a number and the complete list of recommendations can be found in the Appendix to this report. We have grouped some of the recommendations under broader headings than those used by the External Review panel when we saw overlap or similarities between recommendations.

3. Intent of the Report and Cultivating a Culture of Ethics

Covers External Review report recommendations: 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.1.5, and 3.6.1, 3.6.2, 3.6.3

The purpose of the University of Minnesota Human Subject Protection Program is to protect the rights and welfare of all research participants who participate in research, especially those with impaired capacity to consent. U of M scientists, clinicians and programs are fundamentally

obliged to promote the welfare of each research participant. We do this with a beneficent regard for their health and a commitment to avoiding harming them. As an academic research center, the U of M seeks to discover and test emerging ideas and products to improve the health of all persons and the health of the broader community. To this latter end, researchers enroll research participants in experimental studies. Notwithstanding the importance of those studies individually or collectively, regard for the individual well-being of those who volunteer to be research participants and respect for their freedom to consent to and to refuse treatment or research interventions must never be eclipsed by the research interests of the U of M or its individual researchers.

The aim of improving the care of research participants who participate in research is simple to state but has many complex parts and ramifications.

First, it entails unambiguously affirming the primacy of the U of M's and each individual investigator's duty to keep the well-being of patients who become research participants firmly in mind and at the center of the policies and procedures of the U of M. We must be mindful that individuals who make the gift of consenting to participate as research participants are entrusting us to faithfully promote their well-being and to respect their freely given, informed consent as they enroll in research, and that they retain the right to decline to continue to consent to that research project for any reason but especially as new data, side effects, or unexpected circumstances occur during the course of the study. We are aware of the special responsibilities toward those persons whose capacity to consent to research is impaired during participation in a study or fluctuates during the course of a study.

Second, the research enterprise must recognize that the population of potential research participants is a valuable resource to the community and to the scientific enterprise. The U of M as a whole is a steward of that resource. Any action that harms the trust between potential research participants and researchers affects the entire scientific enterprise. In this sense, one

failure adversely affects the particular study, all present studies, all future studies, and even the broader community.

Third, the work plan of this implementation team must speak to all elements of the health research enterprise and must:

- Provide education in ethics to all of those who oversee and conduct research on human beings.
- Protect and promote the rights and interests of research participants who are vulnerable to various kinds of coerced consent or who lack (or may come to lack) the capacity to consent to (or continue to consent to or decline) continued participation in research.
- Comply with the letter and be committed to the spirit of the laws and regulations that pertain to the treatment of patients and of persons who are enrolled in research.
- Be transparent and accountable in all research activities. This includes a culture where anyone who observes a breach of the ethics or rules for research may report his or her observations without fear of retaliation and with confidence that his or her concerns will be investigated.
- Manage individual and institutional conflicts of interest that potentially undermine the well-being of research participants regardless of whether they arise from financial, career, or personal interests.
- Sustain a culture of engagement among all colleges in the U of M that recognizes the special status of university-based research. This status is grounded in the integrity of academic research, as well as in respect for cultural diversity and for the social, economic, and cultural implications of biomedical research.
- Effectively engage in a dialogue with the broader community that has a stake in benefitting from research and an interest in protecting their loved ones who may participate as research participants.

- Reinforce that communication without action is discouraged. In other words, changing the culture on research participant protection is not a communications-driven activity.

The work plan presented here signifies an awareness that reforms are needed and offers a roadmap for improving culture. Culture is an attribute of a community, not an institution. Institutions' policies, procedures, practices, and leadership creates and sustains the ethical culture for its activities. Sustaining an ethical culture for research with research participants will require institutional time and resources. More importantly, it will require personal commitments and an understanding that cultural reform is necessary if health research is to be able to keep its promise of creating better knowledge to serve human health.

Specific Actions

In addition to the principles put forth above, the following actions are designed to address recommendations 3.1.1 to 3.1.5 in the Leadership Initiatives section, and 3.6.1 to 3.6.3 in the Institutional Culture section of the External Review report.

- Create a document that explains the U of M's commitment to research participant protection, including the ethical conduct of research involving research participants.
- The HRPP, IRB, OVPR, and AHC websites as well as departments that are involved in research with research participants, will incorporate clear statements, in a prominent location, about the U of M's commitment to research participant protection, including the ethical conduct of research involving research participants. The statements will be written for audiences that include current and potential research participants, investigators conducting research with research participants; U of M faculty; the general public and others who are concerned with the U of M's maintaining the highest ethical standards. In addition, there will be a one-stop web location that has easy-to-access consolidated information regarding IRB policies, educational materials and programs plus resources for getting advice and consultation on legal, regulatory, and ethics topics related to research participant protection.

- Statements and websites will be reviewed and discussed with a newly created Community Oversight Board described later in this report as well as the Research Compliance Advisory Committee (RCAC). The RCAC is a high level faculty advisory committee who provides guidance and consultation to the Vice President for Research on issues related to research risk and compliance.
- Future strategic plans for segments of the U of M that relate to research participant research will include statements on the U of M's values as they relate to research participant protection.
- Planning for basic and advanced education of researchers conducting studies that use research participants will include the voice of research participants, research ethicists, and educators. Section 12 "Educating and Training of Investigators" has further details on including these voices.
- Educational opportunities on human research participant protections will include moderated discussions at department faculty meetings that will involve peer-to-peer education.
- The U of M will host a Campus Conversation or other forum on the topic of human research participant protection.
- The U of M will regularly benchmark itself against its peers to ensure that our human research participant protection programs meet or exceed the norm.

4. IRB Membership

Covers External Review report recommendations: 3.2.1, 3.2.2, 3.2.3

The External Review focused on the biomedical IRB and noted there were no comments made during interviews or findings in any of the documents reviewed that suggested there were problems in the performance of the Faculty Social /Behavioral IRB or the Student Social/Behavioral IRB. Currently, the U of M medical IRB has nine member slots with a requirement of five members for quorum. There is a pool of 37 potential members including physician scientists, other scientists, and non-science members. On average, an IRB member

attended only 6 of 26 meetings during the first half of 2014. This use of a "rolling roster" of members causes a lack of continuity and consistency by the IRB. Historically, at most meetings of the medical IRB there were only 5 to 7 members to handle large agendas. The External Review also noted that the expertise on the medical IRB did not sufficiently match the types and numbers of research protocols reviewed: there were no members from adult hematology, oncology, transplant, cardiology, surgery, or neurology although those specialties comprised over 300 protocols from October 1, 2013 through September 30, 2014.

The Implementation team agreed that major changes are required concerning the perception of service on the IRB, the composition of the IRB, and compensation for service on the IRB as noted in the following recommendations:

- **The U of M must promote measures to increase the value of service on the IRB**

  To recruit U of M faculty to serve on the IRB, IRB service must be viewed as a valued activity. Among some faculty and in some departments at the U of M, the current culture is that IRB service is burdensome, unvalued, and to be avoided at all costs. This is in contrast with serving on or chairing an NIH study section, which is not only valued but encouraged and celebrated. Change will require the following: the President, the Provost, the Vice President for Research, the academic deans (including the Dean of the Medical School), and department chairs must make it clear that serving on an IRB is a service activity that is valued and encouraged; faculty members, when judging their peers for tenure and promotion should view IRB service as an important contribution. In addition, faculty, when considering whether to serve on the IRB, must recognize that reviewing studies for the IRB will improve their own scientific process of conducting human research using research participants, just as reviewing proposals for NIH improves their own proposals.

- **Increase the number of full IRB committees and limit the number of items on each agenda**

The Implementation team recommends increasing the number of full board medical IRBs from one to four, each with weekly two hour meetings. This would increase the number of biomedical meetings per month from five to 16 (and the hours of convened meetings to 32 hours per month) which should be sufficient to handle the workload. Each medical IRB should have at least 13 members with a quorum of seven members. The IRB staff should triage the agenda items such that the workload for each meeting can be completed in the allotted time. Each agenda could include new submissions, continuing reviews, modifications, and deferral responses. We also recommend that one of the full board biomedical IRBs have significant expertise in research with vulnerable research participants.

- **Increase number of IRB members**

Increasing the number of IRB members will require representation from departments and divisions that constitute the highest volume of reviewed protocols. Based on the number and type of reviewed protocols, each of the following departments and divisions should have one or more members on one or more of the four IRBs: Adult Hematology, Oncology, Transplant, Psychiatry, Cardiology, Surgery, Pediatric Hematology/Bone Marrow Transplant, Pediatric Endocrinology, and Neurology. In addition, faculty from the School of Nursing and nurses with research or clinical expertise in these areas should serve on the four IRBs. Board members on each medical IRB committee could also serve as alternates on the other medical IRBs to ensure an adequate pool of members to achieve quorum, to foster uniformity between the decisions of the four biomedical boards and to share the expertise of members between the boards. There will also be times when relevant scientific or human research participant expertise may not exist on the standing biomedical IRBs and will necessitate recruitment of other board members with special expertise that is either internal or external to the U of M. These members could include a geneticist, a prisoner representative, an ethicist, or a stem cell expert, each would serve on a least one committee and to serve as a resource for the other committees.

- **Compensate IRB board members**

The participation of members on all of the medical and non-medical IRBs is currently voluntary. The University of Minnesota uses different revenue sources for compensation that vary by school/department/college. Participation on the IRB is an extremely time consuming process, particularly for clinical faculty who must generate partial salary support from clinical service and research sources, and time devoted to IRB service decreases contributions to their salaries from other sources. The Implementation team recommends that clinical faculty board members who serve on all the medical and non-medical IRBs should be compensated by the U of M through the provision of salary support to their department or division to allow 10 percent protected time from other responsibilities to serve on the IRB. The Implementation team further recommends that non-clinical faculty who serve on medical or non-medical IRBs be compensated at an appropriate rate that will be determined before this plan is put into place. It is the expectation of the U of M leadership that the relevant department chairs, division leaders, and deans will embrace and enforce this process. IRB chairs should be compensated by providing salary support to their department or division to allow 25 percent protected time from other responsibilities to serve on the IRB. More community members should be recruited for the new medical boards and to reduce the work burden on each community member. Community members on all the medical and non-medical IRBs should be compensated $3-5K yearly, and also receive parking vouchers, and be invited to an appreciation dinner at least once yearly.

- **Establish requirements for attendance**

Board members should attend at least 60 percent of meetings and those with lower attendance will be asked to discontinue membership.

- **Facilitate use of central IRBs (CIRB) for human participant research**

Many granting organizations including the National Institutes of Health, the National Cancer Institute and some industry sponsors require oversight by a CIRB rather than

individual IRBs at participating research centers. The UMN supports the use of CIRBs as well as the opportunity to serve at the CIRB for some multicenter studies. In the future the use of CIRBs may reduce the workload for the UMN IRB and make it possible for cost-savings and a reduction in the need for some of the boards and some personnel.

5. IRB Protocol Review Process

Covers External Review report recommendations: 3.2.4, 3.2.5, 3.2.6, 3.2.7

The implementation team discussed several issues related to the IRB protocol review process in response to the External Review and Legislative Auditor's reports. Concerns raised in those reports regarding inadequate documentation at committee meetings included: discussion of risk and benefits of participation for research participants; controverted issues; long turnaround times for review and meaningful details on nature of change and the rationale for changes made to protocols. The meeting agendas frequently had multiple items that did not require full committee review and the sheer volume of the agenda items brought into question the ability of the committee to have thoughtful discussion of all the items with the appropriate expertise at the table. There needs to be a balance in the agenda items that takes into account the complexity of the review or protocol, the number of items and the type or review required for a new application or a change in protocol. The effort to standardize meetings will lead, eventually, to more efficiency in review and allow for a turnaround time of two weeks (10 business days) for a review response from date of submission. Current and planned updating to forms allows for better communication during meetings.

Moving forward, IRB meetings will be conducted in a uniform format with focus on the regulatory requirement for approval. The criteria for approval will be discussed and any controverted issues will be voted on or noted. Stipulations that are identified by a reviewer will be associated with a specific criterion for approval. There have already been efforts made by the IRB staff to revise the format of the convened IRB meeting to include a meaningful summary of the study, documentation of discussion related to controverted issues, the resolution of controverted issues, and documentation to support the rationale of the

committee for requesting changes to the application and consent form. Consistent feedback on items should be sought from members and IRB staff at convened meetings. The IRB Assistant Director is present at convened meetings to educate, lead, and enforce these new guidelines.

The IRB will also have adequate administrative staff to provide pre-review of items to determine if it is necessary and required to bring them to full committee. This pre-review will decrease the number of items on an agenda. There already has been a great deal of work done to revise forms for application, reporting, and review to make the process more transparent and efficient. For example, there have been changes to the triage and review forms used by research compliance supervisors used in protocol reviews. Guidance and training needs to be developed and implemented for IRB staff to assure their expertise in the independent review and decisional capabilities on the need for full committee review. In addition, the adoption of an electronic IRB system will better facilitate communication and processes.

We recommend that some IRB staff and members conduct benchmark visits to other institutions to gather information and learn about best practices outside of the U of M. These benchmark visits will allow the opportunity to review forms and documents from other institutions as well as to observe IRB practices.

6. Scientific Review of Studies

Covers External Review report recommendations: 3.3.10, 3.3.11, 3.3.12, 3.3.13, 3.3.14, 3.3.15, 3.3.16, 3.3.17

Studies using research participants must undergo scientific review to ensure that the study has scientific validity and that the research procedures are appropriate for the study. That assurance is an integral part of the process that the IRB uses in its consideration of weighing the scientific knowledge that will be gained from the study against the risks for study participants.

UMN IRB Policy 904 covers scientific review. Under current policy, for studies involving minimal risk that are processed under expedited review, the scientific review is conducted by the IRB reviewer. For studies involving greater than minimal risk that are reviewed by the social and behavioral sciences IRB panels, the IRB members perform scientific review. For studies involving greater than minimal risk that are reviewed by the full biomedical IRB committee, scientific review must be done by independent peer reviewers, and researchers must provide documentation of that review.

IRB Policy 904 allows four methods for completing the independent peer review requirement: 1) Full peer review that is part of applying for funding to federal agencies such as NIH and NSF. 2) National non-federal agencies (e.g., March of Dimes) that use peer review as a part of their funding process. 3) Peer review done locally at the University of Minnesota. 4) Peer review facilitated by the University Human Research Protection Program (HRPP) and including review by a biostatistician.

Method 3 above has three options for peer review: (a) review by the U of M's Cancer Protocol Review Committee (CPRC), (b) review of by Clinical and Translational Science Institute (CTSI) of their pilot funding awards, (c) Department peer review.

The External Review raised concerns that when Method 3c, departmental peer review, is employed, a number of issues exist including a lack of appropriate expertise of the peer reviewers, a failure to follow appropriate conflict of interest guidelines for peer reviewers (including when the peer reviewer is superior to or subordinate to the investigator), lack of sufficient detail in the review documentation, violations of the policy requiring a minimum of two reviewers, and insufficient documentation in IRB minutes that scientific review was adequately considered. The panel made eight recommendations related to scientific review. The action plan below addresses all eight of the recommendations.

In response to the External Review report recommendations, we will:

A. Eliminate Department Review

Method 3c, department review will be eliminated and that function will be combined into a new Method 4 called "HRPP Managed Scientific Review."

B. Revise HRPP Managed Review Procedures

For the new "HRPP Managed Scientific Review" the review process will be revised according to the following:

1. The review criteria will appropriately combine what is now listed in IRB Policy 904 for review method 3c and review method 4.
2. Criteria will be developed for determining which studies require review by a biostatistician prior to the scientific assessment.
3. Peer reviewers:
    a. A minimum of two appropriately qualified experts will be required. The HRPP can require more than two reviewers if in their judgement scientific review would be aided by additional expertise. Reviewers can be from inside or outside the U of M.
    b. If the HRPP determines that a specialized reviewer is required from outside the U of M, the HRPP is authorized, on a limited basis, to provide an appropriate honorarium to that reviewer.
    c. Potential reviewers may be suggested by the investigator or may be suggested by the HRPP independently of the investigator. The HRPP, however, determines who will review and invites the reviewers.
    d. The names of the peer reviewers are not released to the investigator.
    e. Reviewer suggestions must come with a short statement of the expertise of the reviewer so that it is clear they are qualified to conduct a scientific review of the study in question.

f. Peer reviewers must have no real or perceived conflict of interest that would influence their work as reviewer. For the purpose of this review process, the definition of "conflict of interest" is, "Any situation that could cause a reasonable person with all the relevant facts to question the impartiality of the committee member or that leads a committee member to question his or her objectivity," which is the definition used by NIH for reviewers participating in the review of NIH grant applications. Before reviewing the application, the reviewer must assert they have no conflict of interest related to the study in question.

g. Subordinates may not serve as a peer reviewer for a study where their immediate superior is a named investigator. For example, faculty may not peer review a study of their department head.

h. Those who have collaborated on a study with the investigator during the previous 12 months may not serve as a peer reviewer.

i. Other examples of conflict include: an investigator or member of the research team conducting the study; holds a financial interest in the business entity sponsoring the research; and could financially benefit from the results of the research (e.g., holds a key patent related to the research.)

4. Create a review form to be used by the peer reviewers. This form will replace the "ScientificReviewTemplate.doc" form and will require peer reviewers to address each point of the set of new criteria. The form should provide explicit instructions to the peer reviewer on how to conduct the peer review, much in the way that NIH provides instructions to reviewers of NIH grant applications.
5. HRPP staff will screen peer reviewer submissions for incomplete reviews, and work with the reviewer to complete an adequate review.
6. HRPP staff will not make any conclusions based on the peer reviews, but will organize and submit the required number of peer reviews to the IRB panel that is reviewing the study.

7. The investigator will receive the scientific reviews, with reviewer names deleted.
8. The HRPP managed review process could be done through the CTSI Clinical Translational Research Portal. However it is implemented, the process should have a single flow so that investigators are clear about the process.
9. Ideally, the goal is to provide a 10 day turnaround time on reviews.

The intent of this new process is not that the IRB panels conduct the scientific review, but rather that the HRPP manage the scientific review. The new process is intended to add no additional burden while at the same time ensuring that appropriate experts are performing the scientific review and that only those without conflict perform the review.

C. Revise IRB Panel Review Procedure

1. Add to the IRB meeting checklist an item to discuss the type of scientific review that occurred for the study being considered and whether the scientific reviewers had any concerns.
2. Document the IRB's review of the scientific assessment documents in the IRB minutes.

D. Revise IRB Policy 904

Revise IRB Policy 904 to reflect the above changes.

7. Fairview University Research Oversight Committee

An oversight committee that can monitor the entire spectrum of clinical research across the Fairview health care system is essential. This committee would have the following charges: (1) ensure that both the research and clinical regulatory obligations of Fairview are met (2) ensure that research protocols conducted at Fairview are appropriate and feasible within the concurrent demands of patient care and (3) ensure that staff members at Fairview have a voice in the conduct of research at Fairview. The

committee will propose and approve policy and procedure changes, as needed, to achieve the charge. This oversight committee would include senior leader representatives from the Fairview Research Office, Fairview clinical staff, UM Physicians, University Academic Health Center and the University Office of the Vice President for Research. Convened meetings will occur quarterly with additional meetings if needed. The activities of the meetings will be posted on a website accessible to the research and clinical staff at Fairview and the U of M. Fairview staff, U of M faculty, and the public may contact this committee with concerns. Although this committee may need to address issues that arise with specific research studies that may impact policies and procedures, the FUROC will not function as a protocol review committee.

8. Monitoring of Studies

Covers External Review report recommendations: 3.3.18, 3.3.19, 3.3.20, 3.3.21, 3.3.22, 3.3.23

The most effective way to determine if clinical research studies are being performed as they should is to monitor them after IRB approval. There are currently two processes by which this monitoring occurs at the U of M: 1) the Post-Approval Review (PAR) program that reports to the IRB and OVPR and 2) the clinical trial monitoring service that reports to the Clinical and Translational Science Institute (CTSI) and the Academic Health Center.

As noted by the External Review, the PAR program may review, based on policy and procedures, any human subject research protocol reviewed by the IRB. This review is not equivalent to regular and ongoing monitoring of individual research protocols as described in the International Conference on Harmonisation Good Clinical Practice Guidelines (ICH GCP E6 5.18) that is generally conducted by the CTSI. Review by PAR is, generally, the review of the conduct of a protocol at a single point in time. The CTSI clinical trial monitoring service, however, is a service that is intended to assist U of M sponsor-investigators and conducts monitoring over the entire lifetime of the study. This assistance includes the above described GCP monitoring required by FDA regulations.

The External Review noted that post-approval monitoring has not effectively addressed concerns raised about research at Fairview and suggested that educational initiatives related to the functions of PAR may be warranted to promote greater awareness. The panel also observed that publication of policies about post-approval review, including the methods by which research protocols are selected, might also promote awareness of this program. Communication about PAR activities and results was a recurring theme in the External Review report. It was also suggested that the U of M consider the reporting relationship for the PAR function.

The Implementation team agreed that changes are required as noted in the proposed actions for each of the following action items:

- **Increase and expand PAR monitoring**

  It is recommended that results of PAR monitoring be reported to FUROC and the IRB. Fairview and the U of M would each disseminate information to their respective communities. In addition, at Fairview and UMP this reporting would extend to the clinical care functions as well as the research function. At the U of M, reporting would extend to the Office of Institutional Compliance. OVPR would prepare communication about findings for the community. Policies related to post-approval review, including information about risk-based selection of protocols for review, should be posted and available to the public.

  At the time of approval, the IRB shall determine if a protocol should be reviewed by the PAR during the first year of activity based on the anticipated risks of the study. In addition, the PAR will audit a sufficient number of other studies, as determined by statistical methods, to insure appropriate oversight of institutional research. A standardized evaluation is recommended that would identify compliance with protocol specified procedures and measures modified, if any, to enhance research participant safety. The newly created OVPR

Research Compliance Office should establish a process for monitoring follow-through on any recommendations for changes in study procedures.

- **Report PAR findings and IRB follow-up to department and school or college leadership**

The OVPR Research Compliance Office should provide information to department and school or college leadership about IRB follow-up to PAR reports. Reports to academic unit leaders and other institutional leaders should provide information about all PAR activities to share information about research that is well and properly performed as well as findings that require corrective action. Implicit in this recommendation is that the department and school or college leadership will be held accountable for making sure any corrective action is put in place in a reasonable time frame. Failure to do so could result in suspension of the further enrollment in the trial including suspension of the trial.

- **Perform live consent monitoring**

Live consent monitoring should be a part of this model with patient consent. The process would include: memorializing the interaction by recording, preferably by video; monitoring the process; and contributing to capacity assessment and consent via dialogue between the investigator and the consent monitor.

9. For Cause Investigations

Covers External Review report recommendations: 3.2.8, 3.2.9, 3.2.10

The External Review stated that "one of the most challenging but critical functions of an IRB is addressing incidents of researcher noncompliance" and noted that "in alignment with these federal regulatory requirements, the U of M's IRB has policies and procedures to address noncompliance. The IRB policies not only address the requirement that researchers report incidents of noncompliance to the IRB, but also outline the IRB's processes for handling the incident reports once received". However, it was noted that "neither of the active

investigations to which it was privy during this evaluation had members with relevant expertise." Further, the report noted external resources could have been used to help with the work of IRB investigation committees, but were not.

To address these issues, we propose the following:

- Place responsibility for these investigations in a newly created Research Compliance Office in the OVPR.
- The newly created Research Compliance Office in the OVPR will review and revise procedures related to the composition of the investigation panels to insure that membership includes members with relevant expertise.
- When a complaint is received, the complainant should promptly receive a response that includes information about what will happen next and a later response about the resolution.
- For a significant adverse event related to participation in a research study resulting in death, disability, or injury, the U of M must have a system for response to research participants and families that is prompt, empathetic, and informative. The principal investigator of the study must be an integral part of this process and should receive training on these types of discussions. This training should be incorporated into routine training for investigators.

10. Human Research Participants Who Have Impaired or Fluctuating Capacity to Consent

Covers External Review report recommendations:

Capacity to Consent 3.4.1, 3.4.2, 3.4.3, 3.4.4

Vulnerability to Coercion 3.4.5, 3.4.6

Longitudinal Assessment of Capacity 3.4.7, 3.4.8

Legally Authorized Representatives 3.4.9, 3.4.10

Use of Surrogate Consent 3.4.11, 3.4.12

The policies and procedures described in this section of our report will create additional protections and inform best practices when proposed research involves adults who lack the ability to provide consent to participate in a study or whose ability to consent might wax and wane during the course of a study.[1]

Capacity to Consent

Definitions:

Prospective research participants lack "consent capacity" (i.e., the ability to reflect on information about the experimental proposal and their experience of being a research participant) when they cannot make or express an informed choice to enroll or continue in a clinical trial in light of their understanding of the risks and benefits of the research and their own values.

All persons who are individually adjudicated or classified by law as "incompetent" shall be deemed to lack "consent capacity."

Best practices shall refer to all aspects of this policy. Essentially it refers to a receptivity to considering new publications, research, and peer models for amending all aspects of the use of research participants insofar as such material is empirically validated and consonant with applicable laws and regulations.

General Considerations:

Impaired consent capacity occurs in a wide range of conditions and disease states. The IRBs should inform investigators that impaired consent capacity is not limited to specific disorders and provide a list of those conditions where impaired consent might exist.[2]

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[1] National Bioethics Advisory Commission. Research Involving Persons with Mental Disorders that may Affect Decisionmaking Capacity December 1998. Volume I. https://bioethicsarchive.georgetown.edu/nbac/capacity/TOC.htm

[2] Research Involving Individuals with Questionable Capacity to Consent: Points to Consider (November 2009) http://grants1.nih.gov/grants/policy/questionablecapacity.htm

Consent capacity is task-specific both to the research proposal and to the complexity of decision-making required of the person considering consent to the study. Therefore, a judgment regarding an individual's capacity to consent may not be the same for all research studies.

In many individuals, consent capacity is not static. A research participant's consent capacity may improve, deteriorate or fluctuate during the course of a research study. Study protocols, consent forms and procedures should anticipate and address this phenomenon. Safeguards must in place prior to participant enrollment and, as appropriate, throughout the course of research participation.

IRB Review Procedures:

The IRB may determine that research that includes individuals who lack consent capacity may be accepted for research under the conditions that the research is likely to benefit persons with impaired capacity who are similarly situated with regard to benefiting from the medical knowledge to be gained by the research.

The IRB may accept that persons with mild impairments of decisional capacity (as defined by an instrument that has been validated for assessing the capacity to consent for research) may consent to research that is minimal risk and eligible for expedited review.

The IRB may approve any instance of greater than minimal risk research that is likely to benefit persons with impaired capacity who are similarly situated with regard to benefiting from the medical knowledge to be gained by the research provided such consent from persons with any decisional impairment results from the use of a Legally Authorized Representative to consent and give ongoing consent for the research participant. A Legally Authorized Representative (LAR) is defined as "an individual or judicial or other body authorized under applicable law to consent on behalf of a

prospective research participant to the research participant's participation in the procedure(s) involved in the research." 45 CFR 46.102(c).

Policies, guidance, application and review forms, as well as the IRB review process should be reviewed and restructured for clarity and consistency to promote clear understanding and compliance with policies and procedures to assess and monitor capacity to consent. This review should align research participant screening or other protections with the degree of risk involved in a study or the level of risk of impairment in a targeted or enrolled population. This review should also promote strategies to enhance research participant decision-making, including the research participant's ability to select a surrogate decision-maker in the event that the research participant loses decision making capacity during the course of the study.

IRB reviews should include a substantive assessment of the appropriateness of protocol-specific procedures addressing consent capacity in light of the research participant population being approached.

The IRB should devise means to verify decision-making capacity and to assess matters pertaining to vulnerability in all protocols.

Adults who lack consent capacity may not be the research participants of research when the research can be performed with research participants who possess consent capacity and the research is not directly relevant to investigating the disorder causing impaired consent capacity.

Studies involving greater than minimal risk but presenting the prospect of direct benefit to persons with impaired capacity may enroll adult research participants who lack consent capacity with at least the use of a LAR and in some cases an additional consent auditor.

Investigators and research staff who obtain consent should consider every potential research participant's capacity to consent to the research. In studies where the recruitment of individuals with impaired consent capacity is not anticipated, the judgment that prospective participants have the capacity to consent to the research can ordinarily be made informally during routine interactions with the participant during the consent process.

Planning Before the Study for Impaired Consent Capacity

The method used to assess capacity, and when appropriate, the documentation of this assessment, should be tailored to the study population, the level of risk, and the likelihood of the involvement of participants with impaired consent capacity. An appropriate assessment tool, such as the tool developed by the University of Kentucky (or others listed in footnote 4 below), should be employed to assess capacity to consent before beginning the formal consent process.

Investigators and research staff responsible for the consent process and consent capacity determinations should be qualified and trained in the assessment of consent capacity, the difference between minimal risk and greater than minimal risk, the difference between competence and consent capacity and vulnerability, and the use of the chosen instrument used to assess consent capacity.[3]

When it is anticipated that the research might include individuals who have impaired consent capacity, researchers should assess prospective participants' consent capacity and determine whether it is adequate to permit informed consent. The principal investigator must propose the use of an instrument that has been validated for

[3] Definitions of minimal and greater than minimal risk and of competence and consent capacity are present in regulations. Minimal risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons (45 CFR 46.303(d)).

assessing the capacity to consent for research.[4] This determination should be documented in the research participant's individual research record or case report form.

When it is anticipated that the research might enroll persons whose capacity to consent or revoke consent during the study may become impaired, researchers should devise a consent capacity monitoring plan to last for the duration of the study. Re-assessment of consent capacity will be based on risk, initial consent capacity, and the likelihood that the consent capacity might change over time. The plan should describe the steps to be taken (e.g., either seeking a legally authorized representative or discontinuing the research participant from the study) if consent capacity is lost while a study is underway.

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[4] There is an increasing body of research validating ways to assess capacity for consenting to research. The use of validated instruments for assessing consent capacity for research should be considered evidence of best practices. The External Review included the current instrument developed by the University of Kentucky as an example.

For example:

- Jeste DV, Palmer BW, Appelbaum PS et al. A New Brief Instrument for Assessing Decisional Capacity for Clinical Research. Arch Gen Psychiatry. 2007;64(8):966-74.
- Rowbotham MC; Astin J; Greene K; Cummings SR. Interactive informed consent: randomized comparison with paper consents. *PLoS ONE 8(3):e58603, 2013.*
- Palmer BW; Lanouette NM; Jeste DV. Effectiveness of multimedia aids to enhance comprehension of research consent information: a systematic review. *Irb: a Review of Human Subjects Research. 34(6):1-15, 2012 Nov-Dec.*
- Karlawish J; Kim SY; Knopman D; van Dyck CH; James BD; Marson D.*M*ultimedia consent for research in people with schizophrenia and normal subjects: a randomized controlled trial. *Schizophrenia Bulletin. 35(4):719-29, 2009 Jul.*
- Jeste DV; Palmer BW; Golshan S; Eyler LT; Dunn LB; Meeks T; Glorioso D; Fellows I; Kraemer H; Appelbaum PS. Interpreting the clinical significance of capacity scores for informed consent in Alzheimer disease clinical trials. *American Journal of Geriatric Psychiatry. 16(7):568-74, 2008 Jul.*

Screening devices for cognitive dysfunction (e.g., the Mini-mental State or SPMSQ) or for clinical decision making capacity (e.g., MacArthur Competency Assessment Tool (MACCAT) are less desirable than instruments that are validated for assessing research consent.

If a patient with consent capacity loses capacity during a study and remains enrolled under the consent of a Legally Authorized Representative or a prospectively established Durable Power of Attorney for that study, then IRB policies should specify the requirement for a plan to secure that research participant's re-consent if capacity to consent is regained. The plan for this eventuality should be part of the original IRB proposal when fluctuations in consent capacity are expected to be common.

At the time of enrollment in the study, the research team should inform and encourage the research participant to designate an individual to serve as a legally authorized representative (LAR) or a durable power of attorney for their participation in the study. This representative will act in the event that consent capacity is lost during the study for that study only. Such delegation of authority may not be used for other research studies.

Assessing Capacity to Consent and Obtaining Consent

IRB will request that the consent process be witnessed and the form be completed by a person who is not also IRB approved study staff for the protocol, such as a UMP or Fairview nurse not associated with the research department or investigator. The IRB or the investigator may elect to have the consent interaction video recorded.

During the Study

When a research participant is found to have possibly lost consent capacity (either by the prospective monitoring plan or as an incidental finding by the research team, the person's treating clinical treatment team, or feedback from family/friends), a Legally Authorized Representative must be engaged to evaluate the study and to either consent or withdraw consent to participation.

If the potential research participant revokes consent or assent at any time, then study participation must be put on hold. If the person reconsiders, there will be additional discussion with the advocate and a reconsent process.

Legally Authorized Representatives

The legally authorized representative (LAR) is understood in the sense of (45 CFR 46.111, 46.102(c) and 21 CFR 50.3(1)): "A legally authorized representative (LAR) is defined in both HHS and FDA regulations as an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective research participant to the research participant's participation in the procedure(s) involved in the research)." However, the implementation team requests that the OVPR and the HRPP consult with the OHRP or the DHHS on current law pertaining to who may legally serve as a legally authorized representative to assure compliance and harmonization with applicable regulations and state and federal laws.

Current IRB policies 501, 506 and 703 must be reviewed and revised as needed. The IRB and HRPP will develop educational materials for LARs and investigators to explain the LAR role, authority, and considerations for making decisions. This information should be placed on the IRB webpage that includes "Guidance & FAQs" Adults Lacking Capacity or with Diminished Capacity to Consent" http://www.irb.UMN .edu/guidance/adults.html. This material must also describe all relevant federal regulations to investigators, and provide information about where further guidance can be found.

The investigator will be required to describe procedures that will be used to ensure the research participant's LAR understands his or her obligation to represent the prospective research participant's interests or values in consenting to the study or in consenting to remain in the study while it is underway.

The IRBs should review and provide approval for the inclusion of individuals who lack consent capacity as specified below:

Consent Advocate

The consent monitor could also serve as a consent advocate, including for studies that do not involve vulnerable research participants, if requested. All potential research participants will have access to an advocate at all times during consent discussions. The plan for ensuring that the consent advocate is made available will be identified in the IRB application review.

Conflicts of interest for potential consent advocates will be managed by the IRB. This may include a special panel of consent advocates or possibly ombudsmen or other options.

The consent advocate should perform consent monitoring. When fully implemented, this might include: assisting investigators in finding and using validated instruments to assess capacity and obtain informed consent, memorializing the consent, and monitoring the consent. Such a model would benefit from continuous quality improvement.

Research with Research Participants who are Vulnerable to Coercion or Exploitation

The aim of these recommendations is to create language that provides an understanding of additional protections and to inform best practices when proposed research involves adults who are vulnerable to coercion or exploitation that might influence their consent to research or their decision to continue in research.[5]

[5] National Bioethics Advisory Commission. Assessing Risks and Potential Benefits and Evaluating Vulnerability in Report and Recommendations, Volume I Chapter 4: Bethesda, Maryland August 2001, 69-96. https://bioethicsarchive.georgetown.edu/nbac/human/overvol1.html

Definitions:

Vulnerable research participant are persons who are vulnerable to coerced participation in research. Vulnerability differs from impaired consent capacity in that it arises from the situational context and relationships of the potential research participant rather than from cognitive impairment. Furthermore, not every person of a vulnerable group is susceptible to coercion. Vulnerable research participants and persons from communities that are vulnerable and persons with characteristics that mark them as vulnerable deserve an equitable opportunity to participate as research participants. Research is necessary on vulnerable populations to enable them to benefit from biomedical research.

Vulnerable persons have consent capacity. Any person who lacks consent capacity or is adjudicated by law to be incompetent shall be fully covered by policies addressing that issue.

A complete list of examples of vulnerability is not possible. The list below suggests some situations where it may be relevant to research with research participants.

Class of Vulnerability	**Description**	**Example remedies**
Fear of Institutionalization as contingent on research participation	Potential subjects fear psychiatric or custodial or penal institutionalization	Research protocol and personnel should emphasize that no civil rights or procedural rights or treatment rights are tied to consent to research. Research should not have any role in the process pertaining to commitment or judicial determinations of competence. Clinical personnel who are engaged in competency hearings should not have any role in the research process.
Communicative Vulnerability	Potential subjects who are non-English speaking, sensory impaired, dyslexia, medical illiteracy or innumeracy	Medical translators, Translation and back translation of consent documents.
Institutional	Potential subjects who are	Students: when research participation is part of a

Vulnerability	subject to the *formal authority* of persons who have an interest in the potential subject consenting to the study, e.g., persons in the armed forces, students or employees of the PI or academic health center.	class assignment, a time and effort equivalent alternative should be provided for those who do not wish not to consent. Course grades should not be based on consent. Data on research participation should not be available to the grading instructor until grades have been filed. Employees: work performance should not be based on research consent. Nursing home residents, day care students etc.: Participation in research should not determine access to special programming or basic services.
Deferential Vulnerability	Potential subjects who are deferential because of in*formal hierarchies such as social class.*	Care must be taken to emphasize choice and to minimize secondary consequences, e.g. loss of clinic care if the clinical trial is declined. *Not* all deferential behavior is subordinating. Some persons defer to their doctor's expertise.
Medical Vulnerability	Potential subjects with health conditions for which there are no satisfactory standard treatments may have unreasonable expectations about the potential benefits or investigators may mislead them about risks and potential benefits.	Researchers must anticipate the *therapeutic misconception* in which potential subjects see research as benefitting them personally rather than benefitting persons in the future or that participating in an approved clinical trial implies benefit to risk ratio that is more favorable than conventional care. This is especially important in Phase I studies that are not designed to produce a therapeutic result. It is sound practice to separate the identities of the treating physician from the investigating physician so that treating physician can be a neutral sounding board for the patient's questions. Their health care provider should explicitly tell patients that to decline research will not jeopardize their ongoing treatment.
Economic Vulnerability	Potential subjects who lack basic needs i.e., income, housing, or health care. Such persons may consent to research to meet these needs, which then may constitute an undue inducement.	Financial inducements for research should cover the time and expense of participation. Research which includes medical care, examinations, or social services can be more difficult and to the extent feasible such services should not be offered in a manner that is contingent on research participation.
The classes of vulnerable patients of pregnant women, children, and prisoners are covered by specific HHS regulations and will not be addressed here.		

General Considerations

The IRB expects that principal investigators will:

- Demonstrate awareness of the nature of the vulnerability of research participants in the trial under consideration.
- Create procedures to avoid the coercion or exploitation of vulnerable persons by: ensuring that each potential subject understands that participation is voluntary, that to the extent feasible comparable health and social services will be available regardless of consent to participate in a clinical trial, that ensuring other people, including supervisors, in closed communities like schools, military units, prisons, or chronic care facilities will not know who in their institution has and who has not consented to participate in research.
- To avoid the risk of therapeutic misconception, protocols, and consent documents for studies in which treating caregivers are also investigators should contain a paragraph to note that the potential participant's caregiver has dual responsibilities to both care for the patient and to conduct the research. The potential participant may request to see another caregiver to discuss treatment options before deciding to participate in the study.

The IRB will:

- Use internal reviewers (including consultants where necessary) who have the appropriate expertise to address the vulnerability of the research participants in the proposed study.
- Ensure that there are safeguards to protect the rights and welfare of vulnerable potential research participants.
- Record the nature of the vulnerability and any special protections required for research participants in its minutes and in communications to the principal investigators.

The IRB may require the use of independent consent monitors, particularly when the

treating physician is also the investigator, in order to minimize the possibility for undue influence or coercion.

11. Department of Psychiatry

Covers External Review report recommendations: 3.5.1, 3.5.2, 3.5.3, 3.5.4

Department of Psychiatry research studies have raised particular concerns and criticisms including, but not limited to, the role of particular investigators, informed consent processes, IRB expertise in psychiatric research, and the role of Fairview staff's involvement in protocol review, gatekeeping functions, and research monitoring. We see an opportunity to address concerns and create a culture of trust and transparency to enhance and support both clinical care and research within the whole of the U of M and Fairview.

The relevant parties include clinical investigators in the Department of Psychiatry and their study staff, IRB members who review psychiatric protocols, Fairview Research Administration staff, and M Health nurses, managers, and leaders as well as advocacy groups such as the National Alliance on Mental Illness (NAMI).

The overarching goal of our recommendations is to create a method for conducting clinical research in the University/Fairview health system that incorporates best research practices and a culture that is inclusive, built on shared values, and fosters trust between all participants listed above. To that end, we propose that CTSI accelerate the process for assuming management of interventional drug and device trials in the Department of Psychiatry. This had been under discussion for the past several months but a timeline had not been established. We recommend that CTSI work with Dr. Grabowski, Director of Research in the Department of Psychiatry to rapidly implement a plan where all activities related to project management and study coordination be transitioned to the CTSI. When the new chair of Psychiatry is identified CTSI will work with this individual to identify how they would like to have interventional drug and device trials managed. In addition, we recommend the actions described below:

Education

In coordination with Section 12 "Education and Training" of this report, the education recommendations are:

- To develop a culture of shared respect by creating and implementing an educational curriculum with cross-training of clinical staff, investigators, and IRB members on the ethics, mechanics, and importance of research. The training programs will be taught and facilitated by the CTSI in collaboration with the Center for Bioethics using methods and curriculum that has been reviewed, tested, and validated by the larger CTSA consortium and the HRPP.

- To require that any investigator and their research staff working with individuals who have impaired or fluctuating capacity to consent or who are vulnerable (as defined in section 9), will take additional training that is specific to clinical research with this population. As discussed in section 12, the curriculum could be developed and administered by the CTSI however content will be determined in collaboration by the HRPP, CTSI, Center for Bioethics and other U of M resources. This process should engage community members and include research participants.

- To form a specific IRB panel with specialized training on the unique needs of research with individuals who have impaired or fluctuating capacity to consent or who belong to vulnerable populations, and to ensure that all research with populations that meet this definition be evaluated by this panel. The curriculum provided to this panel could be coordinated by the CTSI but will include input from the IRB, Fairview psychiatrists, UMP, U psychiatry and psychology faculty, nurses, and bioethics faculty. We also recommend consideration of a pool of psychiatrists from other sites conducting clinical research who can serve as expert scientific consultants to the panel, providing reviews of protocols and independent assessment of capacity to consent of these individuals when necessary.

Enhancing a Culture of Mutual Trust for Clinical Care and to Foster Research

Climate Assessment

To better understand all aspects of the current clinical and research environment, an external expert will be engaged to determine the assets and liabilities in the current "climate" in which clinicians, researchers, and staff do their work. This assessment will involve how Fairview and UMP nurses, physicians, and staff members do their work. The climate assessment conducted through Fairview and UMP will inform the development of a plan to address areas of concern and achieve best practices to develop an environment of inclusion, shared values, trust, transparency, and integrity for psychiatric clinical care and research. Performance under the plan will be monitored to assure that the plan is meeting the desired goals and the climate is improving towards best practice. Confidential input through "hot lines" will be available to assure that all voices are heard. Responses to concerns will be made available according to the best practices identified. These could include postings on web sites and town hall meetings. The climate assessment will be repeated at intervals identified in the results of the initial assessment.

Creating a Culture of Inclusion

The proper conduct of a clinical research study requires input from all members of the research team at all stages of the study, including the clinical staff that is involved in recruitment or conduct of the protocol, and support of the research participant in the study. We propose developing a process where selected members of the clinical team (the non-research staff who provide standard of care for the participant) participate in all aspects of the protocol development and administration. This process includes participation in 1) protocol development to provide input on how the protocol will affect standard of care and 2) discussion of risks to the participant from the clinical perspective (such as drug-drug interactions, quality of life issues). The CTSI has an established process that can be used to evaluate the feasibility of a proposed protocol

(such as whether there is a population of eligible patients and appropriate resources), that could help facilitate this process. Appropriate members of the clinical team can be added to the feasibility assessment process and provide valuable input into the study design. On completion of the research project, a presentation will be made to staff to inform them of the results of the research.

Fairview Health Care System Oversight

We believe it is essential to create an oversight committee that can monitor the entire spectrum of clinical research across the Fairview health care system. The FUROC committee as proposed earlier in this report (see section 7 for full detail) will regularly monitor all of these activities and propose aggressive, innovative solutions to problems as they are identified. The charge to this team will include (but not be limited to) process improvement to remove barriers for research implementation while ensuring excellent clinical care, participant safety, ethical conduct of studies, and ensuring that research results are effectively communicated to participants.

Enhanced Research Training and Oversight of Two Investigators in Department of Psychiatry

The External Review recommended that because of ongoing concern and criticism, two investigators in the Department of Psychiatry specifically should receive supervision, coaching in leadership, and advanced training in human participant protections. Part of this will be dealt with by the methods described in section 13. In addition, these investigators will be required to review all of the publications and associated sets of information cited previously in the references of section 9. More enhanced post-approval review will be undertaken (on a bimonthly basis) to make sure that all clinical research protocols that these investigators participate in are proceeding appropriately. The OVPR is planning a national symposium on human research participant ethics and these two investigators will be required to participate in this activity. Finally, a plan for

leadership coaching of the two investigators will be developed and overseen by the Dean of the Medical School.

Required Resources

The required personnel and resources to implement this plan include professional coaches, external trainers, and potentially the support to create a new committee for protocol review, monitoring, and gatekeeping which requires personnel time and effort to make successful. All of these action items will require additional responsibilities for joint Fairview and U of M leadership, an OVPR Research Compliance Office and CTSI. Clinical and faculty experts will be needed on a case by case basis for protocol review, gatekeeping, and monitoring of studies through the new committee and subcommittees for investigative reviews.

12. Engaging Research Participants

Covers External Review report recommendations: 3.3.24, 3.3.25, 3.3.26, 3.3.27, 3.3.28

Although there are channels that exist for soliciting feedback from research participants, the External Review found that these were insufficient and require improvement. The External Review recommended that mechanisms be amplified, systematized, strengthened, and sustained for engaging and communicating with the research participant community. These mechanisms involve both soliciting and recognizing feedback and providing information on study outcomes.

The OVPR, HRPP, IRB, CTSI, Fairview Research Administration, investigators, research personnel, clinical staff, research participant family members, legally-authorized representatives, and the public play a crucial role in engaging with the research participant community.

Several approaches will be needed to fully engage with research participants, family members, and surrogate decision-makers in order to learn about their research experiences, and be responsive to any concerns shared or feedback provided. The CTSI's Community Engagement Core could play a leading and coordinating role in developing community resources to advise and assist on soliciting research participant feedback. A new staff position in the CTSI Community Engagement Core, a community liaison officer, should be created to provide day-to-day management of the research subject engagement activities and to regularly report defined metrics to OVPR. The Community Oversight Board (see Section 15) also has a vital role including providing input into the communication processes developed, monitoring their implementation, evaluating their outcomes, and providing recommendations on strategies for improving the research participant experiences, including addressing concerns and providing recognition and feedback for concerns raised.

Specific approaches for increasing communication with research participants, their family members and their legally-authorized representatives include:

- Create a research participant satisfaction survey that is distributed to research participants and surrogate decision-makers to evaluate their research experiences. (The CTSI is currently piloting a standardized process to regularly solicit research participant feedback about their research experiences.)
- Develop procedures for collecting, analyzing, and reporting results from the research participant satisfaction surveys, including a sampling procedure developed in consultation with a statistician.
- Revise IRB application forms to include a section for expressing appreciation for participation and sharing final results with research participants; if there is no plan for sharing final results, this should be justified.
- Develop and post on the HRPP website a list of best practices for expressing appreciation for research participation and sharing final results with research participants (e.g., letter, newsletter, research website, departmental website, etc.).

- Incorporate monitoring of distribution of materials related to research participant reporting and implementation of plans to express research appreciation in IRB annual and final reports, along with any deviations.
- Create and broadly publicize policy and procedures for handling concerns about research from research participants, family members, legally-authorized representatives, research personnel, and clinical staff.
- Create and broadly publicize mechanisms for potential, current, and past research participants, family members, and LAR to provide confidential feedback and/or report concerns about the research process (e.g., toll-free telephone number, website).
- Create a mechanism for promptly addressing all reported research concerns and notify the reporter when the matter has been fully addressed.
- Develop and require investigators to distribute a handout (such as a small card) at study enrollment to research participants, family members, and LAR regarding where and how to provide confidential feedback or share concerns about the research procedures, including the mechanism for handling reported concerns. This is in addition to information provided on the informed consent form.
- Establish a process for reporting results to individual research participants when practical and when the participant has indicated they would like to receive study results. This process may vary from study to study because of differences in study design. For example online survey studies may be anonymous and feedback would be impossible or studies requiring samples to identify molecular mechanisms of disease may not yield results that can be easily translated to the non-scientific community.

The CTSI Community Engagement Core could develop and implement this plan, including the hiring of a community liaison officer (new position) who can develop materials, monitor channels of communication, and respond to research participants' concerns. The Community Oversight Board will provide input on the policy, procedures, surveys, and educational materials, and strategies relevant to research participant engagement, monitor all complaints or concerns reported and their resolution. The OVPR's newly created Research Compliance

Office should provide independent oversight of the research participant satisfaction surveys and reported research concerns and should provide oversight for the plan outlined here. Additional staff and IT infrastructure will be needed to fully implement this plan, including monitoring its implementation and summarizing results on a regular basis. In addition, researchers and research personnel will now need to distribute handouts and satisfaction surveys.

13. Education and Training of Investigators

Covers External Review report recommendations: 3.3.1, 3.3.2, 3.3.3, 3.3.4, 3.3.5, 3.3.6, 3.3.7, 3.3.8, 3.3.9

The report from the External Review stated that "It is essential that individuals at all levels of the human subjects research protections program be knowledgeable about the ethical principles, as well as the specific regulatory, policy, and procedural requirements related to human subjects research" and "while some improvements have already been implemented (or are in the process of being implemented) in the area of basic research participants protection training, it is critical that training in research participant protections not fall prey to "right size" educational requirements in the wake of ongoing institutional efforts to reduce the administrative burden placed on researchers"[6]. Several recommendations are advanced that mandate advanced training in research participant research protection, especially where study procedures are noncompliant with HHRP policies and procedures and in studies that involve vulnerable populations and/or those with limited decision making capacity. Those most impacted by the proposed changes include investigators, Center for Bioethics, AHC schools, Bioengineering, CTSI, IRB, individual departments, Fairview Research Staff, and research participants.

[6] AAHRPP. 2015. An External Review of the Protection of Human Research Participants at the University of Minnesota with Special Attention to Research with Adults Who May Lack Decision-Making Capacity. 38-39.

More effective, in-depth, reinforced, and refresher training opportunities for investigators and research personnel will improve the quality of ethical clinical research, and will provide enhanced safeguards and greater clarity to potential or active research participants. It is recognized that numerous bodies all have efforts directed toward research and research ethics training at the U of M, including the HRPP, CTSI, and individual departments, schools, and centers. While broad educational opportunities remain of value and numerous training venues expand access and opportunity, a dis-coordinated training platform can leave gaps in content and, hence, gaps in investigator and research staff comprehension of the most important principles in research participant protection and research compliance. To that end the team adopted the following solutions to the recommendations made by the External Review panel.

- Create a new position of a Human Research Procedures, Policies and Ethics Education Coordinator within the CTSI with links to the Center for Biomedical Ethics. The education coordinator will be responsible for establishing guidelines for basic and advanced research compliance and research participant protection training that is reviewed and approved by an oversight process in the HRPP. The education coordinator will ensure that both required and optional training modules are available and kept current.
- Provide clear expectations and education for documenting the education of investigators and their teams with respect to RCR, HIPAA, GCP, and CITI training.
- Conduct an evaluation of the educational resources of the HRPP, schools, departments, and divisions in the AHC, CTSI, and the Center for Biomedical Ethics specifically dedicated to the education and training of the research community to ensure that appropriate resources are in place to offer basic and advanced training opportunities in research participant protections.
- Provide appropriate training opportunities for all personnel working with vulnerable populations and mandate it be completed before the study can begin. It is important to note that CTSI can be an effective partner by supplementing the NCATS endorsed training in best clinical practices (GCP) with appropriate content on these issues that reaches the entire translational and clinical research workforce.

- Design a coordinated plan for delivery of research participant protection updates that could involve newsletters, websites or presentations prepared for department, division, center or other academic unit investigator meetings.
- Address mandated requirements for advanced training including content prepared or presented by the Center for Biomedical Ethics that will specifically address research in vulnerable populations.
- Supplement current requirements for minimal training to initiate research involving research participants with both required and recommended advanced refresher training that should be promoted by departments, divisions, centers and other academic units by recommending that these topics be included in regular faculty, investigator and research staff meetings.
- Provide easier access to training tailored to different research topics: social behavioral studies, observational or epidemiologic studies, therapeutic intervention studies, studies on vulnerable research participants, or those with diminished capacity to consent. Topics on HRPP policies and procedures should be included.
- Engage the community on relevant research related committees, task forces, and educational programs to help researchers, research staff, research administrators, and U of M leadership form relationships with community stakeholders and thus more directly solicit their input on community priorities and areas of community concern. This can be facilitated by the CTSI Community Engagement Core which regularly and successfully engages in such activities.

14. Accountability Metrics

The implementation team has made several recommendations to further advance the Human Subjects Protection Program and the U of M research community. As part of implementing the recommendations, metrics will need to be established and collected to assure that the changes made are meeting the expectations of research participants, the U of M community, and our partners. Metrics can also allow for continued quality improvement with the expectation that

they will be reviewed at minimum twice each year by the Community Advisory Board and the newly created OVPR Research Compliance office.

The following are metrics to consider and correspond to each of the recommendation categories:

IRB Membership: Data will be maintained so that departmental and specialty representation are identified. Meeting attendance of members will be tracked to assess the representation at meetings and confirm that they are meeting expectations of commitment to membership. Compensation models for members will be defined and tracked.

IRB Protocol Review Process: Data will be tracked on the number and type of review (new application, change in protocol, response to deferral, report, protocol review time) that are on each convened IRB meeting agenda. The number present and role of members at convened meetings will be tracked. In order to assure equal and appropriate distribution of expedited reviews, the reviews will be tracked by the member to whom they were distributed. Use of expert consultation to inform review (either expedited or full committee) will be documented and tracked. Turnaround time from protocol submission to IRB review response will be tracked.

Scientific Review: For all biomedical applications determined to be greater than minimal risk, the method of scientific review will be captured. This will include those methods defined and agreed on by this document. For those undergoing review by the HRPP mechanism the following data will be captured: the type of protocol defined by specialty and funding; the number of individuals that complete the review; the specialty of the reviewer; the number that recuse themselves from review; the outcome of the review; communication from the reviewer about concerns.

Monitoring of Studies: It is anticipated that this activity will increase as staffing levels increase in the IRB. The number of staff required for review will be tracked. The number of reviews and the reason for the reviews, for cause or random, will be captured. There will be comprehensive communication of findings. There will be a mechanism for the IRB to do quarterly reports of generalizable findings to the research community for education and compliance. There will be

more consistent communication of follow-up with research teams and our partners, including Fairview and Gillette.

For Cause Investigations: This activity will be moving into a newly created Research Compliance Office in OVPR. The number of investigations will be tracked. The number of individuals required to do the investigation will be captured. The outcome of the investigation will be communicated in generalizable terms for the education of the research community.

Research with Vulnerable Populations: The following data will be captured: who performed the consent (research coordinator or investigator); who signed the consent (research participant, single parent, both parents, guardian, LAR); if an advocate participated in the consent process and signed the document. For specific protocols, at study initiation, there will be a plan established for timed prompts to investigators to have them consider re-evaluation of capacity of consent for research participants for the duration of the study. The newly created OVPR Research Compliance Office can review this data and target studies that may be appropriate for post-approval review. Tracking the inclusion of adults with diminished or fluctuating capacity as part of the application process will occur.

Department of Psychiatry: Because we are recommending that interventional drug and device trials in the Department of Psychiatry are managed by the CTSI, we also recommend that for these trials, the CTSI conduct all routine monitoring for those studies. Metrics will be collected on the management of protocols in the department. Examples of this include: training of Department of Psychiatry investigators; time of presentation of protocol to FUROC; number of revisions to Department of Psychiatry protocols; number of events of significance identified by PAR program; number of findings on OVPR Research Compliance Office reviews; number of people who leave the trial; and number of inquiries or full investigations.

Engaging Research Participants: The creation and broad publicity of policy and procedures for handling concerns about research from potential, current, and past research participants, family members, legally-authorized representatives, research personnel, and clinical staff to provide confidential feedback and/or report concerns about the research process (e.g., toll-free telephone number, website), will be monitored. The creation of a handout (such as a small

card) at study enrollment to research participants/family members/legally-authorized representatives regarding where and how to provide confidential feedback or share concerns about the research procedures, including the mechanism for handling reported concerns (Note: this is in addition to information provided on the informed consent form), will be monitored and quantified. Feedback from a newly created research participant satisfaction survey using procedures for collecting, analyzing, and reporting results from such surveys will also be analyzed. Materials will be distributed related to research participant reporting and implementation of plans to express research appreciation in IRB annual and final reports.

Education and Training of Investigators: Currently these data are collected by automatic reporting to the U of M upon completion of a class or by self-reporting. With the enhanced number of opportunities for education and training, CTSI and HRPP's capabilities in this area should be employed to track the necessary metrics regarding training and education of clinical research investigators.

Managing Conflict of Interests: This will be continued to be managed by the U of M mechanisms that are already in place and as described in section 15.

The Implementation team is charged with improving the U of M environment for clinical research and allowing for improved protection of research participants. Effective and meaningful data capture is critical for this mission. This collection, interpretation and dissemination of accountability metrics will require technical expertise and personnel to implement these recommendations. Appropriately resourcing this effort will ensure that proposed changes are followed and the outcome of these changes is measured. All stakeholders should be kept appropriately informed.

15. Managing Conflicts of Interest

The University of Minnesota encourages the collaboration of UMN investigators with industry for the discovery and development of new technologies and therapies. At the same time, we recognize the importance of disclosing and managing real and perceived conflicts of interest

when such research is undertaken. The purpose of this section is to identify and manage through the process of open disclosure and review, conflicts of interest between an investigator's research project obligations and their private interests and obligations. The policies described in this section would apply to all internally or externally funded research involving humans, animals, biospecimens and all other research requiring IRB approval.
The current UMN procedure for evaluating interests and managing conflicts of interest is available at:
http://www.policy.UMN .edu/Policies/Operations/Compliance/CONFLICTINTEREST_PROC02.html

The new policies we recommend are consistent with Public Health Service (PHS) regulations, "Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors," 42CFR, Part 50, Subpart F and 45 CFR, Part 94, effective August 24, 2012. Because we are suggesting a change in UMN policy, it will need approval by the normal UMN policy process, including review by faculty governance.

We recommend that the University of Minnesota adopt a more stringent reporting structure than dictated by current UMN policy or PHS guidelines. We propose that henceforth, for all human research studies, a financial interest, including equity, consulting income, speaker fees or royalties, must be disclosed from the first dollar or from contractual rights to receive funds for the study. In addition, we recommend that an investigator not receive any personal income from consulting or for honoraria for speaking or participating in meetings from a company during the time that investigator participates in any research study funded by that industry sponsor. The investigator may receive reimbursements for travel, salary support for effort committed for performing the research, and other study related expenses as approved in the research budget. With approval of the Conflict of Interest Review Panel, an investigator may concurrently consult for a company and conduct research sponsored by that company if the payments for the consulting are directed by the company to the U of M and not to the investigator.

While the new policy will prohibit personal compensation, some exceptions may be allowed. The case for an exception may be made by the investigator and will be reviewed by the IRB and by the Conflict of Interest Review Panel. To proceed, the exception must be approved by both entities, and a conflict management plan must be in place before the study can proceed. Some, but not all, examples of possible exceptions include the following:

1. An investigator who has intellectual property that has been licensed to a company and the investigator wishes to conduct research by the company, assuming the research does not add financial value to the intellectual property. This might arise if the research is on a drug or device not covered by the intellectual property owned by the investigator.

2. An investigator has a study in which the participants have come off the study, the primary paper is published but the study is still open with the IRB to allow for continued data analysis not directly related to the study drug.

16. **Community Oversight Board**

The External Review and the Legislative Auditor report noted that there were insufficient channels of communication to change public perception of research oversight. President Kaler's letter (3/18/15) to the Legislative Auditor and the subsequent Board of Regents' resolution (3/27/15), call for a Community Oversight Board (COB) to be established to ensure that the U of M is using best practices in the protection of research participants.

The COB will be composed of external academic, professional, and community experts in human research participant research ethics, with special emphasis in the area of interacting with individuals with diminished mental capacity. The purposes of the COB will be to: 1) protect community interests and ensure community benefit from research conducted at the U of M; 2) provide input on policies, procedures, research participant and surrogate decision-

maker education, and activities designed to solicit community engagement with understanding of research; and 3) critique U of M communications and recommend dissemination strategies related to research ethics and research participant protection; The COB will help to build and foster trust and mutual understanding of research values, culture, and research participant protection, including the development of communication strategies for use within and outside the U of M.

The composition of the COB will include 12 members including external experts in research participant protection programs, ethicists, research participants, surrogate decision-makers/legally authorized representatives, research advocates, community leaders, and service providers from community-based, non-governmental organizations from diverse profiles (e.g., race, ethnicity, gender, age, disability, and socioeconomic status), experiences, and expertise. Members who have professional or personal experience with human participant research will be selected so that representation will cover a broad range of topics and vulnerable populations, including those with impaired decision-making capacity.

COB external members may include:

- Director of a human subjects protection program that is nationally renowned for its excellence
- An expert in the protection of vulnerable populations, including those with impaired decision-making capacity
- Ethicist whose expertise is in human research participants protection
- Clinical research investigator
- Several past or current participants in greater than minimal risk research studies at the University of Minnesota or other institutions.
- One or more family members and/or surrogate decision-makers/legally authorized representatives whose family member has participated in research
- Research coordinator involved in studies with vulnerable populations

- Research or patient advocate (e.g., representative from the National Alliance of the Mentally Ill or similar type of organization)
- Community leader (e.g., advocate for dealing with health disparities and provision of health care and other services to marginalized and vulnerable populations)
- Service provider involved in care of vulnerable patients

The chair of the COB will be appointed by the Vice President for Research and will be an external expert in human participant protection. The COB will report regularly to the Vice President for Research.

The COB will convene within one month of appointment. The chair will determine a meeting schedule and procedures. Administrative support and reimbursement of expenses will be provided by the U of M. The U of M will provide administrative support, reimbursement of expenses, and honoraria for COB members for whom participation on the COB does not fall within their professional responsibilities.

Responsibilities of the COB will include:

- Advising the Vice President for Research on best practices for human research participant research, community norms and expectations
- Providing input on topics related to research ethics, culture, and education (researchers, research participants/surrogates), and strategies for integrating research participant protection into practice.
- Providing feedback related to U of M messaging and communication strategies about human research and research protection.
- Advising the Human Research Protection Program (HRPP) on the development of policies and procedures related to the development of informed consent forms/processes, recruitment materials and other study-related documents, and strategies for soliciting feedback from the broader community and research participants.

- Advising the HRPP on best practice methods for disseminating research findings and other reports to the community.
- Suggesting strategies to address ethical and operational aspects of study conduct with vulnerable populations, including those with impaired decision-making.
- Informing the HRPP about information, misinformation, or rumors circulating in the community and concerns from the community and research participants/surrogate decision-makers.
- Advising how to address negative research experiences with the community.
- Helping build trust with the community by conveying information about research to the community.
- Completing research ethics and other required training and providing feedback on that training and suggestions for its improvement.
- Assisting in the dissemination of COB results and activities to appropriate audiences.

17. External Advisor

The charge to the Implementation team included engaging an external advisor with deep knowledge in human subject protection programs, regulations and law to work with the U of M on implementation of the recommendations of the Implementation team. We recommend engaging an external advisor as described and will do so once the report of the Implementation team is formally adopted by the U of M Board of Regents.

We will identify and retain an individual who is considered an international expert in the area of human participant research. We may start by re-engaging one of the members of the External Review, and if this is not possible, identify an expert in this area based on academic scholarship, practice and international reputation. This person will be provided with a copy of the Implementation team report and will work with the individuals named in section 7 to advise on implementation strategies and provide input and feedback to the Vice President for Research and Vice President for Health Sciences about the progress of the implementation process. It is

expected that this person would engage on a monthly basis until the implementation is complete.

It is important to note that the HRPP program will also be receiving substantial input into its future structure, philosophies, policies and procedures from those who comment on this report and from the June 2015 accreditation site visit by the American Association of Human Research Protection Programs (AAHRPP).

18. Post-Report Activities

We have listed those individuals who could be assigned responsibility for implementing the actions that fall under each section of the report. These assignments include both faculty and administrative key stakeholders.

Above Section #	Assigned Individual(s)	External Report Recommendation/Implementation team Action Plan Number	Implementation Timeframe
1)	Tremaine, Herman, Jackson	N/A Exec Summary	N/A
2)	Implementation team	N/A Process	N/A
3)	Jackson, Herman, Schacker/CTSI, Deans, Department Chairs, President, Provost, BOR	*3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.1.5, and 3.6.1, 3.6.2, 3.6.3*	6-12 months
4)	Dykhuis, Billings, Biros, Jackson, Herman, Wyman	*3.2.1, 3.2.2, 3.2.3*	3-6 months
5)	Dykhuis, Billings, Biros, Schacker/CTSI, Herman, Studham, Jackson	*3.2.4, 3.2.5, 3.2.6, 3.2.7*	6-12 months (exception: electronic IRB scheduled implementation 2017)
6)	Dykhius, Billings, Biros, Jackson, Herman, Schacker/CTSI,	*3.3.10, 3.3.11, 3.3.12, 3.3.13, 3.3.14, 3.3.15, 3.3.16, 3.3.17*	6-9 months
7)	Herman, Jackson, Wilson	N/A FUROC	3-6 months
8)	Herman, Jackson, Schacker/CTSI, Dykhuis, Wilson, Department Chairs, Internal Audit	*3.3.18, 3.3.19, 3.3.20, 3.3.21, 3.3.22, 3.3.23*	6-12 months
9)	Herman, Waldemar	*3.2.8, 3.2.9, 3.2.10*	3-6 months
10)	Miles/Bioethics, Scheman, Wyman, Billings, CTSI, Dykhuis	Capacity to Consent 3.4.1, 3.4.2, 3.4.3, 3.4.4 Vulnerability to Coercion 3.4.5, 3.4.6 Longitudinal Assessment of Capacity 3.4.7, 3.4.8 Legally Authorized Representatives 3.4.9, 3.4.10 Use of Surrogate Consent 3.4.11, 3.4.12	6-12 months
11)	Jackson, Wilson, Paller, Ext. Advisor	*3.5.1, 3.5.2, 3.5.3, 3.5.4*	6-12 months
12)	Waldemar, Dykhuis, Billings,	*3.3.24, 3.3.25, 3.3.26,*	6-12 months

	Biros, Schacker/CTSI, Jackson, Herman, Miles/Bioethics	*3.3.27, 3.3.28*	
13)	Billings, Biros, Dykhuis, Schacker/CTSI, Herman, Jackson, Miles/Bioethics	*3.3.1, 3.3.2, 3.3.3, 3.3.4, 3.3.5, 3.3.6, 3.3.7, 3.3.8, 3.3.9*	6-12 months
14)	Dykhuis, Billings, Schacker, Waldemar	Metrics - TBD	6-12 months
15)	Herman, Jackson, Zentner	COI - TBD	6-12 months
16)	Wyman, Scheman, External Advisor, CTSI, Herman, Jackson	COB - TBD	3-6 months
17)	Ext. Advisor, Herman, Jackson	Ext Advisor - TBD	3-6 months

19. Analysis of Resources Required for Implementation

Resource Description and Estimated Cost	**Resource Responsibility/Management**
1. Paid IRB member salaries (10% effort), Co-Chairs 25%	IRB
- 50 faculty avg. salary $150K annual- $750,000 annual; co-chairs- 75,000 annual- total- $825,000 recurrent; community members (at least 12) each 3-5 K yearly.	
2. Additional Internal PAR monitors (3 additional FTE)	IRB
- $100k (salary plus benefits)- $300,000 recurrent	
3. Paid scientific review activities	IRB
- Assume $100/protocol; 5,000 protocols/year- $500,000 recurrent	
4. Additional IRB administrative staff (2FTE?)	IRB
- $200,000 recurrent	
5. Media culture campaign staff (1FTE staff?)	OVPR
- $100,000 one time	
6. HSP training staff (1 FTE?)	CTSI
- $100,000 recurrent	
7. Community Oversight Board staff (0.5 FTE)	OVPR
- $50,000 recurrent	
8. Additional IRB staff (2 FTE)	IRB
- $200,000 recurrent	

9. External Advisor on implementation	RESEARCH COMPLIANCE OFFICE
- $50,000 one time	
10. External consultant for Dept. of Psychiatry implementation culture change	AHC
- $50,000 one time	
11. Co-review by PAR and an external IRB of protocols that involve decisionally impaired research participants.-	IRB
$2500/protocol; 25 protocols/year- $62,500	
12. eIRB- electronic IRB system	OVPR
$5,000,000 (one time)	
13. Chesapeake IRB audit review of 100 random protocols.	RESEARCH COMPLIANCE OFFICE
- $2500/protocol- $250,000 one time	
14. Community liaison officer – 1 FTE	CTSI
15. CTSI management of psychiatry studies – unknown until audit of current trials and feasibility assessment completed.	CTSI
TOTALS: One-time costs: $5,450,000 Recurring: $2,237,500 (additional to current $2,182,123 base budget) = total $4,419,623.	

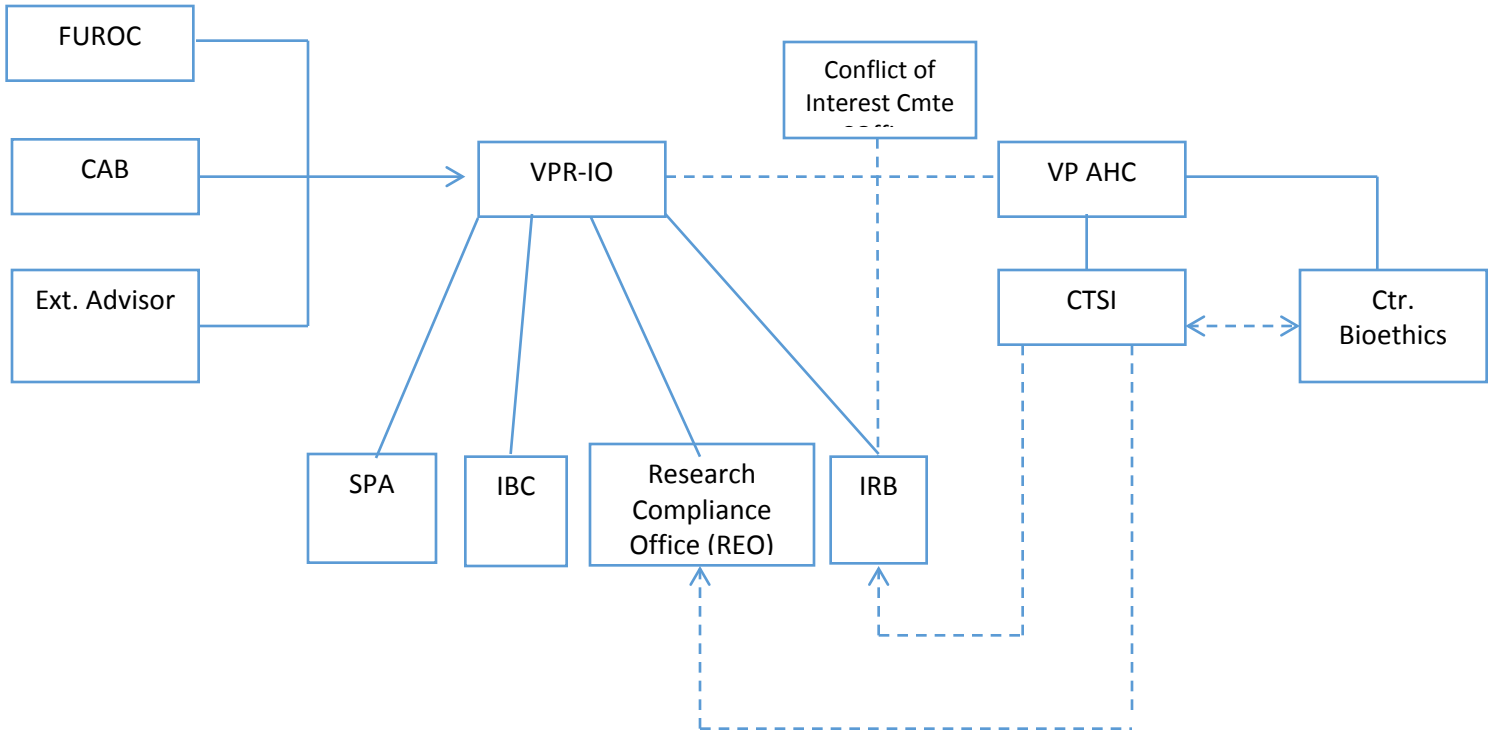
Another way to calculate the needs of the HRPP program is by median budget per protocol managed. Programs with volumes similar to ours (> 4,000) average $607/protocol. Last year we had 5,814 protocols which results in recurring budget of $3,529,098. The current HRPP budget is $2,182,123.

20. Conclusion

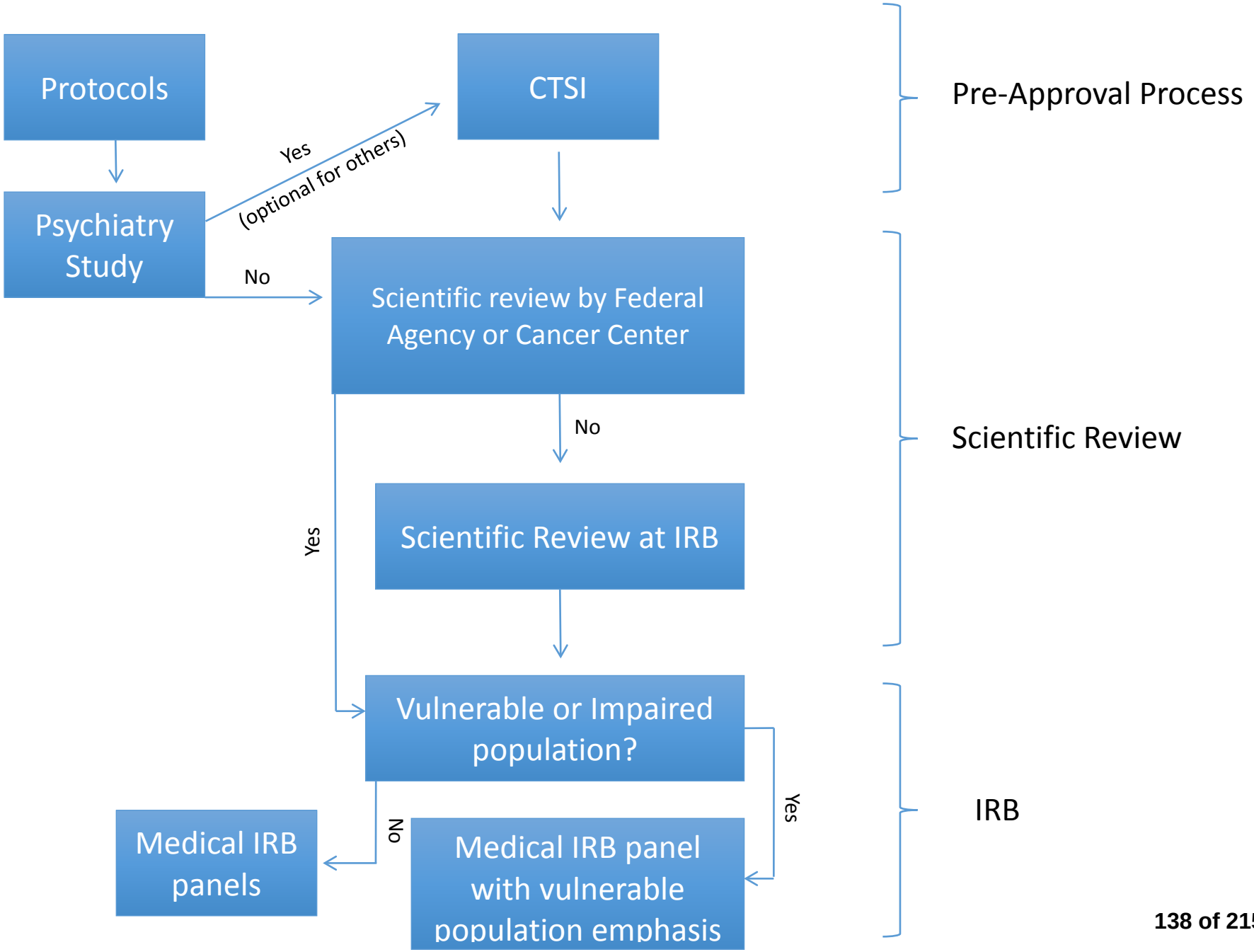
The External Review identified cultural and procedural shortcomings in the Human Research Protection Program (HRPP) at the U of M. In this report, the implementation team has addressed those deficiencies with a comprehensive plan that includes disruptive changes to transform the culture and improve multiple processes. Currently, the HRPP has many positive attributes, including policies and procedures that uniformly align with regulations, certification by the Association for the Accreditation of Human Research Protection Programs, and a past history of excellence. The current plan will help preserve what is good about this program and restore confidence and pride in the human research endeavor, collegiality among the research community, and will better ensure the safety of human research participants and scientific excellence.

21. Appendices

21.1. Advancing Human Subjects Research Organizational Chart



21.2. Advancing Human Subjects Research Protocol Process Flowchart



21.3. List of External Review Recommendations

The following is the list of recommendations from the February 23, 2015 report of the External Review. The recommendation number is the number assigned to a recommendation in our report.

No.	Report Section	External Review Page	External Review Recommendation
3.1.1	Leadership Initiatives	20	Publicize unequivocal statements on the administration's intention to create and nurture a culture of ethics in research; the OVPR must then animate these values to life by investing in their visibility and adoption at all levels of the University's research enterprise.
3.1.2	Leadership Initiatives	20	Convene a task force that would include research participants, research ethicists, educators, researchers, and HRPP/IRB staff to consider ways in which ethics and ethics education on the topics of research participant protections will be integrated into practice.
3.1.3	Leadership Initiatives	20	Explore ways in which an acknowledgement of the primacy of research participant protections and ethical research could be integrated into relevant University publications, materials, and web pages.
3.1.4	Leadership Initiatives	21	Incorporate the University's stated commitment to, and plans for strengthening, research ethics and research participant protections in future strategic planning.
3.1.5	Leadership Initiatives	21	Require all departments engaged in clinical research to acknowledge this refocusing of University research priorities and craft statements reflecting their own commitment to excellence and accountability in human subjects protections.
3.2.1	IRB Membership	27	Implement guidelines regarding IRB meeting attendance in order to ensure that a larger, more critical mass of members are present at each meeting.
3.2.2	IRB Membership	27	Broaden the membership of the Medical IRB to ensure that it includes individuals with expertise reflecting the nature and volume of the University's research.
3.2.3	IRB Membership	27	Consider providing compensation, or alternate incentives (e.g., released teaching time, reduction of other responsibilities, consideration during promotion, etc.) to foster and support qualified faculty participation on an IRB.
3.2.4	IRB Review Process	30	Revise the format of the convened IRB meeting minutes to include a meaningful summary of the study, any controverted issues that are discussed, their resolution, and documentation to support the IRB's rationale for requesting modifications to the study

3.2.5	IRB Review Process	30	Consider whether certain actions may not warrant convened IRB review and therefore may not require discussion at the convened IRB meeting, freeing up time for the discussion of more complex and challenging protocols
3.2.6	IRB Review Process	30	Consider developing a system for evaluating the appropriate number of action items per convened meeting agenda with consideration of the expertise of those present and the planned length of the agendas.
3.2.7	IRB Review Process	31	Consider making arrangements for the University's IRB staff to attend IRB meetings at peer institutions so as to better assess best practices and to determine ways in which the University's IRB can be improved.
3.2.8	IRB as an Investigative Body	34	Reconsider the reliance on IRB membership to staff ICs looking into incidents of noncompliance; a. Consider whether one or more non-IRB individuals might also be appointed to the ICs; b. If the University will continue to draw only from IRB membership to formulate these panels, expand the IRB membership to ensure sufficient expertise to meet this charge, a.recommendation that was independently made in the foregoing section.
3.2.9	IRB as an Investigative Body	34	More rigorously make use of other internal resources (such as the PAR Monitoring Program discussed in section 3.3.3 below) and external resources to supplement the work of the ICs.
3.2.10	IRB as an Investigative Body	34	Evaluate the mechanisms through which IC findings and any corrective action required are disseminated, particularly with regard to follow-through with complainants.
3.3.1	Education and Training	39	Conduct an evaluation of the resources of the HRPP specifically dedicated to the education and training of the research community to ensure that appropriate resources are in place to offer basic and advanced training opportunities in human subjects' protections
3.3.2	Education and Training	39	Create opportunities for advanced training in human subjects protections for all individuals involved in human subjects protections including investigators, IRB members and staff, research personnel, and clinical staff on units that conduct research
3.3.3	Education and Training	39	Evaluate whether additional mandatory training requirements, comparable to the new mandatory training for sponsor-investigators, should be implemented. Careful attention should be given to areas of research that are considered to be "high-risk," including those involving vulnerable populations such as individuals with the potential for limited decision-making capacity
3.3.4	Education and Training	39	Institute a more substantive requirement for advanced level training for investigators and research teams when a determination has been made by the IRB of serious or continuing noncompliance, and develop a mechanism for ensuring compliance with this requirement

3.3.5	Education and Training	40	Evaluate the mechanisms through which HRPP policies and procedures are communicated to the broader University research community in order to ensure that all its members are knowledgeable about and have ready access to the policies and procedures related to human subjects research
3.3.6	Education and Training	40	Create expectations for the involvement of research departments and centers in the development of educational programs tailored to the nature and context of their research activities
3.3.7	Education and Training	40	Consider ways to involve the University's Center for Bioethics in the educational programs focusing on human subjects research
3.3.8	Education and Training	40	Consider efforts to engage the local community of patients and prospective subjects with programs on the ethics of research and the University's HRPP
3.3.9	Education and Training	40	Upgrade and professionalize education in, among other subjects, the responsible conduct of research and research ethics
3.3.10	Scientific Review	45	Carefully consider the impact on the IRB's overall ability to conduct an appropriate risk-benefit analysis when the evaluation of study merit is delegated to the department
3.3.11	Scientific Review	45	Carefully consider whether a robust review at the department level is feasible for each department, taking into considerable the size of the department, reporting relationships, and the volume of research
3.3.12	Scientific Review	45	If the University chooses to maintain a department-based process for scientific review: a. Ensure the applicable policies delineate departmental and IRB responsibilities regarding the assessment of study design; b. Develop guidelines for careful scientific review and ensure that the de minimis requirements are adhered to when department-level scientific review is used.
3.3.13	Scientific Review	47	Revise the HRPP policy on scientific review and related guidance on the IRB's website to state that individuals with a conflict of interest or conflict of commitment may not serve as a scientific reviewer. Conflict of interest should be operationally defined in these documents.
3.3.14	Scientific Review	47	Revise the template titled "Departmental Scientific Assessment Form" (used pursuant to Method 3) to ensure that this form includes a statement defining potential conflicts of interest and affirming that individuals with such a conflict of interest may not serve as a scientific reviewer.
3.3.15	Scientific Review	47	Consider whether additional protections are needed to ensure that scientific reviews of research proposed by senior faculty are not reviewed by subordinates. Given these concerns, the University should determine whether department-based review is feasible for individual departments.
3.3.16	Scientific Review	49	Develop a mechanism for systematically incorporating scientific reviews into the IRB review process to ensure that scientific concerns impacting the criteria for IRB approval are sufficiently addressed.

3.3.17	Scientific Review	49	Require that the IRB meeting minutes specifically document the IRB's review of the scientific assessment documents and any substantive concerns raised in the course of this review.
3.3.18	Monitoring	54	Efforts to expand monitoring conducted through the PAR program and/or via the application of its methods to other HRPP monitoring efforts should be considered. Specific emphasis should be placed on increasing PAR monitoring efforts for research conducted at Fairview with an active dialogue with the Fairview staff so that they can be actively engaged in the process.
3.3.19	Monitoring	54	PAR should track and measure IRB follow-through on its findings and recommendations and report these to research leadership including department chairs and the Dean of the Medical School.
3.3.20	Monitoring	54	PAR should regularly share summary reports of its findings with department chairs and other institutional leaders charged with research oversight responsibilities to ensure that key areas of investigator and programmatic noncompliance can be readily identified and addressed.
3.3.21	Monitoring	54	Deficiencies in IRB review processes/functioning should also be addressed through existing reporting and supervisory hierarchies, and not be addressed solely within the more limited authority of the IRB and Office of the Vice President of Research.
3.3.22	Monitoring	54	In the context of ongoing concerns about problems related to subject recruitment and consent in psychiatric studies, PAR should include live consent monitoring of such studies in its repertoire of subject safeguards.
3.3.23	Monitoring	54	Separate reporting chains for IRB review and Post-Approval Review should be considered.
3.3.24	Engagement of Research participants	58	Establish accessible and reliable electronic and non-electronic channels (in addition to existing complaint mechanisms) for facilitating sustained communication among research participants, their family members and other advocates (within the permissible bounds of the Health Insurance Portability and Accountability Act (HIPAA)), researchers, research team members, and HRPP/IRB administration.
3.3.25	Engagement of Research participants	58	Develop mechanisms to regularly solicit, evaluate, and respond to research participant feedback.

3.3.26	Engagement of Research participants	58	Partner with researchers to incorporate mechanisms for soliciting feedback regarding the research participant experience so that it can be secured contemporaneously with the individual's agreement to participate in research;10 For example, the HRPP might afford research participants an opportunity to complete a research participant satisfaction survey at the end of study participation, or add an option to the University's template consent form asking subjects if they would agree to be contacted by the HRPP about their experiences as a research participant. Contact information for individuals who agree to this option could then be shared with HRPP officials and, post-participation, these individuals could be surveyed about their experiences. Data from these evaluations could be used to assess the research participant experience more broadly and would afford the HRPP a road map for developing programmatic changes that are directly responsive to the expressed needs of the research participant community.
3.3.27	Engagement of Research participants	59	Include members of the research participant community on relevant research related committees, task forces, and/or educational programs as another means by which researchers, research staff, research administrators, and University leadership can form relationships with them and thus more directly solicit their input on community priorities and areas of community concern.
3.3.28	Engagement of Research participants	59	Consider systematic approaches to express appreciation for subject participation, develop mechanisms to share research findings, and where appropriate, individual research results with subjects as a method of demonstrating partnership, showing respect and building trust.
3.4.1	Capacity to consent	65	Policies, guidance, application and review forms, and the IRB review process itself, should be redrafted and/or restructured for clarity and consistency to ensure that they will be appropriately used to prompt consideration of the methods used for assessing capacity to consent.
3.4.2	Capacity to consent	65	The IRB should ensure that its review includes a substantive assessment of the scope and appropriateness of protocol-specific procedures that address the capacity to consent in light of the subject population being approached.
3.4.3	Capacity to consent	65	Revised policies on legally effective informed consent should: a. provide the means for verifying decision-making capacity and voluntariness in all protocols as preconditions for all human subjects research; b. reject the standard that presumes capability by establishing a test of "substantial evidence otherwise" for adults with impairments.
3.4.4	Capacity to consent	66	The IRB must provide adequate review and oversight of its policies to ensure that they: a. align subject screening or other protections with the degree of risk involved in a study or the level of risk of impairment in a targeted or enrolled population; b. promote the use of strategies to support or enhance subject decision-making, including the advance selection of a surrogate decision-maker by a subject who may later lose decision making capacity.

3.4.5	Vulnerability to Coercion	68	Develop standards that protect against real or perceived coercion in psychiatric treatment settings in which individuals may fear involuntary court proceedings.
3.4.6	Vulnerability to Coercion	68	Encourage and support the use of independent consent monitors, particularly in those cases where the treating physician is also the investigator, so as to minimize the possibility for undue influence or coercion.
3.4.7	Longitudinal Assessment of Capacity	69	IRB policies should more clearly require that protocols involving adults with potentially limited decision-making capacity include a plan for monitoring subjects who are likely to have fluctuating capacity, including the steps to be taken if capacity diminishes over the course of study participation.
3.4.8	Longitudinal Assessment of Capacity	69	IRB policies should more clearly require that protocols involving adults with potentially limited decision-making capacity specify the plan for re-consent when a subject regains capacity.
3.4.9	Legally Authorized Representatives	71	Policies and procedures related to the use of LARs must be comprehensively re-assessed in accordance with the foregoing observations and conclusions.
3.4.10	Legally Authorized Representatives	71	The OVPR and HRPP leadership should consider consultation with OHRP or DHHS on this topic.
3.4.11	Use of Surrogate Consent	73	The HRPP should develop effective strategies to educate research personnel on the legal use of surrogate decision-makers when considering the involvement of research participants with limited decision making capacity.
3.4.12	Use of Surrogate Consent	73	The IRB's review of protocols proposing the use of surrogate decision-makers be rigorous and in keeping with applicable laws and best practices, as well as with University policies.
3.4.13	Use of Surrogate Consent	73	IRB policies should require: a. A process for informing prospective LARs about their responsibilities; b. Maximization of assent, with consideration of the use of an assent form in appropriate circumstances; c. A verification of the lack of dissent when assent is not possible; d. A plan for re-consent if a subject regains capacity; and e. A plan for monitoring subjects who are likely to have fluctuating capacity, including the steps to be taken if capacity diminishes.
3.5.1	Department of Psychiatry	84	IRB membership, expertise and training should more effectively address risk evaluation and management for psychiatric research.
3.5.2	Department of Psychiatry	84	Best practices regarding consent and capacity to consent should be introduced and made routine.
3.5.3	Department of Psychiatry	84	Fairview staff should be involved in protocol review, in gatekeeping functions, and in research monitoring.

3.5.4	Department of Psychiatry	84	[The investigators] as the focus of ongoing concern and criticism, should receive supervision, coaching in leadership, and advanced training in human subjects protections.
3.6.1	Institutional Culture	89	Define a hierarchy of accountability for human research ethics and thereby expand oversight responsibilities beyond the IRB. Department chairs should be expected to review and approve the submission of IRB protocols, be engaged in follow-up compliance activities, develop department-specific educational programs, and share ultimate responsibility for human subjects protections within their departments.
3.6.2	Institutional Culture	90	Rework institutional messaging in policies and procedure to include unequivocal statements on the administration's intention to create and nurture a culture of ethics, and adopt communication strategies to bring these core values to life by investing in their visibility and adoption at all levels of the University community and beyond
3.6.3	Institutional Culture	90	Establish both formal and informal means of stimulating a university-wide conversation about the manner in which this newly endorsed culture of ethics can be most effectively realized.

Advancing Human Subjects Research
Public Comments
Website: http://research.umn.edu/advancehsr/index.html

The implementation team invited public comment on its draft. To submit comments to the team, emails were sent to advancehsr@umn.edu. The public comment period began May 18 and continued through June 1. The team considered all feedback, created a response and finalized the work plan for the June 11th Board of Regents meeting.

Categories assigned align with work plan sections: Policy, IRB, Scientific Review, Conflict of Interest, PAR/Investigations, Psychiatry, Education, Metrics, External/Community. All team members reviewed all comments and responses.

#	Comments/Feedback	Faculty, Staff Student, External	Date	Category (Report Section)	Response
1	When situations arise, like the present pressure on the administration to change the methods that we regulate research on humans, the pressure is to go with the regulators who do not have to stay and live with the newly created regulations. Please do not regulate human subject's research so tightly that we can no longer afford to do it. The existing is difficult enough.	Faculty	5/6/15	Policy - undue burden (Section 14 Accountability Metrics: IRB Protocol Review Process)	**We agree that we must find the appropriate balance such that research participants are protected without excessive burden on the investigator and without unnecessary regulation. The committee recognizes that this may take some time to sort out. The clarifications we have made to the report based on public comments should help to explain our intent that while some of the changes apply broadly, others are targeted at specific types of studies that require more attention to ensure participant protection. Any new policies and practices will review administrative burden as a part of their implementation.**
2	Overall this is an impressive step forward. There are some ambiguities, however, that I'd like to see clarified, and there is at least two large issues that needs to be considered that I feel is missing:	Faculty	5/18/15	IRB (Section 4 IRB Membership)	**2.1 We agree that clarification was needed and we have changed the report to indicate that the changes regarding compensation for IRB**

	1. What changes will apply to the non-medical IRBs? It needs to be clear which changes apply only to medical IRBs and which also will apply to social and behavioral sciences. In particular, I think it would be a mistake to change the policies and procedures regarding: * compensation * required attendance * record keeping * departmental scientific review only in the medical IRBs, while not applying these best practices across human subjects research protection. 2. What does it really mean for CTSI to manage Phychiatry research? The bullets talk about training and related items, but the real question is who gets to approve the research proposal (is the director of CTSI taking over for the Psychiatry head?), under what conditions will the authority be returned to the department? Who makes that decision? And will it be possible to recruit an excellent head if the department will remain under "experimental receivership" after he or she takes over? 3. One of the issues I feel is a challenge for the IRBs is the lack of specific expertise. While this plan might address that issue for subjects with impaired consent capacity, it isn't clear that it addresses that problem in other areas. Should the other IRBs also specialize (e.g., having certain IRBs with specific expertise on cancer therapy trials or surgical trials)? Should the IRB maintain, in addition to its standing panels, stand-by panels of experts who are "on call" when specific studies warrant consulting them? Our IRB did this years ago with Internet research (though in practice, the expert panels was rarely consulted).			COI (Section 15) Scientific Review (Section 6) Psychiatry (Section 11)	**members, required attendance, and record keeping will apply to both the medical and non-medical IRBs. Departmental review for non-medical studies will not be changed as no issues have been identified with the current model.** **2.2 We agree this needs more clarity. Language has been added to Section 11 documenting that CTSI will work with the Director of Research for Psychiatry to. This will include overall project management and coordination of participant activities. We note in the report that CTSI had been in discussions with Psychiatry to perform this transition prior to the preparation of this report. We are simply accelerating the process. We also note that when the new Chair of Psychiatry is named CTSI will work closely with that individual to structure the research infrastructure in Psychiatry according to the way they would like it done.** **2.3 The medical boards will be expanded to include members from the departments that are high volume users of the IRB so that expertise will be available for the majority of research activities. In addition, *ad hoc* reviews will be used for studies for which expertise is not available on one of the IRBs. Limiting certain types of protocols such as oncology studies or surgery studies to just one board can create backlogs and delays for review compared to placing protocols on**

	4. The elephant in the room is the issue of conflicts of interest that DO NOT TRIGGER THE UNIVERSITY'S CRITERIA. It is very clear that we have serious individual and institutional conflicts around money that flows through appropriate channels. Faculty in many units (particularly in the AHC) are under intense pressure to raise their own salaries, and face very unpleasant reprisals (from loss of resources to clinical assignments) if they cannot do so. This impacts both untenured and tenured faculty. Even faculty outside the clinical fields (e.g., science and engineering, liberal arts, biological sciences) depend on grant funds for summer support, and in some cases to release them from some teaching obligations. Departments and Colleges are also under immense financial pressure -- pressure that often requires sufficient research funding (and ICR) to sustain their budgets and staffs. A result is that everyone's decision-making is inherently biased towards "take the grant and do what you need to keep it and get the next one." This isn't a problem that can be fixed, but it is a conflict that can be disclosed so that the IRB (and the public record) can make clear exactly how much PI (and other investigator) compensation and department/college ICR is at stake, giving the IRB and the public the tools to examine when there may be systematic relaxation of local standards that warrants more careful scrutiny. Honestly, until the University comes to grips with the fact that most of our serious research conflicts are ones that don't trigger University reporting we cannot be seen as taking a serious approach to research ethics. Thank you for moving swiftly and thoughtfully in putting together such a plan.				**the next available board, but this could be considered after the 4 medical boards are functioning.** **2.4 The committee recognizes that the pressure to receive grant money, federal or non-federal, is intense for many faculty at any research university, including the University of Minnesota. This is a larger problem than the one the Implementation Team is charged with addressing and is connected with how research is funded in the United States. The team suggests that discussion around this issue should occur in other forums, perhaps facilitated by faculty governance. As for conflict of interest that could impact protection of human subjects, the team feels that the changes proposed in Section 15 of the report are a step forward.**
3	Required resources: The current HRPP office annual budget is $2.2M. The estimated cost for this action plan is a $5.5M one-time cost and an increase of a more extensive human subjects protection program annual	Staff	5/18/15	Resources (Section 18 Post-Report Activities)	**Currently, the HRPP budget is part of the budget of University research budget and is paid for out the research cost pool. The annual**

	budget to $4.4M. Millions. It is being thrown around like it was a ten dollar increase. Where is this going to come from? The taxpayers? aka: us?				**budget increase will likely be covered by an increase and a change to a tiered research cost pool charge which allocates costs to users. The source of the $5.5M one-time expense has not been determined.**
4	I would like to begin by thanking you for providing such a comprehensive review of IRB practices and recommendations. I greatly appreciate your efforts and your transparency in these matters, as well as the opportunity to offer feedback. I have a number of comments regarding specific aspects of the draft report. For convenience, these items are enumerated below: 1) The report calls for "timely assessment of all aspects of the proposed research." I couldn't agree more. Currently, the IRB often takes many months to get back to researchers on projects. This delays research progress and makes the academic enterprise very inefficient. Furthermore, there is little transparency in communicating the time that it will take to hear back regarding a given project. Often, one needs to call or email the IRB several times in order to get projects reviewed. This is frustrating. It would be better to have specific criteria and a specific timeline for reviewing projects. 2) The report states the following: "A process should exist to deliver information back to the participant on the outcome of the research they participated in." However, in the interest of protecting the anonymity of participants, we often avoid collecting identifying information, including contact information. Protecting anonymity is important, and is encouraged by the IRB. However, it's difficult to accomplish this when researchers are expected to provide information to participants on the outcome of the research. There are other reasons why this may not be necessary, feasible, or even preferable. First, participants may not	Student	5/18/15	IRB (Section 5 Protocol Review & Section 14 Accountability Metrics) Engage Research Subjects (Section 12 and Executive Summary) Policy- good policy, rather than reactionary policy IRB Membership (Section 4)	**4.1 We agree. One of the challenges is that to date, there have been an insufficient number of IRBs and the workload of the IRBs has been excessive. By increasing the number of IRBs and having the IRBs focus on critical issues, the response time should be improved. The report suggested that 10 days be the target turn-around time for IRB review.** **4.2 The intent is that this suggestion not be burdensome nor compromise the research, but rather to provide interested research participants with a way of finding out more about the results of the study they volunteered for. For example, a handout given to the participant at enrollment time could provide a link to a website where at some later date, a list of publications related to research results are posted. As for plain language, currently, trials posted on clinicaltrials.gov require plain language explanation of the study, as does the consent form.** **4.3 See response to Comment #1.** **4.4 We have clarified in the report what parts apply to all human subject studies, including social and**

	understand the results presented to them, particularly when hypotheses involve complex interactions between variables that are unfamiliar to those who aren't trained in a given field. Second, many studies conducted in the social sciences utilize online contexts, such as Amazon's Mechanical Turk, in which respondents may be taking multiple surveys. In these cases, precise awareness of the analyses conducted by researchers may inadvertently interfere with responses to future surveys. When participants are too informed about the precise hypotheses that researchers are testing, they may respond in ways that are congruent with hypotheses that are familiar to them from previous studies, rather than responding naturally. Although some degree of transparency is important, it's likely not important for participants to have a complex understanding of the precise hypotheses that researchers are testing, and this may be detrimental to the research process. 3) Regarding the Dan Markingson case, was there any attention given to the probability that any one individual enrolled in a study would commit suicide, relative to individuals not enrolled in a study? As of 2013, the overall suicide rate in the U.S. was 12.6 per 100,000 people per year. This means that out of every 7937 people enrolled in studies for a given year, we would expect at least one person to commit suicide by chance alone. Moreover, among people with schizophrenia, suicide rates are substantially higher (Hor & Taylor, 2010), and among patients with bipolar disorder, 25-50% attempt suicide at least once (Jamison, 2000). Rather than going on a witch-hunt in response to one very tragic case, it's important to first evaluate whether or not negative outcomes (e.g., suicide, depression, etc.) are statistically more likely among people enrolled in studies, relative to those with the same conditions who are not enrolled in studies. Would different IRB policies have actually prevented this tragedy? Is there any actual evidence that the drug increased suicidal thoughts and behavior among				**behavioral studies, and what parts are targeted to studies involving more than minimal risk or vulnerable populations.**

	participants, overall? Although preventing tragedies such as this is essential, it would also be a mistake to implement draconian regulations or prevent studies that are greatly beneficial to participants, even when there are occasional negative outcomes for a few participants. This is particularly true when there is no systematic evidence that these negative outcomes are associated with participation in a given study. These are controversial issues, but I think that they are important to consider if one is interested in good policy, rather than reactionary policy. 4) A few places in the document, there are distinctions made between biomedical research and social/behavioral research. As I understand, the investigation pertains primarily to biomedical research, as it should. However, I would like to underscore the importance of distinguishing between these research areas. The National Research Council (NRC) has recently offered guidelines that are somewhat more flexible that current standard practices, and these guidelines also reflect those of the Office for Human Research Protection (OHRP), as well as the Department of Health and Human Services. Links to these pertinent sections of these guidelines are provided below: http://www.nap.edu/openbook.php?record_id=18614&page=50 http://www.nap.edu/openbook.php?record_id=18614&page=153 In particular, the report suggests that research projects that pose minimal risk should be excused from IRB review: "Studies where the research procedures involve informational risk that is no more than minimal risk (when appropriate data security and information protection plans are in place)"				

	This would almost certainly include the vast majority of research in the social and behavioral sciences, in which people are exposed to information that they are likely to encounter in everyday life, standard survey questions, etc. Indeed, even in experimental research involving the use of mild deception, risk to participants is generally minimal. Given the presence of secure data storage practices, informed consent, and debriefing to explain any deception that may have been used in the study, research in the Social and Behavioral Sciences should be largely excluded from the IRB review process. I sincerely hope that efforts made to protect human subjects and improve the human subjects review process will not result in unnecessary burdens on researchers in the social and behavioral sciences, whose research is of minimal risk to participants, almost without exception. Thank you very much for your time and your thoughtful consideration.				
5	Hello - My lab has IRB approval to collect peripheral blood from healthy donors to isolate particular blood cells, DNA/RNA, or proteins, and the data obtained is not connected to the donor. I believe obtaining certain human tissues through Univ. procurement facilities (Cancer Center) is non-exempt as well. While I see the need for an improved IRB procedure for clinical procedures, I hope this does not become a one size fits all application and approval process, and instead certain more low risk IRB protocols can be streamlined and customizable to the procedure. For instance, IACUC is a more module process in that certain basic information is provided and this is supplemented by relevant procedures as modules. Thanks.	Faculty	5/19/15	Org Chart Policy - undue burden	**The changes at the IRB should further streamline the review process for your studies. Currently, a number of studies that are minimal risk such as yours are reviewed at the full board convened IRB meetings, In the future, all such studies will be triaged to the expedited review process so the turnaround time for your studies should be faster.**

6	https://drive.google.com/a/umn.edu/file/d/0B20cWO6w77sPUldJSjJiTUhicTRzd09mNGRrNVIyN3E3UE9v/view?usp=sharing	Faculty	5/19/15	Org Chart Policy - undue burden	**We have added flow charts to the report appendix to help explain some of the new procedures. Many of the suggested language edits provided in this comment were incorporated into the revised report.** **We agree that we must find the appropriate balance such that research participants are protected without excessive burden on the investigator and without unnecessary regulation. The committee recognizes that this may take some time to sort out. The clarifications we have made to the report based on public comments should help to explain our intent that while some of the changes apply broadly, others are targeted at specific types of studies that require more attention to ensure participant protection. Any new policies and practices will review administrative burden as a part of their implementation.**
7	re: A more stringent structure for managing conflicts of interest, including a new policy that prohibits investigators from receiving personal compensation from industry while conducting a research study funded by that industry sponsor. I believe this is too broad a statement. There should be consideration of exceptions such as: 1) investigator initiated industry funded research which is not for the conduct of a clinical trial 2) performance of laboratory aspects of a clinical trial for which the UMN investigator is masked as to treatment assignment and has not enrolled patients in the trial I agree that investigators should not receive personal	Faculty	5/19/15	COI (Section 15)	**Thank you for comments. We agree that the COI section of the report needed further clarification and this has been added. Investigators may continue to receive industry funding for research that includes salary support for the FTE devoted to the research. Investigators may continue to do consulting and engage in educational activities sponsored by industry while participating in a research study sponsored by the same company, but they may not receive personal income for that**

	compensation from industry while conducting a clinical trial funded by that industry sponsor, when this means enrolling patients in the trial or serving as a site or study PI. One thing I forgot to mention is the following, by i**nvestigator initiated grants from industry** I am referring to grants from industry which require application and review and where the research and the data belong to and are analyzed by the investigator, and where the content of presentations and publications is controlled by the investigator and the company can't exercise control over the scientific process or output. I think this is very distinct from investigators participating in industry sponsored clinical trials where patient recruitment and follow up are essential components.				**consulting or educational activity—the payment can go to the University. These changes will apply to all human studies research. Extensive changes were made in Section 15 to clarify these points.**
8	Thank you for the opportunity to weigh in with a seemingly minor -- yet actually pivotal -- recommendation on the draft work plan. In my academic field of English rhetoric, it is a truism that language both reflects and shapes reality, so I urge you to help shape a more egalitarian reality by jettisoning the word "subjects" when equated with human beings. Whether or not the writer or speaker means to, using the dehumanizing term "human subjects" suggests a hierarchy in which kingly or queenly researchers objectify, look down upon, and lord it over, subtly or otherwise, mere "clinical material" (to cite another phrase that caring academics should never deploy). Synonymous noun phrases abound that acknowledge the equal worth of humans who so generously give informed consent for research, e.g., "human research participants," "study participants," "trial enrollees," "human volunteers." I would pick 1 such term and stick to it throughout your document. This is a topic near and dear to my career. In fact, I	Faculty	5/19/15	Term - language change throughout report	**Thank you for this insightful suggestion. We agree, and “research participants” will be used throughout the plan.**

	wrote my dissertation-turned-book, *First Do No Harm: Empathy and the Writing of Medical Journal Articles* (New York and London: Routledge, 2002), on this very topic: how patients are too often demeaned, because of the top-down power structure, by insensitive labels unwittingly applied to them by physicians, insurance companies, and others in the health care industry. We at this wonderful University of Minnesota should be above such condescending nomenclature and, instead, should take the lead in foregrounding, in word and deed, the dignity of all humans, including those participating in research. Again, many thanks for the chance to offer this constructive idea. Relatively easy to implement, it would effect a sea change in tone whose positive impact, though hard to measure, would be profound.				
9	I would like to talk to the committee about research on typically developing, healthy children that is conducted here at the U of Minnesota, much of it in the Institute of Child Development in the College of Education. This research does not quality as exempt or as minimal risk because it involves minors. However, I don't think it often is the type of research risk that you all were contemplating when you wrote these new recommendations. Much of this child research goes to the social science IRB panel, but some has to go to medical panels. The work that goes to medical panels may involve blood sampling, heart rate measurement (involving electrodes), and brain wave measurement (involving electrodes). There certainly are risk, but they are of a different level than the risk of randomly assigning patients to different treatment conditions. And there are consent issues, but the parents of the children we test are not typically in a vulnerable group. And, while sick	Faculty	5/20/15	IRB Protocol Review Process (Section 5)	**Thank you for sharing your perspective on the implementation plan. Although it would be ideal to direct the studies you mentioned to just one IRB board, and likewise direct studies from other specialties such as Oncology, Surgery, Cardiology, etc., to just one board it may not be practical because of the backlog and delay for review at the IRB. This could be reconsidered after the 4 medical boards are functioning.**

	children who need treatments for medical reasons often cannot refuse procedures; healthy children who are doing research solely for research purposes can and do refuse to play our games and the child's refusal is always a reason to terminate the session. .....if for no other reason than you don't get good data from a child who isn't cooperating. We are wondering if it would make sense to designate a panel that deals with healthy (i.e., not medically or psychiatrically ill) child research that could be appropriately calibrated to the nature of risk in that research.				
10	I have read the report that you helped co-chair and am puzzled about whether it applies at all to researchers whose work is reviewed through the social sciences panel. It doesn't seem like it does. This clarification has implications for a variety of factors related to implementing the recommendations made.	Faculty	5/21/15	IRB Protocol Review Process (Section 5)	**We agree that clarification was needed and we have changed the report to indicate that the changes regarding compensation for IRB members, required attendance, and record keeping will apply both to the medical and non-medical IRBs. Departmental review for non-medical studies will not be changed as no issues have been identified with the current model.**
11	One thing that is lacking in this assessment is addressing the efficiency and effectiveness of the practices in the HRPP team to review and track submissions. An electronic system that allows for consent tracking (versions and approvals), document tracking and submission processing essential to improve the IRB ability to improve efficiency and reduce errors. Likewise, they IRB needs to develop a different way of conveying stipulations and deferrals. The letters are wrought with errors and misinterpretation; which is often due to the unnecessary time lag between the meeting and letter completion. The disorganization of the IRB team is wasting University resources trying to track down and interpret poorly done reviews. I am concerned unless	External	5/21/15	IRB Protocol Review process effectiveness (Section 5)	**See response to comment 4.1. The plan is to purchase and implement an electronic IRB process system that should facilitate the flow of information throughout the IRB application and review process.**

	real infrastructure support is provided, adding additional staff to train them on a broken system will lead to a bigger mess rather provide a way to move forward in a positive way.				
12	I am very concerned about the ability to provide meaningful scientific review if the proposal eliminates or significantly hinders review by those within the department of the investigator or who have previously collaborated with the investigator--for many of the studies that is going to be the only pool of people from within the institution with the appropriate expertise to actually provide the appropriate review. While we certainly can draw from external sources, I am skeptical that we can get a meaningful and particularly timely review if we need to make frequent use of external reviewers. Within the cancer realm, we are required by our NCI Cancer center designation to provide separate scientific review of all cancer related studies, and the draft doesn't seem to address if these same standards apply to the CPRC. I assume that is the intention and if so that should be made quite clear, as well addressing that we aren't going to start duplicating scientific review between the CPRC and the IRB.	Faculty	5/21/15	Scientific Review (Section 6)	**We agree. The report language has been revised.**
13	I think the proposed plan needs some revision. I did not see any mention of using a central IRB. I think this is necessary. Our current IRB is overloaded and understaffed. The ability to get an email or phone call often takes weeks. While I know the cost of central IRB is immense one way to decrease the load on the current IRB is to have sponsored projects go to the central IRB as they pay a fee anyway and have the internal projects use our IRB. I don't think increasing meetings or staff will be enough to fix the current issues. One other area is in regards to conflicts of interest. I'm	Faculty	5/21/15	IRB (Section 4) COI (Section 15) Scientific Review (Section 6)	**We agree that the plan should include information about Central IRB and it has been included in section 4.** **Thanks for also pointing out that the COI section needed clarification. The proposed changes in the conflict of interest policy will not prevent you or other researchers from continuing any of your current research and educational activities. You will be able to consult or participate in**

	uncertain why one would not allow anyone with a conflict of interest to be a PI. While I know that is the stance at Mayo, I have email confirmation from over a dozen other major academic institutions who allow conflicts of interest hold a PI position as long as they have a COI plan with the COI committee or similar committee at said institution. COI does not prevent good research done with integrity. My current COI allows me to be able to teach anesthesiologists all over the world how to better manage patient's pain which has an impact on thousands of patients. My impact on humanity is likely higher with my COI than with my research. I think if you have a COI plan and abide by it good research can be done and I beg you to reconsider this stance. I think having a zero tolerance for breaking the COI plan is a better option. There are other issues but those are minor compared to these two. I hope you consider these options. Thank you *These additional comments were submitted on 5/26/25:* After further thought I also think the plan to bring the scientific review to the IRB is troublesome. Currently it takes months to just get an IRB approval, bringing this to the IRB will further delay things. Furthermore, I'm not confident there is sufficient knowledge on the IRB to say whether certain studies are scientifically sound especially in the area of anesthesia/pain management. I suggest to keep these within the departments ensuring that each department does have a scientific committee. Thank you				**educational programs sponsored by a company and at the same time perform research with that company. The change is that you will not be able to get personal income from a company for consulting or participating is speaking or other educational activities while you are also participating in research sponsored by the company: the COI management is that you can direct the payments for those activities to the UMN. Extensive changes were made in Section 5 to clarify these points.** **We agree it is critical for the IRB to provide efficient service with a shortened turnaround time for reviews and for the IRB to have the necessary expertise to insure scientific rigor in studies. For this reason the number of human studies boards and the number of reviewers will be increased substantially. The group carefully considered the current departmental review process and concluded that there were more risks than benefits for continuing it**
14	I think we should follow the practices of the other top 10 research universities and the FDA and NIH. Many of the recs in this report are well beyond these standards.	Faculty	5/21/15	Policy - undue burden	**The intent is that the University of Minnesota be a leader in the protection of human subjects. However, see response to comment 1 on undue burden. Moving ahead, benchmarking against peers will be part of the implementation process**

					and we have added this point to the report.
15	The phrase 'reinventing the wheel' comes to mind with such exercises. To what extent, for better or worse, do our new formulations compare with our nearby peers.	Faculty	5/21/15	Policy - undue burden	**See comment above for 14**
16	I have four brief suggestions. (1) *IRB relationship to the researcher:* IRB solutions are often bureaucratic. Our current IRB functions through forms, and typically, with limited relationship to investigators. This often does not allow the IRB to adequately assess (a) unique ethical demands of a particular research context, and (b) the current knowledge base, skills, and attitudes of a particular researcher in match to this particular context. A pre-IRB review meeting interview between the applicant and an IRB staff person to review the application is a potential opportunity both to resolve questions and misunderstandings from the initial pre-review of the application, and to assess this match. This would require training and empowerment of IRB staff into a more active and sophisticated role. Relationships between the IRB and researchers can and should be collegial and supportive of the researcher (and I am happy to say, this has been my experience at UMN when I have called). In most all cases, adversarial and even antagonistic relationships with the IRB do not advance research participant protections. (2) *Personalized Ethics Training:* The IRB process offers an opportunity to provide ethical decision making training that is individualized to the outcomes of an assessment of (a) the research context of the IRB proposal, and (b) the knowledge base, skills, and attitudes of the investigator. This has far greater likelihood of protecting research participants; in some cases, a focused and highly relevant training curriculum	Faculty	5/22/15	IRB Protocol review process (Section 5) Education (Section 13) Community Engagement (Section 16 and Executive Summary: Engaging Research Subjects)	**16.1 thru 16.3** **Thank you for these excellent suggestions. After this implementation plan is formally approved by the regents there will be a process to create a detailed plan for how each part of the proposal will be implemented. We will include these suggestions in this process.** **16.4** **We agree that the CTSI Community Engagement Core will play a central role in the implementation of many of these recommendations.**

	might both be more in depth and briefer than a bureaucratic, one size fits all, broad, exhaustive training model that uses a uniform research ethics curriculum. The later approach assumes one curriculum can address every context. (3) *Research Ethics Lectures and Seminars:* One positive outcome of recent events is opportunity for a stimulating University-wide lecture series on contemporary issues in research ethics with human participants. A peer-reviewed program funding invitations to research ethics speakers in interest areas of faculty and students could provide topics and speakers. There is also a similar opportunity to augment seminars of traineeships at the undergraduate, graduate, and postdoctoral level with research ethics trainings by prominent scholars in these areas. (4) *Community Engagement Model:* Use of the CTSI Community Engagement Core, and a community engagement model plays to our existing institutional strengths. Elements of community engagement approaches suggest promising models for enhancing protections of our research participants.				
17	My clinical research career at the University of Minnesota began in 1976, and having lived through the creation and growth of IRBs (there were none in 1976), I would like to share a few thoughts regarding the proposed changes. The best clinical research, from both an ethical and outcomes perspective, is done by investigators who have respect and compassion for the volunteers. In addition, the investigators should be respected and not unduly burdened by administrative requirements that have become increasingly complex and often counterproductive. In reading both the Auditor's and AAHRPP report, I	Faculty	5/23/15	Policy - undue burden Education (Section 13) Engaging research subjects (Section 12) FUROC (Section 7)	**We agree that we must find the appropriate balance such that research participants are protected without excessive burden on the investigator and without unnecessary regulation. The committee recognizes that this may take some time to sort out. The clarifications we have made to the report based on public comments should help to explain our intent that while some of the changes apply broadly, others are targeted at**

	believe that we are responding with a plan that is too expensive, too cumbersome, and will not meet the goals intended. The two major conclusions from the AAHRPP report that we need to address are excerpted from their executive summary, and my suggestions follow. "While there is no explicit requirement for ethics education for investigators imposed by the federal research regulations, such education is a requirement of NIH and NSF supported research and is widely considered to be a valuable element of a research protection program. The external review team noted the University's recent introduction of policy changes that mandate additional training of IRB members. However, the broader educational policies and practices at the University fulfill minimal standards but represent a missed opportunity for a richer and more sophisticated institution -wide In my opinion, the training programs I have been required to take are inadequate and in some ways counterproductive. Being required to listen to lectures about shortcomings of research done many years ago, as if the standards of those days are still in practice, and working through an Internet program detailing regulatory minutia is not helpful. To foster respect and compassion for the volunteers, I suggest that we establish forums in which senior researchers discuss the hopes and fears of participating in a research trial with subjects who have experienced this. I believe that young investigators would develop the needed respect and compassion for those who sacrifice their time and literally blood to aid in translating research into clinical use from these interactions. These may be much more productive than lectures. "Some research subjects, by virtue of impairment or incapacity, may be unable to fully protect their own interests at the point of study enrollment and during the course of research participation. The external review			Scientific review (Section 6)	**specific types of studies that require more attention to ensure participant protection. Any new policies and practices will review administrative burden as a part of their implementation.** **We appreciate this excellent suggestion. In this plan we recommend that we use the current infrastructure of the CTSI around curriculum development and have that group partner with HRPP and OVPR to create a comprehensive, modern curriculum that addresses the needs of the research community (across the entire spectrum of clinical research). We recommend they review training programs already in place at other institutions to see what could be imported for our use as well as develop new curricula where needed. These suggestions will be made available to the group tasked with this activity along with our recommendation that they be strongly considered for implementation.**

	team observed that inadequate attention has been paid in IRB review and in University, hospital, and IRB policies to research with these subjects. One opportunity the University could consider in order to enhance subjects protection would require the involvement of clinical staff and others who are independent of the research team in formal gatekeeping roles. Such individuals may serve to mitigate or eliminate the conflict inherent in procedures related to recruitment, consent, and study exit. At Fairview Health Systems, where the relationship between research and clinical priorities in Psychiatry is strained and mistrust of researchers is widespread, the involvement of clinical staff in research functions as independent gatekeepers may help resolve this longstanding problem. “ Although the intent is good, I believe that gatekeepers will be overly costly and burdensome, and again, if paid by the University, be subjected to criticisms of conflict of interest. More useful would be to establish and “ombudsman” independent of the U to whom research subjects and their close ones could turn to for concerns. In addition, the IRB could establish a system of randomly contacting research subjects to enquire about their comfort level with the team of clinical investigators. In addition, I have concerns about returning scientific review back to the IRB. It was relegated to departments some years ago because it was felt that IRB members may not have always had the expertise to judge the scientific merits of some proposals. Sometimes overlooked in judging scientific merit in clinical research is that some studies are not major breakthroughs, but may improve the care and quality of life of patients. Unfortunately, we live in an era where experts are often mistrusted and perceived as being biased. This often leads to persons with little knowledge of a field, such as the intricacies of clinical research, making reports and				

	recommendations that may have little evidence of effectiveness and may be counterproductive. I hope that pressure from some individuals who have their own biases, such as beliefs that university faculty should not work with industry, do not lead to rapid implementation of policies that are more of a response to criticism than evidence based solutions. We should take seriously the criticism in the reports, but act only after fully determining if the proposed solutions will truly enhance the clinical investigator's respect and compassion for volunteers.				
18	I submit my feedback on behalf of my family who also had issues within the Fairview - Riverside - UMN - Department of Psychiatry research program. Having read through the draft plan and also having attended the open public forum hosted by Dr. Brooks Jackson, I personally feel an initial first step towards resurrecting the research program and human subjects protection is being presented. However, that is a small first step until I see and accept that the U of M fully understands and truthfully acknowledges that there were and are still major obstacles to clear as far as credibility is concerned. You don't exonerate yourself and make false and misleading statements for a decade and then when exposed expect the public to pat you on the back. The chair of the department stepping down should have been forced on the him years ago, and whether or not the Markingson treating physician was able to convince everyone that he does not coerce his patients is highly questionable since the Legislative Auditor's report states the opposite, and that very abusive and aggressive behavior has been his trademark. Eliminating the Peer Review should have taken place years ago, as well as the proposed moratorium on accepting industry money for speaking etc while	External	5/24/15	Engage Research Subjects (Section 12) Psychiatry (Section 11) Scientific Review (Section 6) Community engagement (Section 16)	**The committee was keenly aware of the circumstances and history of the Markingson case. The 2013 Faculty Senate resolution calling for an examination of current human subjects protection was a result of the Markingson case and led to the external review of the University human subjects protection program. The committee hopes that the forward-looking actions presented in the report will change the culture at the University and that the University will embrace a human subjects protection program that meets the highest ethical standards.**

	conducting a research trial for that very same company. Long overdue. Soliciting help or advice from the community stands out as a very strong idea, and I don't mean from advocacy groups such as NAMI etc, I mean actual past patients or their family members that might be willing to offer advice in areas that were of concern while they participated in a trial. The Markingson case at the U of M has brought to light so many issues for so many others that had been afraid or lacked the stamina that it must have taken for the Markingson family, to have carried the fight for so long. Please listen to the family, listen to the patient, and just don't assume your research staff have their priorities always in place. That's the real issue.				
19	I have comments regarding two topics: IRB Community Member Reimbursement Compensation for community members should be comparable to faculty members rather than the $3-5K per year recommended. Like it or not, in our society, compensation carries with it an indication of value. At present community members are viewed as equals to faculty members and are expected to perform the same functions. The draft work plan does not contain any recommendations for change in that role. Therefore, if the role of community members is to continue unchanged, then out of fairness, I believe compensation for community members should be comparable to faculty members. While most of us are not trained clinicians, we do bring unique perspectives and experience to bear on IRB deliberations which is why our presence is mandated. The low level of compensation recommended coupled with the deliberate or inadvertent failure to include it in section 19, Analysis of Resources Required for	External	5/24/15	IRB Membership (Section 4) Post Approval Review/Monitoring (Section 8)	**Thank you for your insightful comments and the work you do for the UMN IRB. Your current workload is excessive and the new plan, which quadruples the number of medical boards should decrease your workload substantially. As you point out, serving as a community member on an IRB is a community service activity. The proposed payment is to acknowledge the work and time and inconvenience that community members expend in service to the university and it is not intended as a salary. The budget in section 19 of the plan has been changed to include funds for community members. As you have recommended, the PAR will stay under the direction of the IRB.**

	Implementation, does not bolster one's sense that members of the Implementation Team fully understand nor appreciate the role of community members. Membership on the IRB requires a time commitment that far surpasses most volunteer engagements. Meeting attendance is a small fraction of that time commitment. At present I spend a minimum of 20 hours and most often 30 or more hours of preparation prior to each meeting. While increasing the number of panels and members is intended to spread out the workload and decrease the time required of each member, weekly meetings with a 60% minimum attendance requirement coupled with the additional preparation time that will be required to fulfill the aim of increasing the scope of panel discussions may not decrease the overall time commitment significantly. Community members do not perform this service for the money. However, fair compensation does provide an incentive to select this alternative over the many other less demanding volunteer opportunities that are available in our communities. Separate PAR from a reporting relationship to the IRB The work plan does not acknowledge the fact that the PAR function was moved from OVPR to HRPP several years because it was creating confusion and friction nor does it it indicate what changes will be made to ensure a successful operation this time around. If one of the main foci of this work plan is to strengthen the role, recognition and effectiveness of the IRB, then moving the PAR out of HRPP seems to me to be a move in the opposite direction.				
20	Thank you for your draft of a Work Plan for Implementing the Recommendations of the External Review of the University of Minnesota Human Research Protection Program. Not being an academic or engaged in academic	External	5/27/15	Culture (Section 3)	**Thank you for sharing your perspective. Your comments get to the need to change the culture at the U of MN regarding human studies research. You are correct that this plan alone will not change the**

	research, I know little about the mechanisms involved or the adequacy of the numerous protections included in your plan. But as a concerned citizen, your plan seems to address the issues raised both by the report of the external review panel and by critics of prior U of M research practices. However, one issue not addressed -- and it probably was not part of your mandate -- is how to ensure that University administrators at the highest levels, whether in the Medical School, the Office of the President, or the Regents, will respond appropriately to critics when and if redress through the mechanisms you recommend prove insufficient. As you no doubt know, the report of Minnesota Legislative Auditor James Nobles claimed that University administrators at these highest levels responded in an insular and defensive manner to critiques of the U of M practices in and response to the Dan Markingson case, and that those administrators ignored "serious ethical issues." I would suggest that so many such high-level administrators were involved that it is unlikely the response -- or lack of one -- was due to who they personally were. More likely, something within the institution produced such a consistent response from so many individuals. I am not at all confident that the external review panel and your subsequent report address this concern. Whether this concern was covered by your mandate or not, it may well need to be further addressed by someone or some committee such as yours. Thank you for your work on what seems to be an otherwise thorough report.				**culture, but we believe it is a step towards that goal. By mandating this process, with transparency, the Board of Regents and University leadership are walking the walk to a change in the culture.**
21-34	https://drive.google.com/file/d/0B20cWO6w77sPbEJ6N2hpemFRRFJCWHM3d1k3OXBrZXRjTndR/view?usp=	Faculty (AHC	5/27/15	Policy - undue burden	**You raise some valid concerns and some reasonable suggestions**

	sharing	FCC)		Org Chart - process flow model IRB Membership (Section 4) Engaging Research Subjects (Section 12)	**Organizational charts have been added. Your comments will be made available on the team's website and forwarded to those who carry out the implementation of the plan will have them available for review and consideration.**
35	Just a couple of comments about the IRB draft 1) I like the plan to have multiple IRBs to review proposals, so that applications can be reviewed more quickly. At one of my former institutions, which is smaller than UMN, we had 3 IRBs. 2) If IRB members are going to be given salary support or paid in some way, there must be accountability regarding participation. Attendance at meetings must be recorded, and if a member misses more that a set percent of meetings, eg 20%, then they should be removed from the IRB or have a percentage of their support decreased. 3) Having shorter weekly meetings for each IRB may be difficult for many faculty. Longer, less frequent meetings may be more desirable for at least some faculty. 4) How do we reconcile the idea that we need eg more heme/onc physicians on the IRB for their expertise, yet at the same time, reviewing the protocol of a division colleague is viewed as a conflict of interest?	Faculty	5/27/15	IRB Membership (Section 4) IRB Protocol Review Process (Section 5)	**At IRB meetings those with a COI for a particular protocol must recuse from the vote. If necessary, ad hoc reviewers can be recruited for specific protocols.**
36	I am writing as an alumni, former employee of the UMN IRB, past Research Compliance Officer in the short lived Office of Regulatory Affairs, Masters student in Regulatory Affairs and recent hire to the department of Psychiatry.	Faculty	5/27/15	Psychiatry (Section 11) Culture (Section 3)	**The committee agrees, and with the exception of Section 11, the report is directed towards the entire university.**

	I have worked in clinical research in every role I could think of, with "Investigators", at a "Sponsor", at an "IRB". I have volunteered to be a research subject. I have enrolled research subjects. I have monitored research. I believe in it. I live it. I am concerned that the department of Psychiatry has been singularly identified. They most certainly do enroll vulnerable subjects, as defined on pages 37-39 of the Implementation Plan ("IP"), however, I believe most subjects enrolled would fit into this category based upon the definition. Why are other departments who also routinely function with this patient population not also identified? As the IP states, "In one sense, one failure adversely affects the particular study, all present studies, all future studies and even the broader community". I understand that while the IP was a reaction to reports released that were directly tied to the department of Psychiatry, it would be remiss to not use this opportunity to create process improvement with all human subject research within the ENTIRE University of Minnesota.				
37	First of all, thank you for the extensive effort and obvious dedication that has gone into development of this plan. I think that you have identified many of the issues that need to be addressed. I do have one overarching comment that I think is not adequately addressed, and that is the concept of "arm's length." For research subjects to be adequately protected, there must be a firewall between the physician who is making medical decisions for the patient and the individuals *and the entity* that is conducting and profiting from the research. It must be recognized that a researcher and an institution profit in many non-financial ways from research that enrolls human subjects. The University of Minnesota receives significant research funding that adds to its stature as a research institution, and also	Faculty	5/28/15	Research and Vulnerable Populations (Section 10) COI (Section 15) External IRB (Section 5)	**We agree that the plan should include information about Central IRB and it has been included in section 4.**

	receives significant recognition for working at the frontiers of medicine. Without research, no advances will be made in patient care. Research is a fundamental part of our mission, but it also raises our stature locally and nationally. But the rewards of research, whether financial or in reputation, to the individual or the institution, create tremendous bias that is difficult to manage, even when aware of it. The Implementation Team has recognized this within a department (Psychiatry) and addresses it, but fails to recognize that the same bias extends beyond a department to a school and to the full university. The school of medicine AND the university as a whole have an equal conflict of interest that is not addressed in any way in the workplan - only the conflict of the individual researcher and the individual's department. The only truly objective review of the appropriateness of research comes from outside, from a body that does not stand to profit, which exists as an external or centralized IRB. There are a number of laudable academic institutions that have contracted their review process to these IRBs, primarily to address the inherent conflict of interest of reviewing research within an institution. At first blush one would think that this would be a terrible way to go - by distancing itself, it appears that the institution is abrogating its responsibility to ensure the safety of patients. In actuality, these institutions are taking the highest ethical and moral stance, making sure that a group with no immediate reward reviews all research that involves human subjects. The centralized IRB can be one that exists as a separate entity with no ties to an individual institution; it can also exist as a "pool" of institutional IRBs that share the work of reviews (Emory is in one such pool), and ensure that each review is conducted by a group not affiliated with the institution enrolling the patients.				

	The FDA has recognized the enhanced objectivity of having external, centralized review boards, and has long accepted their review in sponsored trials. We believe that the FDA is moving to mandate that outside, centralized IRBs manage all sponsored studies, and that institutions that do not permit use of a centralized IRB will not be allowed to participate in these studies. At present, a researcher cannot participate in many large drug trials unless through a centralized review board; we know personally of 10 over the last 3 years that we could not participate in because the UMN IRB refused to allow external IRB review. It seems the UMN IRB felt they had a superior process, which we now see was not true. I would urge the Implementation Team to strongly consider implementing an external review process. As put forward in the workplan, inherent bias continues to exist although perhaps somewhat diluted. The only way to maximally manage bias and conflict of interest is to utilize a centralized IRB. This would not, of course, eliminate the IRB at the University of Minnesota. It would continue to perform a vital regulatory role, providing strong oversight and direction, education and management of ongoing trials. But the final, overarching decision about the ethics and morality of the research would be done by individuals with no personal gain. If an external IRB is not to be employed, it should at least be made available for those trials where the FDA has mandated this approach. To insist that approval must be internal only eliminates opportunities for our patients and researchers to participate in important trials. I hope that this comment will raise some other possibilities for managing the very difficult questions of conflict of interest and bias, not within an individual or department, but within an entire school and a university.				

	Finally, I would ask the Implementation Team to very clearly state that the physician making medical decisions for a patient CANNOT BE the individual who is a named investigator in study. This is a critically important protection that I did not see specifically called out (although I may have missed it in the extensive document). Thank you for the opportunity to comment, and best wishes as you move forward.				
38	I appreciate the tremendous amount of work done in a short time by the "implementation team" and the opportunity to comment on the proposed plan. Most of my concerns relate to the recommendations for scientific review. As background, I have a long history of NIH- and pharmaceutical company-funded clinical and translational research at the University and, as a result, a long history of working with the University of Minnesota IRB. I have a few comments regarding the draft plan. First, I notice that the only (internal) clinically-oriented physicians and the (outside) chair on the committee are from Departments of Medicine. Is there a reason physician-researchers from other departments were not included in discussion and development of the plan? Second, regarding, "Management of Conflict of Interest," there are two issues that I feel need to be specifically addressed: a) Payment for subject enrollment. This can occur in both sponsor-created and investigator-initiated trials. (One can understand a sponsor's perspective - providing a large grant and having zero enrollment would not be acceptable.) Prohibiting such trials at the University would limit clinical research. Consequently, guidelines should be developed. Obviously, physician payment per subject enrolled is a conflict. What other	Faculty	5/28/15	Scientific Review (Section 6) COI (Section 15)	**Committee members included representation from many groups within the university. To be sure, some groups were not included, but there is a trade-off between having a committee that is highly representative but unwieldy and a committee that is less representative but of a feasible size to function effectively. The COI section has been clarified.**

	guidelines can be developed without limiting investigators' participation in these trials? b) The guidelines that are developed for both scientific and human subject protection should include time limits on the review. University of Minnesota participation in multi-center studies is currently limited by extended IRB review and stipulations, followed by re-review and new stipulations, etc. (e.g., we have an application that was submitted in November and after responses to stipulations was sent back and returned with new stipulations, etc. By the time this protocol is IRB-approved [if ever], the multicenter study will have completed [or nearly completed] enrollment and we will have lost the opportunity to learn if the protocol is of benefit to our patient population). This entire process could be streamlined (e.g., a separate group available to review and turn around resubmitted applications.) If there is going to be an additional step in the process - i.e., scientific review - similar streamlining and efficiencies must be included in the plan. Third, regarding "Scientific Review." I am concerned about how the "scientific review" process will be designed and implemented. If Departmental Review is eliminated, then, unlike the makeup of the implementation team, the scientific review group should be multidisciplinary. I am strongly opposed to the statement "HRPP managed" process (for scientific review) could be done through the CTSA Translational Research Portal (as stated in recommendation B.8, page 24). The heavily Department of Medicine-directed CTSI already has considerable power and influence at the University. In my opinion, giving the CTSI additional power would be a mistake. No one small group should have that much control over the University's Medical School research agenda. If moved outside of the Departments, the scientific review should be done by an independent committee (which should have strict, and tight, time limits for review and response).				

	In fact, considering that one recommendation is to pay reviewers, wasn't it a conflict of interest for the Department of Medicine loaded "implementation team" to consider recommending that the scientific review be done by the Department of Medicine-loaded CTSI?				
39	The draft work plan from the President's external review panel offers a number of important and excellent suggestions for improving the conduct of clinical research at the University of Minnesota and it's clinical partner, Fairview. While I support the majority of these recommendations, there are two which I find unacceptable. The first of these is the suggestion of compensation for members of the IRBs, particularly faculty. I certainly agree that the number and composition of the IRBs be expanded and that guidelines for workload be developed. These are important and necessary changes as is the recommendation of targeted participation by specific faculty groups. However committee service is an expected role for faculty and there are many essential committees of the University (Admissions committees, Promotion and Tenure Committees for example) where service of faculty is required but not compensated. To select out one committee function for University payment to the departments for faculty time serves to diminish the importance of service on other vital committees. Rather the workload and term of service on the IRB should be crafted so that it is in line with service on other committees. I strongly disagree with this recommendation. The second recommendation with which I disagree is that all of the clinical research of the Department of Psychiatry be placed under the direction of the CTSI. To single out one clinical department for this regulation is extraordinary and it is extremely punitive. In fact it	Faculty	5/28/15	IRB Membership (Section 4) Psychiatry (Section 11)	**Thanks for your comments. The COI and Psychiatry sections have been modified.**

	ensures that the department of Psychiatry will never be able to succeed in recruiting an outstanding Department leader now that the current Departmental Chair has resigned. This department is essential for the medical school. It educates our students and residents in a specialty which is badly needed by the state and the nation. Psychiatrists are in short supply locally and nationally and we seem to have forgotten the outstanding job in education and training that our Psychiatry department and its faculty have done in what appears to be a frenzy to “punish” the department for what are perceived as lapses in clinical research proceedures. We seem to have forgotten the hundreds of important research studies conducted over the years by faculty of this department which have enhanced our scientific knowledge and the treatments for patients. If all clinical research across all departments is to be put under the umbrella oversight of the CTSI, I would question the feasibility but not object. However I strongly oppose the overreaction which has led to this recommendation for the Psychiatry department. If enacted, the consequences will be serious and longlasting. Finally the suggestions about a new position of Ethics coordinator seem unnecessary given the other substantive changes and the recommendation for no personal compensation from a research sponsor to an investigator, while not unreasonable, requires more clarification. I assume that the investigator is allowed to receive reimbursement for their role in the research study as is any other PI and I am confused by the “EXCEPTION CLAUSE” which weakens this section considerably.				
40	https://drive.google.com/file/d/0B20cWO6w77sPaHRTUWNWVWVKakk/view?usp=sharing	Faculty	5/28/15	Culture (Section 3) Scientific	**Scientific review: The committee feels that moving scientific review to an HRPP managed-process will lessen the burden on departments to**

				Review (Section 6) Research Involving Vulnerable Populations (Section 10) Engaging Research Subjects (Section 12)	**have department-based review processes. Under the new process, PIs and department committees are allowed and encouraged to recommend experts from within and outside their department to serve as reviewers.** **We appreciate this comment and have language in this report that strongly recommends that we use existing resources to help with engaging research participants.**
41	Having reviewed the managing conflict of interest section pages 52-53 I have significant concern over the suggested change in policy stating ".....individuals who seek approval from the IRB as study staff on a protocol may not receive any personal compensation (other than supported thorough research grants) from a company during the time that investigator participates in any new research study funded by that industry sponsor." This policy will prevent faculty from work with industry that is outside the purview of being the site PI for industry sponsored trials; examples include being the National PI for a multisite trial where consulting fees are provided rather than %effort and the site PI for a different study, it would prevent consulting on unrelated studies, i.e. consulting on work such as device development or other technology that has nothing to do with the trial they may be the site PI for, one would be prevented from serving on a DSMB for that company, another example would be the inability for a site PI of an industry sponsored study to participate in studies that are developed by industry in partnership with the NIH. There are numerous examples like this that would significantly limit industry interactions and potentially compromise our ability to compete for dual sponsored	Faculty	5/29/15	COI (Section 15)	**Thanks for your perspective. The COI section has been modified for clarity.**

	grants/studies. The unforeseen restrictions to such a policy can be and will likely significantly compromise our ability to expand collaborations and research programs which depend in part on collaborations with our industry partners. I believe we will find that this policy is going to be too restrictive and will hurt research at this University. I appreciate the need for the community outside and for many inside the University to feel we are doing the things we need to do to address concerns that have been raised, but I truly hope we can do so without compromising the future of research at the institution by instituting the above policy.				
42-44	https://drive.google.com/file/d/0B20cWO6w77sPMHBGb0RmUTJCYWc/view?usp=sharing	Faculty (3 co-signers)	5/29/15	Policy – undue burden	**Thank you for your (always) thoughtful and substantive comments on the draft implementation team's report. As you might expect, we have received other comments on the draft plan, some of which are echoed in your letter. From my perspective, it is absolutely understood that our institution has done exceptional clinical research both historically and currently, and through that research has contributed tremendously to the better health and wellbeing of our society. Thus, our commitment to clinical research is unassailable, and we believe strongly in the need to continue our excellence in this area. I would also state that both the implementation team and the RCAC (as well as many of the comments), have made it clear that whatever changes are made through this process, it should not add inappropriate new burdens on**

					the investigator and the hope is that we can make things easier and faster as we implement the electronic IRB process as recommended by the implementation team. **You also comment on the insufficient detail about exactly how some of the recommendations will be operationalized. Given the time frame available to the team to produce a report in response to the charge from the President, and the scope of the charge, it was not possible to fully work out the operational aspects of every recommendation. Having said that, I want to assure you that as the recommendations are adopted, significant input from the clinical researcher community will be sought to make sure that they are done thoughtfully and appropriately.** **I look forward to continual engagement with you and your colleagues as we move this process forward.**
45	https://drive.google.com/file/d/0B20cWO6w77sPVUdua21QUHNfcVE/view?usp=sharing	Faculty	5/29/15	Community Engagement (Section 16 and Executive Summary: Engaging Research Subjects)	**This comment emphasizes the importance of community member involvement at all steps in the approval and oversight of human research oversight. We agree and the current plan includes provisions to recruit community members for these roles.** **We agree that the CTSI Community Engagement Core will be an important resource as we implement the recommendations of this plan.**

46	https://drive.google.com/file/d/0B20cWO6w77sPNXJWY2UtOGg0bms/view?usp=sharing	Faculty	5/30/15	FUROC (Section 7) IRB Boards (Section 4) Vulnerable Subjects (Section 10) COI (Section 15)	**Thank you for your comments. Several of the sections of the plan to which you refer have been modified for clarity.**
47-48	https://drive.google.com/file/d/0B20cWO6w77sPc3hOSlY0ZUh3RDQ/view?usp=sharing	Faculty	5/31/15	Scientific Review (Section 6) Post Approval Review/Monitoring (Section 8) Psychiatry (Section 11) COI (Section 15)	**We agree that the CTSI will only oversee Psychiatry studies that involve vulnerable participants or are interventional. In addition, these comments question the changes in the COI policy and the potential adverse effects on the ability of investigators to participate in consulting for innovations in medical research. These are good points and the COI plan has been modified to clarify that researchers may continue to consult for industry and at the same time conduct research sponsored by the same company. The change is that the investigator may not get personal income from consulting or from educational activities while participating in research sponsored by the same company.**
49	Thank you for your thorough and insightful response to the report of the External Review committee, and for providing a clear set of recommendations. I have one suggestion below. To frame my comments, I'll mention that I'm a faculty member in the Psychology Department (and former department Chair). I've	Faculty	5/31/15	IRB Protocol Process Review (Section 5)	**The plans to compensate IRB members will also apply to the behavioral boards, so the proposed changes will be harmonized for all the IRBs.**

	interacted with the IRB for many years as a principal investigator, primarily the Social and Behavioral IRB. I realize that the External Review committee did not analyze the operations of the Social and Behavioral IRB, and that, accordingly, your committee focused almost exclusively on the biomedical IRB. My suggestion is that once the implementation plan is adopted for the biomedical IRB, a panel should examine the procedures of the Social and Behavioral IRB in the light of this plan. I have no specific issues to raise concerning the Social and Behavioral IRB. But in order to protect its integrity and harmonize its procedures with the updated biomedical IRB, I think such a review would be valuable. Would your committee consider making a recommendation along these lines?				
50	https://drive.google.com/file/d/0B20cWO6w77sPTWtEb29NVkl4MEU/view?usp=sharing	Faculty	5/31/15	Policy - undue burden IRB Board Model and Process (Section 4) Post Approval Review (Section 8)	**To comment on where 10% compensation for IRB comes from: See response to #3.**
51	A. Background. I have been following these (and earlier) matters quite carefully via the official UM websites together with public legal documents from past years, etc. I am well familiar with the issues involved. I have studied the AAHRPP Report (2/26/15) and the Legislative Auditor's Report (3/19/15). I've also attended the UM Senate meeting where the AAHRPP Report was presented -- and listened to the	Faculty	5/31/15	Post Approval Review/eIRB (Section 8)	**We agree with recommendation #4, and the implementation of an electronic IRB (which is recommended in the draft report), will allow us to accomplish the goals you outlined.** **With respect to recommendations #1-3, we also agree that these recommendations are important and are good suggestions, but feel that they are beyond the specific charge**

	full audiotape of the Minnesota Senate Hearing with the Legislative Auditor. In addition, I attended the Town Forum May 4 and the Board of Regents Meeting on May 7. On April 30, 2015, I served as substitute senator for Albert Marden in the UM Faculty Senate and, there, made an important suggestion to President Kaler concerning the Markingson family. B. Abbreviations. [AAH] = the AAHRPP Report (2/26/15) [OLA] = the Legislative Auditor Report (3/19/15) [P] = the current draft work plan C. My Overview of the Workplan. This Workplan clearly represents a serious attempt at methodical implementation of the specific recommendations in [AAH]. It is laudable for the checks-and-balances which permeate the plan. Likewise for adhering to basic common sense. As a whole, however, the plan's emphasis is largely reactive rather than being pro-active. It is analogous to boiling down a (high quality) 1000 page treatise on bio-ethics in an uninspired way into a new 'executive' sub-bureaucracy at UM. Though the plan is intended to be impressive ("beyond reproach"), it is decidedly less so given certain areas of silence in regard to issues raised explicitly in [AAH] and [OLA]. Likewise in regard to awareness of a gap in existing Minnesota Law. D. My Main Suggestions. There will be 4. Suggestions #1 and #3 are the most important.				**of the implementation team.**

	(1) Do Not Ignore the Past. Why does it seem that this plan [P] is fundamentally disconnected from the past? I.e., that the past is 'finessed'. No statement is ever made that errors were made. Is UM perfect? Pages 86-89 in [AAH] are some of the MOST important in that document, even if the innocuous sounding recommendations on pp.89-90 do not enunciate that. One needs to read between the lines. UM's "defensive posture" was highlighted as NOT being wise (pp.87,88) and it is suggested virtually explicitly that apologies are essential to move forward. I am reminded of the quote in [OLA,p.29] by Dr David Strauss: "The regulations are only the floor. Any institution that aims that low is likely not going to be doing a terribly good job." Lines 4-9 on p.89 of [AAH] concerning UM seeking court costs [$57000] from Mary Weiss are particularly shocking. See also sentence #1 in [AAH, p.89, Section 3.6.3] -- the meaning of which is clear (cf. the word humane). Though UM _has_ publicly apologized for Dan Markingson's CARE, there has been silence (as far as my most recent knowledge goes) about the UM court cost matter highlighted on lines 4-9. This plan should recommend that a_full and sincere__ apology be made as a clear demonstration of institutional culture change starting at the top. This is completely in line with [AAH]. (A big new, corrective, mini-bureaucracy is fine to point to, but, please, pay attention to what started all this.)				

	(2) A Gap in Minnesota Law regarding Psychiatric Patients. [P, section 11, pp.40-44] gives special attention to the Department of Psychiatry. [AAH, p.66, last paragraph] raised serious questions about awareness 'there' as to Minnesota law regarding vulnerable patients and perceptions of coercion in clinical drug studies. Cf. also [AAH, pp.82 (final paragraph), 84 (recommendation 4)]. It is commonly said that Dan's Law, from 2009 [Mn Stat 253B.095 Subd 1 (d4) and (e)] now protects FUMC patients under stays of commitment or in the process of civil commitment vis a vis drug trials. This is NOT quite correct. There is still a serious concern --very pertinent for [P] -- as to the protection afforded patients at FUMC under 72-hour involuntary holds. See Mn Stat 253B.05 Subd 3(a)(e), especially (e). Patients in such a status can very definitely **perceive** coercion to comply with suggestions of an attending psychiatrist, eg, as to medicines, lest action be taken by the facility itself -- for instance, via 'MD spin' -- to extend the involuntary confinement period. To be more specific: clause (e) states the period is 72 hrs UNLESS a court order to hold the person is obtained. How might that order be obtained in the mind of an impaired patient? I quote here from a NAMI document: "An initial hold lasts for only 72 hours. However, there will be a hearing before the 72-hour period is over. The judge can then order the person with mental illness to be confined until the end of the commitment process. (But: regarding the civil commitment process)				

	"The petitioner is _often the head of a treatment facility_(emphasis mine!) where the person with mental illness is being treated, but the petitioner can also be a family member, friend or someone in the community. However, we recommend that family NOT be the petitioner." {Thus: who is?? And note the word 'often'.} SEE: http://www.namihelps.org/assets/PDFs/civilcommitmentSinglePg102108.pdf It would be good to see some attention paid in [P] to the matter of 72 hr holds and appropriate patient protections. And, EQUALLY IMPORTANTLY, to gauging the prevalence of any potentially 72 hr coercive situations ***in the past***. (Federal Guidelines presumably also say something about this matter, i.e. clinical drug study recruitment in a potentially coerced state, but these may not be codified into law.) (3) State Oversight for a Probationary Period. President Kaler's statement "trust but verify" should mean something. Moreover, to be beyond reproach, is it not wise for people "driven to discover" to be prepared to think OUTSIDE the box?? The plans detailed in [P] frankly tend to be an uninspired implementation of the recommendations in [AAH]; very much common sense and "in the box". Picking up on the idea raised in [P, p.8 (External Advisor) and p.56 section 17], I would like to propose that the University of Minnesota INVITE official State oversight of itself for _several_ years (via some sort of State ombudsman + expert deputy helper(s)) at least in regard to the plan's implementation in psychiatry vis a				

	vis vulnerable patients. This oversight ombudsman should ideally have subpoena power. This action would be consistent with [P, p.5 (last line), 7 (metrics), 20 (final paragraph), 42 (lines 5-8), 54 (paragraph 1)] and would, at the same time, represent an alternate time-limited form of [OLA, p.31, recommendation 2]. If one thinks about it, I believe this action has MUCH to recommend it. And it exemplifies a true "trust but verify". (This oversight can, of course, be extended outside of psychiatry, but, in the interest of feasibility and reasonable workload, it is natural to draw the line of demarcation there.) (4) Database for Easy Tracking of Serious Adverse Event Reports. [AAH, p.53, line 12] laments, re: monitoring, the lack of a centralized database for reporting and tracking adverse events -- as well as unanticipated problems and subject complaints. Though [P, p.59, item 12] seemingly addresses this, the connection to the lament in [AAH, p.53, line 12] needs to be made much clearer. Right now, the link is largely opaque. See, eg, [P, p.51, lines 3-6, for Cause]. UM General Counsel Donohue effectively stated in a 2014 letter to Arne Carlson that UM is basically a 19th century institution in NOT having available any type of (even very primitive) centralized database of this kind -- and that it would extremely cumbersome, if not impossible, to create such.				

	Had time permitted me to speak, my comment to the Board of Regents on May 7 would simply have been: "As a Fellow in the Minnesota Supercomputer Institute, I do NOT believe this at all. Creating such a database cannot be very hard, particularly if a graph-based record input is employed. This is not the 19th century." I hope that this input can help in making UM's response to this year mess truly beyond reproach.				
52	Thank you for the opportunity to offer a suggestion towards strengthening the Panels Human Subject Protection Plan. One glaring shortcoming that seems to be missing from the proposal is the way potential study enrollees are being screened and enrolled by the department of psychiatry researchers and their staff. Having witnessed Dan Markingson being in a locked ward for thirty days, and then reading the take from the AAHRPP panel that in itself being confined and restricted can cause patients with already diminished capacity to not fully understand exactly what they are consenting to if they choose to enroll into a study. I realize that an advocate is being suggested, which is a good idea, but I would guess that over 90% of the patients being pushed to consent into psych studies while in Fairview are there on a 72 hour hold, or some type of involuntary commitment. These are the patients that are most vulnerable and susceptible to coercion or misunderstanding about the nature of the study. Perhaps a moratorium needs to be enforced that prohibits these patients from being approached during the first days they are hospitalized and locked in a ward. The attached link may be of some additional value, I would recommend reading it before the draft becomes final.	External	5/31/15	Vulnerable Subjects (Section 10) COI (Section 15)	**Your comments will be available for review by those who implement this plan. Thanks for your perspective.**

	Thank you. http://repository.jmls.edu/cgi/viewcontent.cgi?article=1010&context=lawreview				
53	I fully agree with the comments that Dennis Hejhal has made earlier today. For your convenience I attach these as a pdf file. https://drive.google.com/file/d/0B20cWO6w77sPYTNVd2w4SWVZYTQ/view?usp=sharing Between November, 2003 when Dan Markingson was enrolled in the experimental drug trial and the present, the University of Minnesota's administration, as represented by Bruininks, Kaler, the University attorneys' office headed by Rotenberg, Donohue, Vice President for Research Herman, the Academic Health Center headed by Cerra, Friedman, Jackson, more generally the Board of Regents and Morrill Hall, have not dealt in an honest and forthright manner with regard to the ongoing scandal associated with Dan Markingson, Robert Huber as the VICTIMS, but also in the treatment of all faculty and staff (both at the University and at Fairview) who have attempted to shine the light of integrity on the ethical breaches and, simply put, indecent behavior towards Dan Markingson, Mary Weiss, Robert Huber. The highly critical external review would never have occurred, had not Professors Carl Elliott and Leigh Turner invested considerable effort to bring into the open what Morrill Hall was doing all it could to conceal. In December, 2013, I together with seven other members of the Faculty Senate introduced a resolution calling for an external investigation with particular attention to the Psychiatry Department and the circumstances of Dan Markingson's suicide in May, 2004. This resolution which was illegitimately modified by the Faculty Consultative Committee, formed the basis for the solicitation of the external review.	Faculty	5/31/15	Hejhal see above & Post Approval Review	**These comments underscore the reality that this implementation plan alone cannot be a blueprint to change the culture of human studies research at the UMN: such a change will require additional collegial discussions and planning by the University community.**

	Following the external review's damning report, following the Legislative Auditor's damning report, the implementation task force released on May 18 its recommendations and held a self-congratulatory media briefing. Why their recommendations could not have been issued in September, 2004, why more than a decade had to pass, why the University attempted to obtain $57,000 from Mary Weiss, goes undiscussed and unanswered in the sixty-eight page draft document they produced. To add insult to injury, Kaler publishes today, May 31, a counterpoint op-ed piece in the Star-Tribune in which university public relations sinks to a new low by invoking Miles' quip, "Markingson's legacy" and writes "Critics are important voices, but there comes a point at which criticism of past actions stops being a catalyst for reform and, instead, becomes a barrier to necessary change in the future." Chutzpah unbound! If the implementation task force wants to make a lasting impact beyond its "forward looking" (since it is too painful to look back honestly) recommendations, let it call for the immediate changing of the name of the newly christened Bruininks Hall, to a more justified name Dan Markingson Hall. May his memory be a blessing.				
54	https://drive.google.com/file/d/0B20cWO6w77sPS29IaElzUjAxb2c/view?usp=sharing	Faculty	5/31/15	Language change recommendations IRB Protocol Review Process (Section 5) Scientific Review (Section 6)	**A previous commenter also suggested changing from the word "subject" and throughout the document "subject" has been changed to "research participant." Institutional Review Board is the term used in the U.S. Code of Federal Regulations and to avoid confusion we'll continue to use it in this document. The draft plan has been modified to clarify several points noted in these comments, including the protocol review process and**

				Engaged Community Members (Section 16) COI (Section 15) Engaging Research Subjects (Section 12)	**conflict of interest issues.** **Currently and moving forward, for studies involving minimal risk, scientific review is conducted by the IRB (see revised Section 6 of the report.)**
55	https://drive.google.com/file/d/0B20cWO6w77sPWWQ0cUtmcTdrTEE/view?usp=sharing	Staff	5/31/15	IRB Board (Section 4) FUROC (Section 7)	**As noted in #53, These comments underscore the reality that this implementation plan alone cannot be a blueprint to change the culture of human studies research at the UMN: such a change will require additional collegial discussions and planning by the University community.** **Under this plan, members of the behavioral IRB boards will also be compensated.**
56	I commend the team for their commitment to advancing the care of our human research subjects. I believe everyone desires a system that protects our research participants, while simultaneously supporting the advancement of clinical research at UMN and avoiding imposing any excessive burdens on research participants. In response to the public comment period, I am including responses to the working document in the email text below. Section 4: IRB membership. This section proposes restructuring the IRB including, but not limited to, increased IRB membership, increased number of committees, and payment of IRB members (10% salary support, 25% for IRB chairs, and	Faculty	6/1/15	Section 4: IRB membership Section 6: Scientific Review of Studies Section 8: Monitoring of Studies Section 10: Research with Human Subjects who	**Thank you for your comments and suggestions. We agree that the plan should address the role of Central IRBs and we have added this to the plan. We agree that minimal risk studies will not require pre-review and can be reviewed directly at the IRB. We agree that minimal risk studies will not require routine monitoring. Patients who have just had sedation for an elective procedure should not be enrolled in a study. Using a web-based survey tools is a good suggestion and can be considered. We agree that some research may not require a plan to**

	3,000-,5000/year for community members). There is a compelling rationale for increasing IRB size to accommodate workload, and certainly both monetary and academic compensation are warranted. Recommendation: However, given the amount of (challenging) time commitment needed from faculty and the great expense incurred with the new proposal, I would pose to the committee whether use of a centralized IRB might be a cost-effective option here, and free up faculty time for conducting research. Section 6: Scientific Review of Studies. This includes a proposal to eliminate departmental peer review as an option for scientific review, and move this to a HRPP managed review procedures. Studies that are minimal risk will not require scientific review other than by the IRB reviewer (as is the case currently). The IRB has traditionally considered studies with a simple blood draw or other minor procedure as above minimal risk. These studies (such as a serum draw from a healthy control patient) differ greatly in intensity and participant risk from more complex testing or intervention studies. Recommendation: Consider offering a rapid scientific review mechanism, or even continued departmental review for studies in which: (1) risk represent a minor increased over minimal risk; and/or (2) the test or study procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations. Section 8: Monitoring of Studies Included in this section is a proposal that live consent monitoring should be performed, including video documentation of informed consent and/or monitoring the process (unclear if both or one or the other). While it is somewhat vague, my interpretation in reading this section is that the proposal is for consent monitoring to			Have Impaired or Fluctuating Capacity to Consent Section 12: Engaging Research Subjects	**share results and an investigator could request an exemption during the protocol application process.**

	be performed in every study. This seems quite logistically challenging and also an extra burden on subjects, many of whom may be uncomfortable with being filmed. Recommendation: Monitoring the informed consent process is a reasonable proposal for high risk studies (ie particularly those under an IND or IDE). However, for low risk studies (blood testing, an imaging study, or interview/ questionnaires, for example), this seems unnecessary in every study and could be done in a small sample for auditing. Section 10: Research with Human Subjects who Have Impaired or Fluctuating Capacity to Consent This section includes guidance for subjects who have normal consent capacity at the time of the informed consent process but have a fluctuating ability to consent during the study. I assume this section was drafted primarily with mental health disorders in mind, but the definition of fluctuating consent is unclear. Would this include a surgical patient, who is temporarily sedated but is expected to fully gain consciousness after a number of hours and has in advance consented to the procedures/ interventions? Recommendation: Since the extra procedures to obtain durable power of attorney or representative for patient with expected potential fluctuating consent capacity could be an extra burden to both patients and investigators, and could potentially prohibit opportunities for patients to participate in studies, I would recommend very careful definition, including statement about whether this includes (or specifically excludes) patients with short period of impairment expected for a procedure with sedation. Section 12: Engaging Research Subjects Point 1: The workplan proposes to better assess research subject experiences, including creating a research subject satisfaction survey that is distributed to subjects and surrogate decision-makers to evaluate				

	their research experiences. I welcome the opportunity and mechanisms for subjects to provide feedback on their research experience. I am attentive, however, to not increasing burdens on our study subjects. Recommendation: Any satisfaction survey should be brief, and not mandatory for subjects to complete (which I assume would be the case). A web-based mechanism might be considered to provide opportunities for feedback independent of study visits. Point 2: This section also contains reference to requiring investigators to have a plan for data sharing with subjects, and other plans for expressing appreciation. In our research, we do currently distribute trinkets at study end, birthday cards, and share the manuscript with final results. However, I recognize the spectrum of clinical research. Some studies are long-term, with no immediate results available. Some may be very early translational or mechanistic studies which use human blood or tissue but are not directly to relevant to the healthy volunteer participant. Recommendation: Some consideration should be given to the spectrum of clinical research. Some studies may not be appropriate or feasible to communicate results back to participants. A results communication plan should be a part of any intervention trial; other studies might be subject to individual consideration.				
57	https://drive.google.com/file/d/0B20cWO6w77sPa3FjeUMyRW5vUjg/view?usp=sharing	Faculty	6/1/15	Every section of the report.	**To comment on scientific review: Under current IRB process for review, experts cannot review a study where their department head is the PI. The committee feels that should continue to be the case, and is an example where outside experts may need to be retained to review studies where a department head is the PI.**
58	These standards look fine, but in the end it is about clinical results, too.	External	6/1/15	Accountability Metrics (Section	**It might be difficult to interpret rate changes with regard to research**

	This is important to doctors in our area when deciding about where we wish to refer our patients. Psychiatry is especially an unpredictable field, as some well-intentioned changes have worse outcomes--especially when it comes to suicide prevention endeavors. Thus, one addition to: 14. Accountability Metrics on page 49 to include outcome data before and after these changes. Since suicide events are a sad but easily measured outcome these suicide events should be an important PUBLIC disclosure of the success or failures in these program changes: trend University research program suicide events by department from 2005-14 versus suicide events from 2015-24. It could be adjusted for the number of participants as well, = a rate dividing events by total number of research subjects.			14)	**intervention but this is something that can be considered.**
59	https://drive.google.com/file/d/0B20cWO6w77sPSkVTYmNsLW1TekU/view?usp=sharing	Faculty	6/1/15		**Response to #2 on scientific review: Agreed. Scientific reviewers must have the appropriate expertise as is pointed out in Section 6 of the report.**
60	Thank you for your extensive and responsive work in creating the Implementation Plan for the Recommendations related to our Human Research Protection Program. I strongly encourage increased involvement by community members in your plan. I find in my work at the CTSI that they bring such great value and insight.	Faculty	6/1/15	Section 16: Community Oversight Board	**Indeed, community members unaffiliated with the UMN are included in the plan.**
61	https://drive.google.com/file/d/0B20cWO6w77sPbk8zaXVWaUVUbm8/view?usp=sharing	Faculty	6/1/15	Scientific Review (Section 6)	**We agree that scientific review is an important part of the IRB approval process. The intent of the draft plan was to suggest that the HRPP**

				Research with Human Subjects who Have Impaired or Fluctuating Capacity to Consent (Section 10) COI (Section 15)	**manage the review process and use whatever approach it deems appropriate. With respect to the issue of consent, the report proposes significant new approaches that represent state-of-the art standards for interacting with research participants and as such, we believe will protect the participant interests maximally. The draft report also suggests that involvement of personnel that are not part of the research team to maintain objectivity and to make sure that all parts of the clinical research and care team are engaged is an important step. We agree with recommendation 10. Current thinking with respect to COI is to require investigators performing clinical research to report all relevant income from the first dollar, and with approval of the Conflict of Interest Committee an investigator may concurrently consult for a company and conduct research sponsored by that company if the payments for the consulting are directed by the company to the University and not to the investigator.**
62	I offer comment on two specific areas of the plan. The first is in relation to the “enhanced research compliance office” which is mentioned frequently in the report and will potentially have responsibility for post-approval monitoring and “for cause” investigations among other things. A research compliance office currently exists in the OVPR. The staff, while few in number, have extensive experience resolving issues across all	Staff	6/1/15	Post Approval Monitoring (Section 8 and 9) Education (Section 13)	**We agree that the most appropriate path forward to increase compliance oversight of the UMN's human participant research program is to build on the expertise that already exists in the OVPR Research, Education and Oversight Office (REO). Additional resources will be made available for this office to conduct inquiries/investigations about human participant research**

	levels of the institution. They have formed strong bonds with central offices such as Audits, the Controller's Office, Sponsored Financial Reporting and other research related offices. It is not clear from the report what the intent of the Implementation Team is with respect to this unit. It would seem more expeditious to build on this team's experience and provide sufficient staff and resources to take on additional responsibilities such as the PAR and investigational activities. A well-considered structuring and hiring would result in a compliance unit that has the broadest experience and could provide a much more rounded and robust approach to managing and mitigating risk. This approach is similar to the model which was in place some years ago and which would serve the institution well moving forward. The intent behind moving the PAR function into the IRB was well considered, but it must also be recognized that the objectivity of either type of review was reduced when the reviewers report up to the IRB Executive Committee. In addition, the ability to move investigations forward quickly is severely hampered when the investigation must rely on action by the IRB Exec which meets only monthly. The current research compliance group has extensive experience with conducting various types of investigations – collecting and analyzing the data, developing recommendations and resolving issues. I urge the team to take the time to adequately assess what is already in place, as they begin to develop an enhanced research compliance office. My second comment has to do with the research education aspects of the report. For several years it has been a goal of the OVPR to streamline and facilitate researchers' access to and completion of high quality research-related education. I am gratified that the Implementation Team calls for a				**activities at the UMN. At present, the PAR function will remain in the IRB, clinical trial monitoring will occur in the CTSI and REO will oversee investigational activities.** **We appreciate the thoughtful comments about administrative oversight of the education components of the implementation plan. We want to ensure that we have the highest quality, most modern and up to date training opportunities available across the entire spectrum of the clinical and translational workforce (investigators, coordinators, project managers, etc). We have recommended the point person for this task be administratively housed in the CTSI with strong collaborative relationships with the Center for Bioethics and OVPR. The reason to house this individual in CTSI is because of the established infrastructure they have for curriculum development and assessment. In addition, the University of Minnesota CTSI is part of a network of CTSI's across the country that have many different courses and programs already developed and tested. We can tap into those resources and implement successful training programs here in a more efficient manner. See response to comment #17 also.**

	cohesive plan for managing this important aspect. Currently there is little cohesiveness or consistency with respect to the quality or content of offerings. It is difficult for researchers and staff to identify and confirm completion of required training. Finally, the timing and frequency of educational offerings is not coordinated which results in gaps but also in researchers being overwhelmed. I think it would be extremely beneficial to the researchers and to the institution to have research education continue to be housed in the OVPR and also to partner with CTSI, Bioethics, faculty, and others to develop clear and cohesive policies with respect to required education. We should build on this broad expertise to provide education that is relevant, timely and targeted to meet regulatory requirements, but which also aligns closely with our faculty's research portfolios. This represents another return to a model that was in place within the OVPR previously. From its inception RCR was led by faculty. There existed a Faculty Advisory Committee which reviewed courses given by units external to OVPR to determine if the material presented met a standard which made it eligible for inclusion in the list of approved research ethics training. I would encourage the re-formation of such an advisory committee to provide guidance with respect to researcher education. I would also encourage the consolidation of research training to a single location within the OVPR, again with the charge and expectation that this unit collaborate widely. It will be critical that full cooperation, participation and support from faculty and units be clearly spelled out in the development of this program.				
63	We need more than just researchers on the IRBs. Would be nice to have involved community members	Staff	6/1/15	IRB Membership	**Indeed, community members unaffiliated with the UMN are included as members on all IRBs.**

	and practitioners with knowledge about the field working toward keeping the research grounded too.			(section 4)	**Good idea to have non-research clinicians as well: we encourage those who are interested to discuss IRB participation with their departmental leaders.**
64	I am writing to respond to the Draft Work Plan that was submitted for public comment. I appreciate the time and thought that the team put into this document, especially given the tight timeframe. While I agree with many of the recommendations put forth by the team, there are a few that might need further consideration once they are delegated to people to implement. 1. Video recording: While I understand that there is an FDA information guidance that suggests using video-recording for some consent situations, I am not sure that mandating that all consent procedures for vulnerable subjects needs to be recorded. If this were to be implemented, it should be done by an objective group of consent monitors who report to OVPR rather than to departments or study teams. The video recording should be done with real cameras instead of smartphones, to avoid HIPAA compliance issues and breaches of confidentiality. Furthermore, the consent monitor should always first obtain consent from the subject or LAR to record. I am concerned that there may be a heightened observer effect from the act of recording, such that some potential subjects may feel more compelled to say yes. I do agree with the Implementation Team that consent monitors could be employed to act as third-party witnesses to the consent process, and should be available for any consent situation. It seems to me that consent monitors would be sufficient as a measure to prevent coercion and undue influence, and that recording is not necessary. 2. Metrics: A number of the metrics were focused on	Staff	6/1/15	Research with Human Subjects who Have Impaired or Fluctuating Capacity to Consent (Section 10) Accountability Metrics (Section 14) COI (Section 15)	**Thanks for these comments. They will be shared with those who implement this plan.**

	counts of occurrences. Perhaps in the first year after implementation it is fine to have baseline absolute numbers. However, counts don't necessarily show any improvement or reduction over time for the effects one hopes to see. After the first year, consider using averages or percentages in defined timeframes to demonstrate the effectiveness of the process changes. This approach can help with holding people accountable to the process changes. 3. Sponsor compensation: I am not sure how all compensation to investigators from sponsors is going to be defined once this is recommendation is implemented. Based on what I have heard about the Sunshine Act's Open Payments database, I would caution against using this as the source of truth for determining compensation levels. It seems that there is still some confusion about what is reportable in that database. Perhaps in the interim, the REPA reporting process can be revised to ask additional questions about compensation. Once the Open Payments database has been underway for a while, and is being used consistently, then perhaps it would be a good source of truth.				
65	https://drive.google.com/file/d/0B20cWO6w77sPVnhWR20zVmxOWEU/view?usp=sharing	Staff	6/1/15	COI (Section 15)	**Please note that the COI section of this plan has been modified for clarity. Thanks for sharing your perspective.**
66	My only request is, I believe, vital to creating a research environment of which we can be proud: For changes to be accepted, meaningful, and based on all the relevant information, it is absolutely critical that research coordinators and other staff at the "boots on the ground" level be included in planning and shaping an ethical culture. Because: 1) If you want buy-in, a grassroots, cooperative approach is essential, and 2) These research team	Staff	6/1/15	Culture (Section 3)	**We agree that the input and participation of research coordinators is critical to the success of implementing this plan.**

	members very often have a much better idea than the PIs do of how studies play out on an everyday basis, and they spend more time with the subjects.				
67	https://drive.google.com/file/d/0B20cWO6w77sPQ2t0TVoyTmNRd00/view?usp=sharing	Staff	6/1/15	All sections of the report	**Thank you for these thoughtful constructive comments. The COI section of the report has been modified for clarity. Your comments will be shared with those who implement this plan.**
68	Introducing myself: I have 16 years of experience as an RN in Emergency, Cardiac, and Intensive Care Nursing. I went to a Hospital School of Nursing in Minneapolis, a 3 year program and then back to school to obtain a BA in Organizational Management years later at Eastern University Degree Completion Program in PA. I worked at a pharmaceutical company, Wyeth, now Pfizer, for 12 years with my new degree. Prior to that, I worked as a study coordinator for an in-house trial at a Contract Research Organization for 5 years. I also worked in Data Quality and then obtained Clinical Research Associate training in order to monitor trials across the country. A device company moved me back to Minnesota in 2006. A small medical device company recruited me after 2.5 years because now I had pharma and device experience with clinical research. I was a program manager of 2 EU trials for a novel product for about 3 years. Now I am back working in the clinical setting with patients utilizing my nursing background and 23 years of experience with clinical trials, Phase I- IV as a Clinical Research Coordinator. Comment: With all of the Guidances, GCPs, SOPs, required CITI and HIPAA training, consent training and research knowledge gained through experience, I find it very awkward to be associated with a media blitz that invariably filters down to anyone working in	Staff	6/1/15	FUROC (Section 7) Research with Human Subjects who Have Impaired or Fluctuating Capacity to Consent (Section 10)	**We applaud your positive approach to move forward with high quality and safe clinical trials. Thanks for your perspective. Your insightful comments will be available to those who implement this plan.**

	clinical research at UMN/Fairview locations. The impact will be felt by everyone currently conducting trials or for those considering trails due to the recommendations in this report. I would have liked the focus first to be on those who are responsible for the violations and inconsistencies started in the psychiatry group, rather than a broad approach outlined in this report. It feels like the original problem is now diluted by the trickle down effect of all of Clinical Research and the IRB. Oversight and checks and balances are very important, but what about all of the quality research completed with utmost integrity within the organization? I am surprised that the Sponsor hasn't commented on the psychiatry trials. Typically, with monitoring and oversight, sites that are not doing the right thing are identified and are likely closed due to noncompliance. Is there any information available about the sponsor? Psychiatry trials are invariably difficult to sort out vulnerability. Black box warnings have been applied to the labeling for anxiety and depression drugs due to the fear of suicide in those taking the medications, other trials have been stopped due to similar situations (Lilly, for example). The Implementation Team Members are distinguished in their degrees and positions, however, which of these is currently conducting clinical research? Was Fairview Research Administration (FRA) consulted? FRA provides oversight for Fairview Southdale trials and has an excellent working relationship with Research Coordinators who prepare all of the required documents, from startup to finish - the aim is to get it right the first time in order to not delay the clinical trial from approval by the IRB. I appreciate working with FRA and the IRB and thank them for all that they do to help at all points in the trial, start to finish.				

	Comments: 1. Both FRA and the IRB are short-staffed. 2. Scientific Review -If done by a new group it may impact the timeline for getting documents to the IRB. There need to be medical experts in the therapeutic area that review and comment and turn around time needs to be monitored. 3. When the term, "Fairview," is used, is that all inclusive for all of UMN/Fairview Research? Sometimes the term Fairview is used and in other places, University, is used. 4. The IRB application form contains a section on vulnerable adults. The IRB will be alerted if there is a vulnerable population ahead of time if the form is used correctly. This is Research 101. 5. Train Managers and Supervisors and VPs to follow ethical guidelines and have the fortitude to identify and work with abusers of any clinical research principle immediately. 6. Video Consenting? We will need a consent to videotape the patient first and then consent for the trial. Who will do the videotaping? Who can be spontaneous enough for videotaping in an emergent situation or if a patient comes in requiring a pacemaker in the near future? This idea is fine for on-occasion, but not for all trials. 7. Witnessing Consent - A nurse not involved with the trial would need some training about the protocol; this does not make for an entirely non-biased person then. Nurses need to know what they are witnessing, it is not the ideal for all protocols and will require more time to find someone willing to be a witness. I am out of time! Let's get this sorted out in order to move forward. New drugs and new devices are not going to be approved without clinical trials, obviously. We can do it and do it well.				

69	Thank you for considering my comments re: the implementation report. Despite all the comments, I believe the report is very comprehensive and helpful in highlighting the issues. a) The budget must be allocated to the IRB to achieve the greatest impact on quality improvement. Allocating money to other organizations is <u>not</u> an efficient way to improve the IRB operations. This is due to: such arrangement further requires communication channels via a middleman, and thus is not as effective as additional tools and quality improvements within the IRB. b) There is a balance between promoting research and protecting human subjects. Not having research would expose subjects to 0% risk. That, however, would deprive the subjects from potential new therapies. To that extent, I think the federal conflict of interest policy is sufficient for research. There are instances when receiving payments from the industry sponsors is justified, for example, in the case of an investigator training other investigators in the use of a complex and invasive medical device. In this case, it is likely that such training would be more effective and result in better patient outcomes than training from an uninvolved physician. c) Scientific Review can be an advisory function, but the IRB is ultimately responsible for deciding if it's ethical to involve subjects in a particular research in a particular way. I think the IRB must have more direct consulting resources with the expertise at the meeting, as opposed to devoting more resources to "Scientific Committees". Scientific opinions must be advisory to the IRB discussion. To that extent, they must be more detailed for the IRB to review (some are sufficient by reputation of the associated grant, but some that don't have a published peer review	Staff	6/1/15	Resources COI (Section 15) Scientific Review (Section 6)	**Response 69a: We agree that sufficient funds must be allocated to the IRB to enable it to be effective and efficient. A comprehensive human subject protection program requires more than the IRB, which is why some funding must go to other entities as described in the report.** **Response 69b: We agree that it is important to conduct research on new drugs and new devices while ensuring the highest protection for the subjects participating in such studies. As for conflict of interest, the Implementation Team feels that the new policy described in Section 15, which goes beyond the federal standard, is the right one for the University of Minnesota. We agree that there are narrow circumstances where consulting and conducting research for an industry sponsor is appropriate, which is why exceptions are allowed under the new policy.** **Response 69c: We agree that the scientific review is an advisory function to IRB deliberations. It is important to have the right experts performing the scientific review, and Section 6 of the report describes changed procedures for ensuring this. It is equally important to have the right experts on or available to the IRB for its deliberations and Section 4 of the report describes new ways to ensure that expertise is present.** **Response 69d: Unlike the IRB**

	type evaluation, need to be more descriptive than just check marks). d) The community oversight committee sounds very similar to the function of the currently used "Executive IRB". Why not change/empower the current body instead of creating another committee? Seems very redundant. e) Review response to the IRB application in 10 days is unreasonable (for non-emergency research). An acknowledgement is different than a response, and a response in 10 days is not a requirement in any standard, nor it is a good business practice. Perhaps with unlimited resources, but not with limited resouces when the effort must focus on the sound and thorough evaluation of research. This is just a frivolous number. Thank you for your consideration of the above, and for your effort to strive toward "Beyond Reproach". Have a great day.				**Executive Committee, the new Community Oversight Board is intended to be separate from, and not connected to IRB operations.** **Response 69e: We agree that a 10 day turnaround time from time of submission to review response is aggressive, but attainable given the increased number of IRBs described on the report and the focus at IRB meetings on significant issues. However, appropriate and meaningful review is paramount, which means some protocols many take longer than 10 days to review even under the new system.**
70	https://drive.google.com/file/d/0B20cWO6w77sPNEhJVGlSTHUxWVk/view?usp=sharing	Faculty	6/1/15	All Report Sections	**Thank you for your careful review of the draft plan and for your suggestions. We agree that the positive aspects of the current excellent research program at the U of MN needs emphasis and we added a paragraph to the beginning of the document in which we paraphrased your comments.** **Regarding the IRB, we are confident that increasing the number of boards and the variety of expertise on those boards will help address the issues you identified in having appropriate**

					expertise and reasonable turnaround times for reviews. **Your proposal for review of cardiovascular studies by the Lillehei Heart Institute with operating procedures to insure scientific rigor without COI issues is very reasonable. We'll share your proposal with the IRB administrator and this can model can be discussed and developed during the implementation period.** **The proposed changes in the COI policy for research will not prevent any current industry related research activities. The change is the dollar threshold for reporting and the prohibition of receiving personal income from consulting and educational activities.** **We view the Fairview University Oversight Committee (FUROC) as being complementary to the IRB and not a replacement for the IRB. The primary aim of the FUROC will be to provide a forum for discussion and for concerns about research that is conducted collaboratively.**
71	https://drive.google.com/file/d/0B20cWO6w77sPZlE3eVlOZlgyTEk/view?usp=sharing	External	6/1/15	Community Engagement (Section 16)	**We would like to thank the Cultural Wellness Center (CWC) for their comments and generous offer. We will make the Community Engagement Core of CTSI (tasked with developing the community engagement piece of the plan) aware of the CWC and the opportunity to partner with them in these efforts.**

72	https://drive.google.com/file/d/0B20cWO6w77sPWmVqZ3ZIQWtOQm8/view?usp=sharing	Faculty	6/1/15	COI (Section 15)	**This plan does not prohibit experts in rare disorders in children from working with the pharmaceutical industry to develop new therapies. The proposed policy would not allow an expert on a study team to receive personal income during the study from a company whose product was being evaluated in the study. However one could continue to consult for the company during the study provided any consulting payment was given to the University and not taken as personal income. Also study related travel expenses paid by the company would be allowed as a legitimate expense of the research study such as for study preparation training or presentation of results for example.**
73	We are excited to participate in building an HRPP that can be looked upon as a model of excellence. We hope you will consider our feedback. **Section 4 - Membership** We tremendously appreciate that membership on the IRB will be promoted and tangibly supported by the institution. This has been a chief complaint and significant barrier to attracting and retaining the membership we require. We applaud the recommendation for more frequent meetings allowing for smaller agendas and shorter meetings. This directly aligns with feedback we received from members when we conducted our member evaluation in December 2014. Members were asked to indicate if the IRB meeting is running too long when it enters its 2nd, 3rd or 4th hour. 63% of members agreed three hours is too	Staff	6/1/15	Section 4 – Membership Section 5 – IRB Review Process Section 6 – Scientific Review of Studies Section 8 – Monitoring of Studies Section 13 – Education	**The thoughts presented here are in agreement with the recommendations of the implementation team. The recommendations of the implementation team are not meant to dictate how the IRB conducts its business, and if appropriate changes have already been instituted that meet the suggestions of the implementation team, that is positive.** **With respect to the quality of protocol submissions, I agree that this is an area or opportunity and I am hopeful that increased education coupled with an electronic IRB (and for Psychiatry international drug and device trials, the involvement of the**

	long, 37% objected to meetings lasting four hours but no members objected to a meeting lasting two hours. We have heard, however, that weekly meetings for clinicians may not be an achievable expectation. The work plan noted that members assigned to one panel may serve as alternates for members on other panels. Though this is allowable, it may be more desirable to define both a member and an alternate from departments from which we receive a high volume of submissions. The central benefits of eliminating the rotational membership are allowing members to establish a rapport with one another and a familiarity with the PIs and research assigned to their committee. It is more likely these benefits would be realized by having a member and alternate with similar, required expertise sharing the assignment. We agree that board members who are not fulfilling the attendance requirement should discontinue membership. We recommend that report include a statement that requires departments with a high volume of submission to the IRB to quickly identify that an underperforming member's replacement. **Section 5 – IRB Review Process** The IRB has implemented important changes to meeting management and pre-review that will allow for more accurate documentation of committee decisions and more appropriate risk evaluation. Members are now required to identify the regulatory or policy basis for changes required, our minutes template has been revised and staff retrained to support more accurate documentation. We are confident that our current pre-review and triage process are more appropriately evaluating risk and assigning review accordingly. It is				**CTSI), will improve the quality of the applications and shorten the time for approval.** **The implementation team recognizes that much of what is being proposed will require new resources and has made recommendations for an almost doubling of the current IRB budget. The intent of this new process is not that the IRB panels conduct the scientific review, but rather that HRPP manage the scientific review. The new process is intended to add no additional burden while at the same time ensuring that appropriate experts are performing the scientific review and that only those without conflict perform the review.** **The implementation team recognized that the post approval review and monitoring of clinical trials are some of the most effective means to make sure the research is being conducted appropriately, and to catch any problems that may arise during the conduct of the trial with minimal delay. It debated where this activity should reside institutionally or remain with the HRPP program. As you have recommended, the PAR will stay under the direction of the IRB.** **The implementation team agrees with your contention that greater collaboration and coordination of training efforts is needed at the institution. The rationale for potentially locating this activity in the**

	important to note that the independent inquiry panel's period of agenda review included a period of staff transition and the number of minimal risk studies assigned to fully committee review was unusually and uncharacteristically high as a result. A key component of committee burden not addressed by the inquiry panel or the work plan is the assignment of inadequately prepared submissions for committee review. Such submissions are often the most time consuming to review and document. These submissions frequently result in deferral and require re-review by the committee. Deferred submissions are slow to gain approval and require duplicate committee effort. The work plan notes that "The IRB will also have adequate administrative staff to provide pre-review of items to determine if it is necessary and required to bring them to full committee". Evaluation of risk is one key component of pre-review but an equally significant outcome of pre-review process would be the opportunity identify and allow investigators to correct inconsistencies, errors or omissions. A robust pre-review process will allow for more focused and relevant committee discussion and will positively impact agenda size. The work plan's proposed turn-around time of two weeks for a review response from date of submission could discourage a meaningful pre-review process. We recommend that the work plan statement related to turn around time be revised to "two weeks for review response from the date is a submission is determined to be review-ready". **Section 6 – Scientific Review of Studies** The work plan recommends, "department review will be eliminated and that function will be combined into a				**CTSI is to leverage the national network of translational and clinical research education and training modules that have been developed and deployed by the CTSA network. This represents a much more comprehensive set of resources than any one institution can muster on its own, and more consistent training across a national clinical research network would allow more consistency and better trained investigators. As with other activities assigned to the CTSI by these recommendations, an assessment period will be in place to make sure that these functions are occurring properly and with efficiency. Should the CTSI approach not be feasible, the institution will examine other options.**

	new Method 4 called “HRPP Managed Scientific Review.” The current HRPP administered scientific review process receives approximately 8 submissions per month. The relatively low volume of submissions requires limited staff support and a small base of reviewers to maintain. It is recommended that the work plan acknowledge that a significant increase in the volume of submissions will require additional HRPP staff resources to support. A similar service expectation as IRB membership as well as appropriately scaled institutional support will be require if HRPP staff, not investigators, must identify reviewers. We recommend that we review the current tool to determine if additional functionality could be added to reduce staff burden. **Section 8 – Monitoring of Studies** The Post Approval Review (PAR) program was created as a component of the IRB at the end of 2011 due to concerns about the quality, effectiveness and relevance of reviews being conducted by the previous program. Over the last four years, the PAR program has become a highly valued and a respected component of the IRB. The IRB and the research community view the PAR review process as an important mechanism to assure the quality of the work being performed. The benefits of this program were further described in the report of the AAHRPP led inquiry panel, which indicated that PAR was well conceived and provided thorough, substantive, and meaningful reviews of human subjects research. The most significant criticism noted in this same report was that the program has been under resourced. We are in support of the implementation team’s recommendations related to enhancement of the				

	communication strategy associated with PAR results to ensure higher accountability of the research community and IRB. We also support shifting responsibility to conduct formal investigations out of IRB authority, as these are often extremely resource intensive and require relevant expertise that may not be represented or available. However, both staff and members agree that retaining oversight of the PAR program is critical to enhancing the IRB's mission and assuring the quality and safety of research conducted at this institution. A higher level of accountability and oversight can be achieved via communication strategies and does not require shifting this program from the very entity under which it has thrived. One area not investigated by the AAHRPP led inquiry panel nor the implementation team was related to the work of other monitoring functions at this institution including the CTSI. Greater collaboration and communication across monitoring functions is needed when non-compliance is suspected. It should be the expectation that each monitoring function is appropriately reporting suspected research non-compliance regardless of the mission of the said monitoring agency. Communication expectations across programs should not differ when research non-compliance is suspected. As noted above, the PAR program has been recognized as high functioning and effective. Shifting this critical resource out of the IRB will result in a net loss of resources. It is difficult to understand how removing resources from the IRB addresses the inquiry panel's recommendations. **Section 13 – Education and Training of**				

	Investigators In section 3.3.1.4 of its report, the inquiry panel recommends the University "create opportunities for advanced training in human subjects protections for all individuals involved in human subjects protections including investigators, IRB members and staff, research personnel, and clinical staff on units that conduct research". The panel recognized that the need for ongoing and advanced training in human subjects research protections extends well beyond the investigator. The significant expansion of IRB membership will result in a significant training need. It seems inefficient and potentially ineffective to house the new Human Research Procedures, Policies and Ethics Education Coordinator within the CTSI, not the IRB. Evidence that the IRB is best positioned to identify and implement relevant training related to human subjects protection is provided in the inquiry panel's report. The report noted several positive steps in education and training, specifically: Within the past year, the University has made a few significant changes to its requirements for education pertaining to human subjects research. In February 2014, the University refined its requirements for human subjects training to require that all individuals engaged in human subjects' research at the University complete basic human subjects training through the CITI program. Accompanying this change was a new continuing education requirement: Specifically, all individuals engaged in human subjects research must now re-certify their training every three years. In addition, in January 2015, the University purchased a site license for PRIM&R's E-ROC				

	online learning platform and plans to require this training for all IRB members. In addition to changes in these basic educational requirements, the University also instituted a new CITI course requirement in February 2014 for individuals who wish to serve as sponsor-investigators. Documentation of successful completion of this tailored training is required as part of the IRB submission process whenever a University researcher plans to serve as a sponsor-investigator. It is notable that all of these revised requirements and training opportunities were identified and implemented by the IRB. As with monitoring, it seems curious to respond to criticism that the IRB is under resourced with a proposal to provide additional resources to the CTSI. It is true that we need greater collaboration and coordination of training efforts. Housing this position within the IRB, with an expectation of outreach, collaboration and coordination with CTSI and the Center for Medical Bioethics will ensure that the focus of this new resource remains on human subjects protections and the ethical conduct of research. It will also ensure that training offerings are inclusive of the various learning communities including medical and social researchers, IRB members, IRB staff and clinical staff on units. The IRB currently receives and responds to requests to provide training to research teams, classes and departments. These trainings focus on IRB and human subjects research basics, how-to prepare and submit applications and specialized topics by request. Having a dedicated resource within the IRB will allow the IRB to enhance and expand these offerings.				

	There has been growing awareness of the need for training and mentoring for researchers and research staff on topics extending beyond research ethics and human subjects protection. There are various groups and individuals working to close these gaps. CTSI may require additional, dedicated training resources but it may be most effective for these resources to focus on coordinated these efforts. The inquiry panel pointed to positive steps, led by the IRB, to enhance training. We ask that we be allowed to continue and expand on the base we have worked to develop. **Conclusion** Responsibly conducted, scientifically sound research may hold the potential to ease suffering, prolong life or expand the collective understanding of the human experience. The value of advancing knowledge must always be weighed against the risks of acquiring that knowledge. There are many considerations that shape the feasibility and desirability of pursuing a research question. The Institutional Review Board is the one entity charged with primarily representing those who may be harmed or unduly burdened by the pursuit of knowledge. An HRPP that adheres to best practices and creates an ethical climate that is beyond reproach requires an independent and appropriately resourced IRB. A well-functioning and appropriately resourced IRB is essential to maintaining the public trust. There is much in the implementation team's work plan that moves us in this direction. We understand and embrace the need for greater collaboration and communication across and among the various components of the UMN HRPP and specifically with HRPP. Over the last two years the HRPP office has contributed to efforts that leveraged HRPP and				

	CTSI strengths to create more effective and efficient processes, most notably the HRPP scientific assessment process housed within the CTR portal and the clinicaltrials.gov review process. We are committed to continuing to identify and foster opportunities to collaborate with CTSI but these partnerships require that both entities are appropriately resourced. As noted above, members of the IRB staff and committee members are concerned that some recommendations in the draft work plan may result in reduced IRB resources and potentially diminish the IRB's autonomy and ability to evaluate, monitor and educate.				

BOARD OF REGENTS
DOCKET ITEM SUMMARY

Audit **June 11, 2015**

Agenda Item: Information Items

☐ **Review** ☐ **Review + Action** ☐ **Action** ☒ **Discussion**

☒ *This is a report required by Board policy.*

Presenters: Gail Klatt, Associate Vice President

Purpose & Key Points

The semi-annual Controller's Report provides information to the Board of Regents regarding recent activities in University financial operations that have strengthened financial reporting, enhanced internal controls, improved the management of financial risks, provided better services to the University community, and maximized the institution's financial resources. Highlights include an analysis of three new accounting standards that will be adopted by the University for FY 2015, and the likely impact on the University's annual audited financial reports (if known).

Background Information

The Controller's Report is prepared semi-annually and presented to the Audit Committee in conformance with Board of Regents Policy: *Board Operations and Agenda Guidelines.*

UNIVERSITY OF MINNESOTA
BOARD OF REGENTS AUDIT COMMITTEE
SEMI-ANNUAL CONTROLLER'S REPORT
June, 2015

This report presents a summary of activities completed by the Controller's Office in the last six months to assess and implement new accounting and reporting standards, enhance internal controls, better manage financial risks, improve services to the University community, and maximize the institution's financial resources and financial operations.

I. Accounting and Financial Reporting Matters

The Governmental Accounting Standards Board (GASB) has issued three new accounting and reporting standards that will be effective for fiscal year 2015. The following provides a brief summary of each new standard, and where known, the likely impact.

- **GASB Statement No. 68**, *Accounting and Financial Reporting for Pensions—an amendment of GASB Statement No. 27*, establishes and improves accounting and financial reporting for defined benefit and contribution pension plans administered through trusts or equivalent arrangements. **GASB Statement No. 71**, *Pension Transition for Contributions Made Subsequent to the Measurement Date—an amendment of GASB Statement No. 68*, addresses the accounting and financial reporting matters identified with the implementation of GASB 68. Both of these statements are effective for the fiscal year ending June 30, 2015, and the University will be adopting both standards.

  GASB 68 will require the University to record a pro rata share of deferred inflows or outflows, pension liabilities, and pension expense for both the Minnesota State Retirement System (MSRS) and Public Employees Retirement Association (PERA) pension plans. Based on preliminary information received from the state of Minnesota in May, 2015, the impact of the new standard is expected to have a <u>material impact</u> on the following components of the financial statements:

  - Statement of Net Position (Balance Sheet) - assets, deferred inflows, liabilities, and deferred outflows.
  - Statement of Revenues, Expenses & Changes in Net Position (income statement) – functional operating expenses, and non-operating expenses.

  All governmental entities in Minnesota that participate in these plans will be required to record their pro rata shares of these plans' financial information, similar to the University. Adopting these two standards will only impact the annual, audited financial statements. There will be no changes to the funding policies or benefit levels for MSRS and PERA. The University will not see any changes to its operating budget or cash balances as a result of the new standards.

Once the amounts of the required adjustments have been finalized and confirmed, the Board will be updated on the specific impacts to various components of the audited financial statements..

- **GASB Statement No. 69,** *Government Combinations and Disposals of Government Operations,* was issued in January 2013. It establishes accounting and financial reporting standards related to combinations and disposals of government operations, such as mergers, acquisitions, and transfers of operations. This statement is effective for the fiscal year ending June 30, 2015. GASB 69 will have no impact on the University's financial statements.

II. Activities to enhance internal controls, better manage financial risks, improve services to the University community

Enterprise Systems Upgrade Project

Since December, 2014, all of the Controller's Office resources have been focused on successfully implementing the PeopleSoft upgrades. Virtually all other non-upgrade related projects were put on hold, pending the completion of the upgrade on April 20, 2015. Therefore, there are no other items to report as of June, 2015.