Audit & Compliance Committee

September 2016

September 8, 2016

7:30 a.m. - 9:30 a.m.

West Committee Room, McNamara Alumni Center

AUD - SEP 2016

1. 2016-2017 Committee Work Plan

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    Draft Work Plan - Page 4

2. Internal Audit Update

    Docket Item Summary - Page 7

    Internal Audit Update - Page 8

3. Update on Remediation of Intercollegiate Athletics Audit Findings

    Docket Item Summary - Page 25

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4. Update on Human Participant Research Protection Plan

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    Status Report Implementation of Enhancement to Human Research Protections - Page 40

    Appendix to Status Report - Page 65

5. Review of RFP Process for External Audit Contract

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    RFP Process for External Audit Services - Page 156

BOARD OF REGENTS
DOCKET ITEM SUMMARY

Audit & Compliance **September 8, 2016**

AGENDA ITEM: 2016-2017 Committee Work Plan

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

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

PRESENTERS: Regent Laura Brod
Gail Klatt, Associate Vice President, Internal Audit

PURPOSE & KEY POINTS

The purpose of this item is to discuss the committee's FY 2016-17 work plan.

The work plan helps ensure the committee receives the information necessary to carry out the governance and fiduciary responsibilities assigned to it in its charter, including the supervision of the external auditor and oversight of the internal audit program. The committee also has an obligation to be informed regarding the institution's compliance program.

This year's proposed work plan includes discussions to inform the committee about specific compliance programs and risks. Information will also be provided to the committee throughout the year to enable the committee to oversee the implementation of the Human Participant Research Protection program and Intercollegiate Athletics improvements.

BACKGROUND INFORMATION

The work plan is a means to assist the committee in discharging its responsibilities under its charter and provides a structure to ensure the topics of highest priority receive the committee's attention. Each standing committee of the Board of Regents establishes an annual work plan.

Audit and Compliance Committee
2016-2017 Work Plan

Date	Topics
2016	
September 8-9	• **Update on Human Participant Research Protection Implementation Plan** This item will discuss the continued actions being taken to implement the work plan to improve the Human Research Protection Program. It will also include an update from Dr. David Strauss, who has been engaged as an external assessor of the improvement program. • **Update on the Remediation of Intercollegiate Athletics Audit Findings** This item will discuss the actions being taken by the Athletic Director and his staff to address and remediate the issues identified in audit work performed in Athletics in 2015. • **Internal Audit Update** The purpose of this item is an update on Internal Audit activities, results, and observations, including the status of outstanding audit recommendations. The report is required under Board policy. • **Review of Request for Proposal (RFP) Process for External Audit Services** The purpose of this item is to review and discuss the process for rebidding the external audit contract, and how the committee will be engaged during the process. • **2016-2017 Committee Work Plan Discussion** The purpose of this item is to set the agenda for the committee for the next fiscal year.
October	• **Review Annual Financial Statements** Even though the committee will not meet in October, it must review the annual financial statements prior to their finalization in mid-October. As in previous years, this will be handled by the committee chair via a conference call.
December 8-9	• **External Auditor Report** The purpose of this item is to communicate and discuss the results of the FY 16 external financial statement and federal award audits. This report is required under Board policy. • **Update on Intercollegiate Athletics** This item provides an update on the status of the corrective actions taken to improve financial and operational compliance within Athletics. • **Overview of Equal Opportunity and Affirmative Action Office Compliance Responsibilities and Outcomes** The purpose of this item is to discuss the compliance responsibilities of the Equal Opportunity and Affirmative Action Office, including the responsibilities of the University's Title IX Officer. The item will also include discussion of the Office's outcomes in its high-risk compliance areas. • **Update on Small Business Procurement Compliance with State Statute**

Draft

	This item is a follow-up regarding discussions with the State of Minnesota concerning the University's compliance with statutes involving small business procurement. • **Information Item: Institutional Compliance Officer Semi-Annual Report** The purpose of this item is an update and discussion on the status of the institutional compliance program; compliance-related initiatives; and any current material compliance vulnerabilities. • **Information Item: Semi- Annual Controller's Report** This item reports on initiatives or actions to improve the financial reporting and/or financial internal controls within the University. This report is required by Board policy.
2017	
February 9-10	• **External Auditor's Review of Completed Audit Work and Letter to Management** The external auditors will share with the committee any recommendations they have identified for improving financial statement/ reporting practices as a result of their audit. • **Recommendation for Engagement of External Auditor** This item will review the recommended audit firm to provide external audit services to the University and the rationale for the recommendation. • **Update on the Law School's Progress in Addressing Audit Recommendations** The purpose of this item is to review and discuss an update from Law School leadership on its progress to address the issues identified in the May 2016 audit report. • **Information Technology Audit Outcomes and Cost of Compliance** The purpose of this item is an update and discussion on operational factors related to remediating a number of information technology control issues identified in University audits, and costs related to compliance activities. • **Update on Human Participant Research Protection Implementation Plan** This item will provide an update on the status of the implementation efforts related to human participants in research. • **Internal Audit Update** The purpose of this item is an update on Internal Audit activities, results, and observations, including the status of outstanding audit recommendations. The report is required under Board policy.
May 11-12	• **External Auditor Review and Review External Auditor Relationships and Services Provided** This item will communicate and discuss the scope of work and fees paid for all engagements of external auditors for the last fiscal year; a review of the University's official external auditor's performance; and the need to re-bid the external audit contract. • **External Audit Plan** The external audit firm will present their proposed plan for the FY 2017 audit engagement including the financial statement audit, the federal single audit, and other ancillary work.

Draft

	• **Update on Intercollegiate Athletics** This item provides an update on the status of the corrective actions taken to improve financial and operational compliance within Athletics. • **Compliance Topic (TBD)** A topical compliance item for discussion by the committee will be selected in consultation with the new Institutional Compliance Officer. • **Information Item: Institutional Compliance Officer Semi-Annual Report** The purpose of this item is an update and discussion on the status of the institutional compliance program; compliance-related initiatives; and any current material compliance vulnerabilities.
June 8-9	• **Internal Audit Plan** The committee will review and discuss the internal audit work plan for FY 2018. • **Internal Audit Update** The purpose of this item is an update on Internal Audit activities, results, and observations, including the status of outstanding audit recommendations. The report is required under Board policy. • **Update on Human Participant Research Protection Implementation Plan** This item will provide an update on the status of the implementation efforts related to human participants in research. • **Information Item: Semi-Annual Controller's Report** This item reports on initiatives or actions to improve the financial reporting and/or financial internal controls within the University. This report is required by Board policy.

Each Update on the Human Participant Research Protection Plan is expected to include a topical policy or educational item related to the work underway.

Draft

BOARD OF REGENTS
DOCKET ITEM SUMMARY

Audit & Compliance **September 8, 2016**

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 discuss 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 the committee charter.

- Since the June 2016 meeting, 39 percent of the outstanding recommendations rated as "essential" were implemented by University departments. This is consistent with the expected implementation rate of 40 percent. Four units have 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.
- Four audit reports containing four recommendations rated as "essential" were issued in the last three months.

BACKGROUND INFORMATION

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

Internal Audit Update

University of Minnesota Regents Audit and Compliance Committee
September 8, 2016

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 June 2016

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

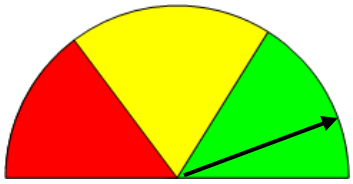
As part of our on-going efforts to provide the Audit and Compliance Committee with critical information in as concise a format as possible, we have developed the following three charts to present a "snap-shot" status report on work performed by the Office of Internal Audit.

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 2017 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).

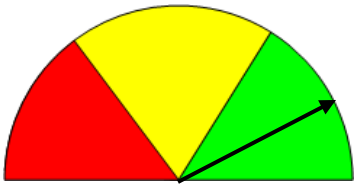
The final chart, "Time Spent on Investigative Activities", provides a status report on the amount of time consumed by investigative activities. Our annual plan provided an estimated budget for this type of work, and the chart will indicate if we expect that budget to be sufficient. Continued readings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

Essential Recommendation Implementation



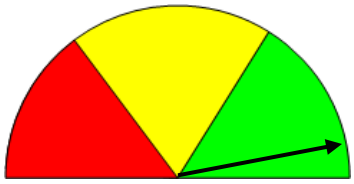
Implementation rates were 39% for the period, consistent with our expected rate of 40%.

Progress Towards Annual Audit Plan Completion



Time spent to date on the FY 2017 audit plan is what was expected and budgeted for the year to date.

Time Spent on Investigative Activities



Time spent on investigative activities and special projects is less than expected and budgeted for the year to date.

Other Items

- Compliance leaders have raised concerns about some former University employees retaining access to confidential data in their University email or Google Docs after they change roles or leave the University. We are participating with a team of technologists to review Google account termination processes and identify potential solutions.

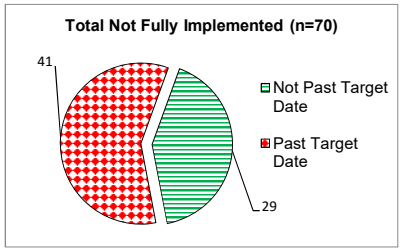
- We are in the early stages of implementing an automated workpaper and project management system. This will allow for electronic (instead of paper) audit workpapers and enable remote access to our work product. This system was purchased using a federal government contract available to higher education institutions, resulting in significant savings to the institution.

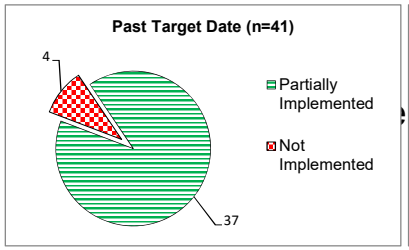
Status of "Essential" Recommendations as of August 26, 2016

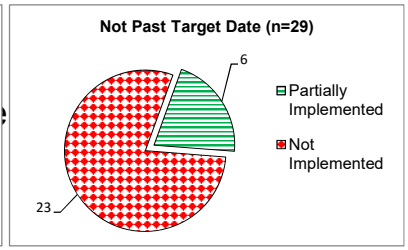
Report Date	Audit **(P) *Indicates a University process audit***	Original Report Control Rating	# of Essential Recommendations in the Report	# of Essential Recommendations Remaining From Prior Quarter	Current Quarter Results					Overall Progress Towards Implementation*
					Implemented	Partially Implemented		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	1			1			Satisfactory (1)
Feb-14	University-wide Purchasing Process (P)	Good	2	1			1			Satisfactory
Jun-14	Identity Management	Needs Improvement	11	1			1			Satisfactory
Audits < 2 years old; have received prior follow-up										
Jan-15	Server Room Security	Needs Improvement	17	6	3		3			Satisfactory
May-15	**OIT Server Administration**	**Good**	**5**	**1**	**1**					**Completed**
May-15	Medical School Duluth	Needs Improvement	25	11			10		1	Satisfactory
Sep-15	Clinical & Translational Science Institute	Good	4	3	1		2			Satisfactory
Oct-15	**CFANS Dean's Office**	**Good**	**3**	**1**	**1**					**Completed**
Oct-15	UMD Athletics	Adequate	12	6	1		5			Satisfactory
Dec-15	Athletics Administration	Needs Improvement	7	5	2		2		1	Satisfactory
Jan-16	College of Pharmacy	Good	5	3	2		1			Satisfactory
Feb-16	Boynton Health Service	Needs Improvement	25	23	11		3	8	1	Satisfactory (2)
Audits receiving first-time follow-up										
May-16	Operational & Compliance Audit Basketball	Adequate	7	7	5		1		1	Satisfactory
Jun-16	OIT Database Administration	Good	7	7		1	1	5		Satisfactory
May-16	Law School	Needs Improvement	8	8	1		5	2		Satisfactory
May-16	UMD College Ed. & Human Service Professions	Needs Improvement	9	9	2	1		6		Satisfactory
Jun-16	Department of Medicine	Good	5	5	4	1				Satisfactory
Jun-16	Athletics Financial & Operational Review	Needs Improvement	7	7	1	3	1	2		Satisfactory
Jun-16	**Masonic Cancer Center**	**Good**	**6**	**6**	**6**					**Completed**
Jun-16	**Dept. of Elect. & Computer Engineering**	**Good**	**3**	**3**	**3**					**Completed**
	Total:		**178**	**114**	**44**	**6**	**37**	**23**	**4**	

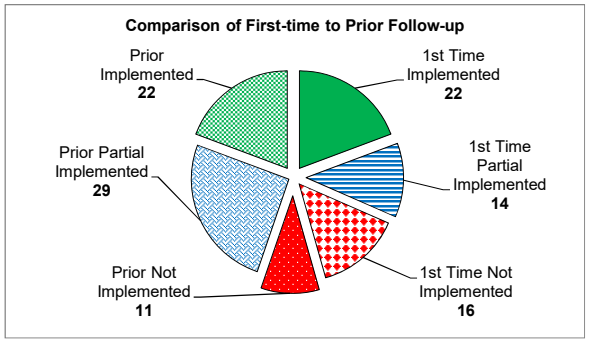
* The following bar charts provide details on progress made towards implementation

(1): UMD School of Fine Arts (Glensheen) has completed the Glensheen inventory, and an appraiser is in the process of being retained to value the inventory. The expected completion date is December 2016.
(2): Boynton Health Service made excellent progress on governance and IT issues this follow-up period; this was achieved in part through close coordination with AHC-IS and OIT.









"Essential" Recommendation Implementation Trends

Month / Year of Follow-up Report

	Sept. 2016	June 2016	Feb. 2016	Sept. 2015	June 2015	Feb. 2015	Sept. 2014	June 2014	Feb. 2014	Average
# of Essential Recommendations Receiving Follow-up	114	108	83	98	60	44	53	34	36	70
# of Recommendations Considered Fully Implemented	44	46	34	16	8	16	12	10	13	22
Implementation Percentage	39%	43%	41%	16%	13%	36%	23%	29%	36%	32%

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 # of Items 1	P	William Payne Bilin Tsai	Glensheen management should work with Accounting Services to develop procedures for reporting the value of its collection.	At the time of the May 2016 audit follow up, the physical inventory of the entire Glensheen collection was complete. Glensheen management has since been working with Purchasing Services on a Request for Proposal (RFP) for appraising the inventory and expects the RFP to be issued shortly. Once an appraiser is selected, Glensheen management anticipates it will take about 2-3 months to appraise the inventory. As previously determined, only items with a value of $1,000 or more will be appraised. The value of the appraised items will be recorded in Collector Systems, Glensheen's cloud-based inventory management application. When the appraisal is complete, the inventory value will be reported to Accounting Services for inclusion in University financial statements.
University-wide Purchasing process Feb-14 # of Items 1	P	Tim Bray Michael Volna	Purchasing Services and the Office for Business & Community Economic Development should work with University senior administration to: • Establish appropriate institutional goals and metrics regarding purchases from Targeted Business Groups to ensure the institution is meeting the intent of the Regents Policy. • Implement steps to measure and ensure compliance with MN. Statute 137.31 subdivision 1.	Per the Director of Purchasing Services: The Board of Regents Audit & Compliance Committee has directed us to work with the Office of General Counsel and the state Department of Administration to attempt to clarify the statutory language or find a different path to compliance. I will be meeting with both parties in the next month to try to determine our strategy.
Identity Management Jun-14 # of Items 1	P	Bernard Gulachek	The University should implement processes to periodically evaluate whether logging and monitoring processes associated with high-risk University systems are occurring in a manner that complies with University's requirements. The evaluation process should be comprehensive and address all logging and monitoring issues identified in the bulleted list in this finding. The review should include University managed systems and systems obtained from the cloud. In order to evaluate cloud services the University will likely need to obtain independent evaluation reports (e.g., SSAE 16 SOC 2 reports) Where systems are found to be non-compliant remediation plans should be developed and processes should be established to ensure correction action is completed in a timely basis. Evaluation and corrective actions should focus first on the highest risk processes and systems.	Operational log management is both a policy requirement for systems meeting the Security High classification (as determined by the Data Security Classification policy) and a regulatory requirement for certain kinds of data in that high classification. While this finding now exceeds the 2 year mark, significant progress in implementing a new operational system log management program has occurred. The Office of Information Technology (OIT) has completed many of the steps that it had outlined in its management action plan / response two years ago. All central IT services are using the new operational log management solution (Splunk) on their servers and databases. Recently, OIT purchased additional capacity and has an active posting for a new position to help manage Splunk in order to continue to expand the service. There are currently over 4300 devices enrolled in the service. Additionally, 71% of the Academic Health Center's and 87% of Boynton Health Services' systems that contain 'Security High' data are using operational log management solution. These numbers have more than doubled since last period. By centralizing log management, the correlation to existing logs will enhance security log analysis. OIT is working with system owners to enhance the log analysis capability for system and application logs. While the goal is to provide operational log management services for all 'Security High' systems across the University, and OIT has recently made additional log management investments, the costs to the institution for all 'security-high' systems will continue to be a challenge. The VP/CIO will continue to work with senior leadership to determine an affordable operational log management service level that meets the regulatory requirements and University policy.

Total: 3

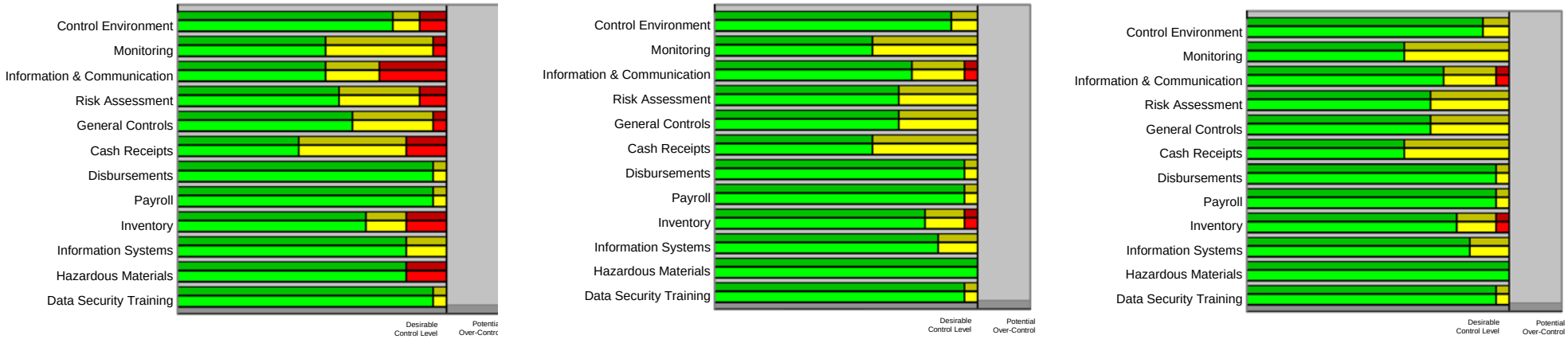
The bar charts shown below are presented to provide pictorial displays of the progress units are making on implementing audit recommendations rated as "essential". The bar chart included in the original report is shown in the left column, along with updated bar charts showing the previous quarter and 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 June 2016, 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.

Original Report Evaluation

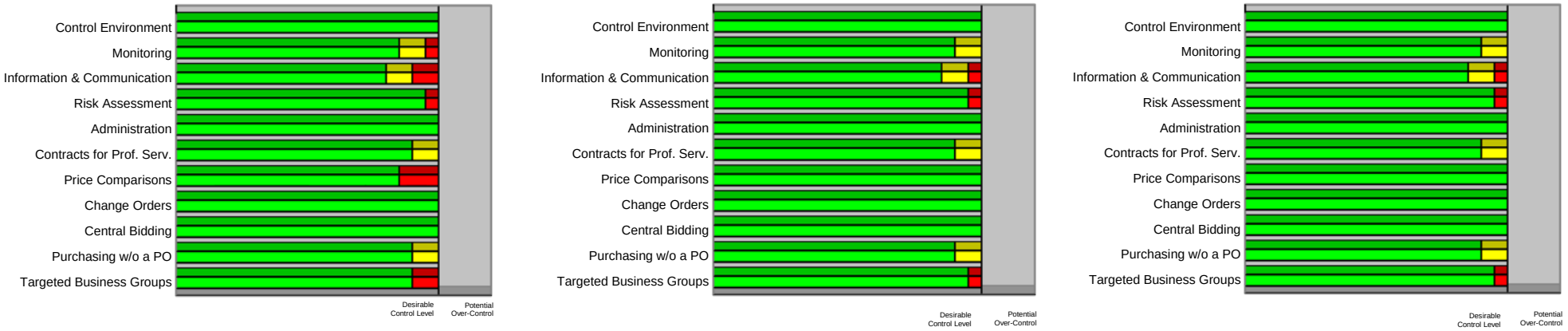
Previous Quarter Evaluation

Current Quarter Evaluation

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



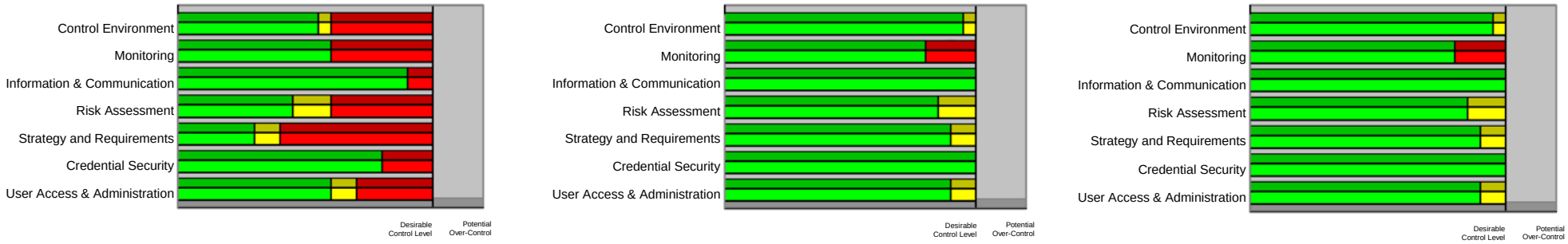
University-wide Purchasing Process (February 2014)



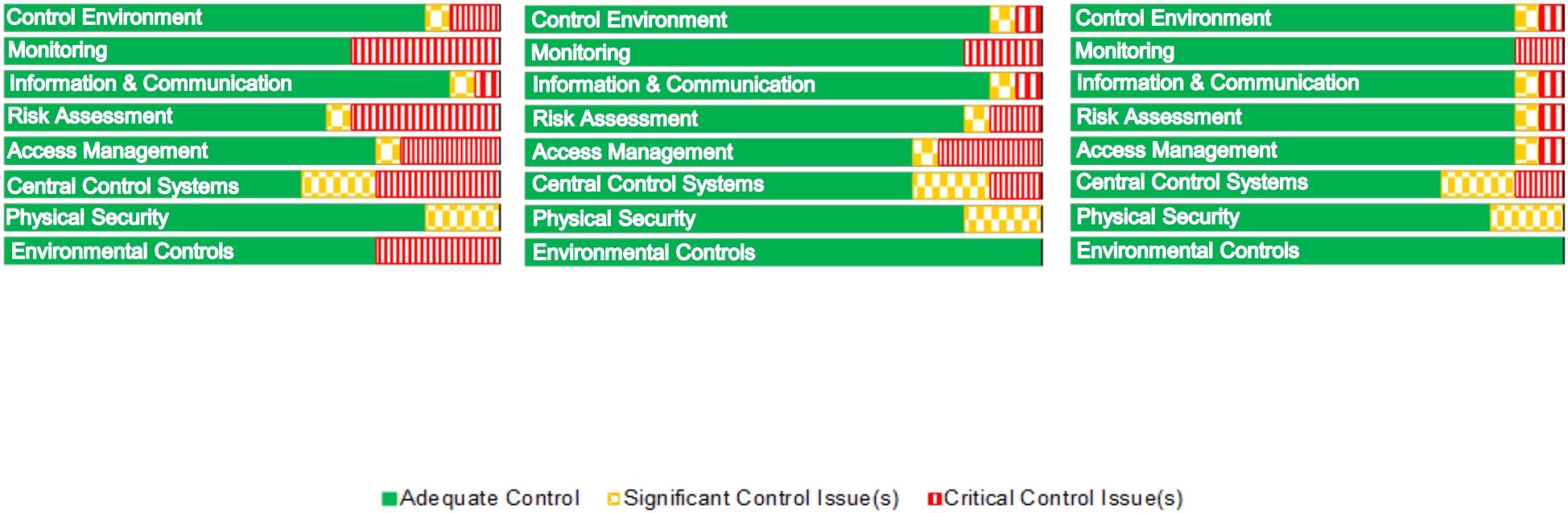
Adequate Control Significant Control Level Critical Control Level Potential Over-Control

Original Report Evaluation | Previous Quarter Evaluation | Current Quarter Evaluation

Identity Management (June 2014)

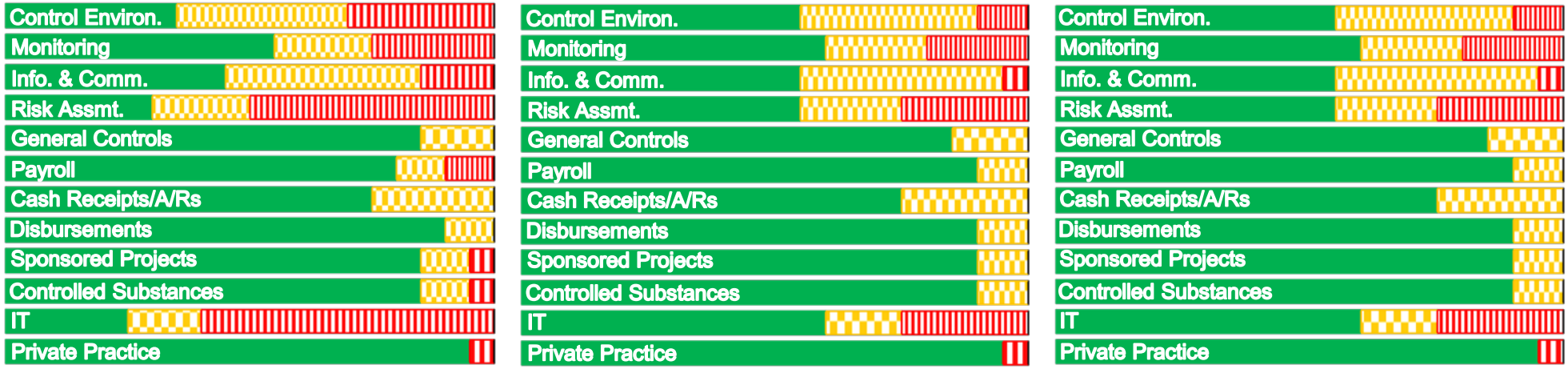


Server Room Security (January 2015)

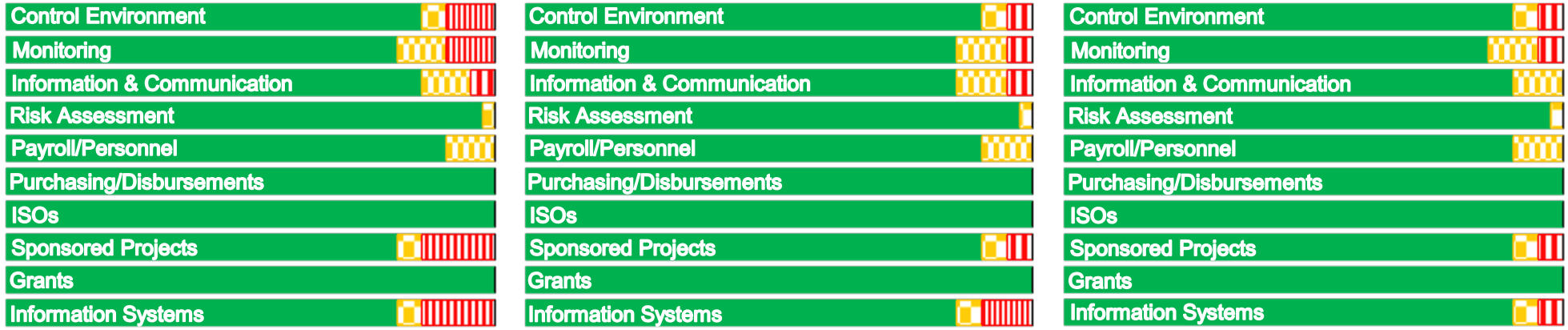


Original Report Evaluation | Previous Quarter Evaluation | Current Quarter Evaluation

Medical School Duluth (May 2015)



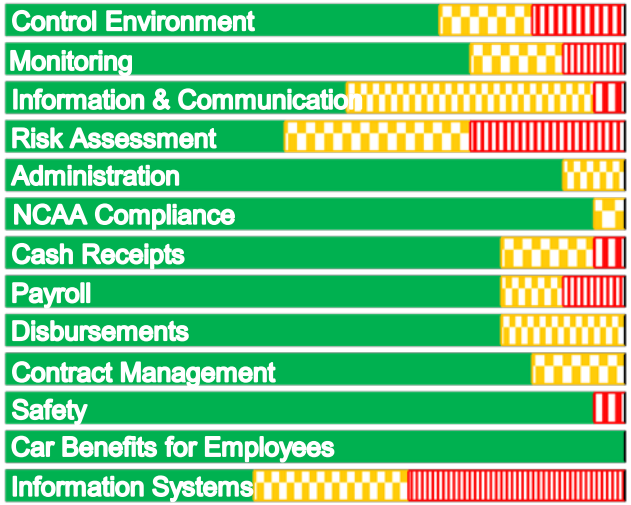
Clinical and Translational Science Institute (September 2015)

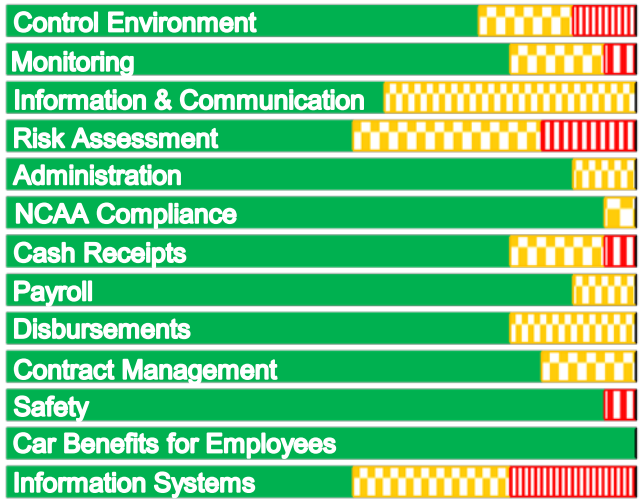


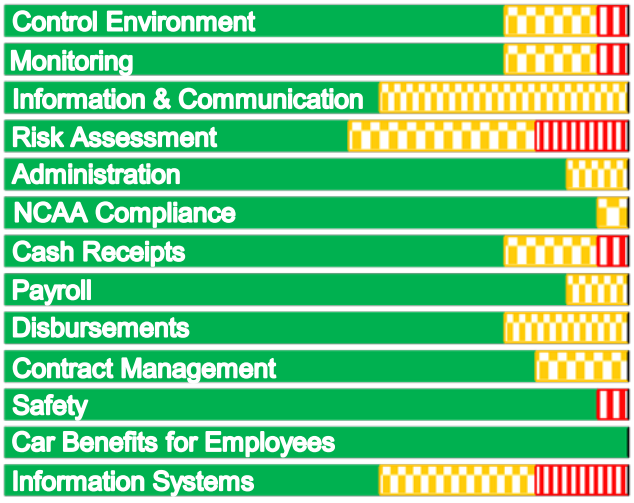
Adequate Control | Significant Control Issue(s) | Critical Control Issue(s)

Original Report Evaluation | Previous Quarter Evaluation | Current Quarter Evaluation

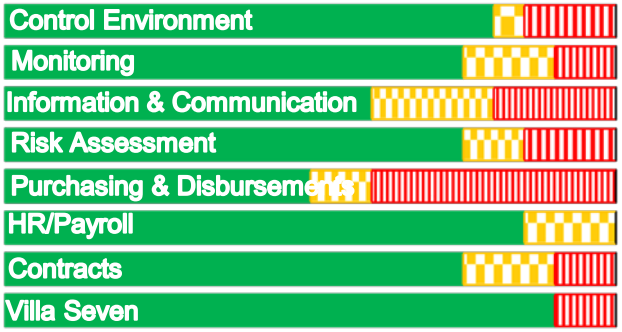
UMD Athletics (October 2015)

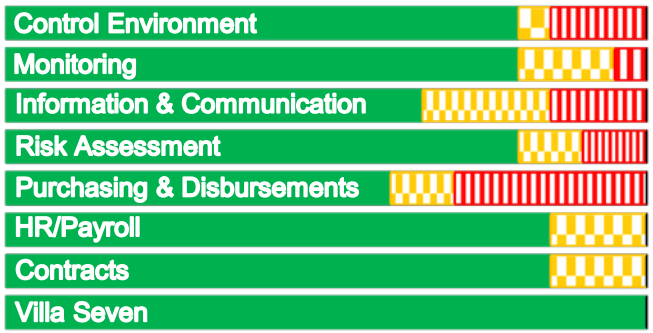


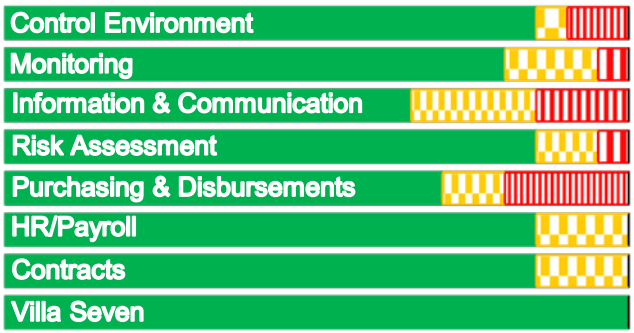




Athletics Administration (December 2015)



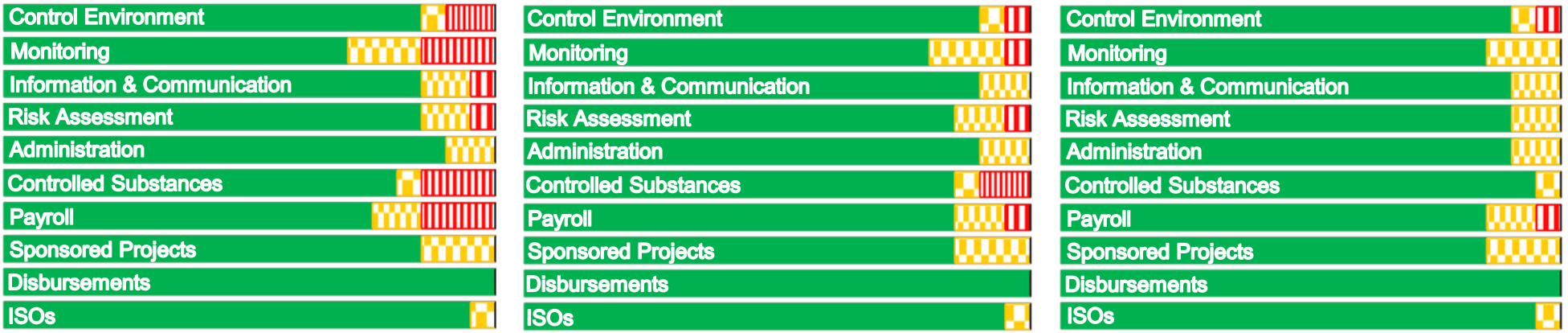




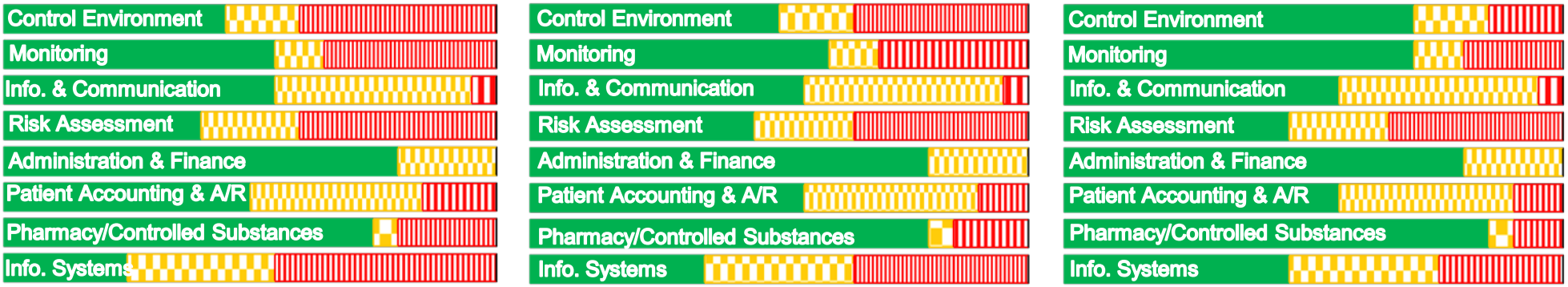
Adequate Control | Significant Control Issue(s) | Critical Control Issue(s)

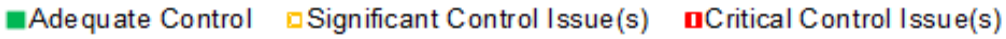
Original Report Evaluation | Previous Quarter Evaluation | Current Quarter Evaluation

College of Pharmacy (January 2016)



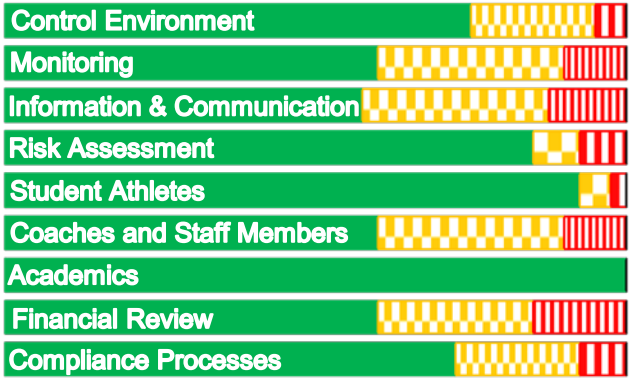
Boynton Health Service (February 2016)





Original Report Evaluation | Previous Quarter Evaluation | Current Quarter Evaluation

Operational and Compliance Audit - Basketball (May 2016)



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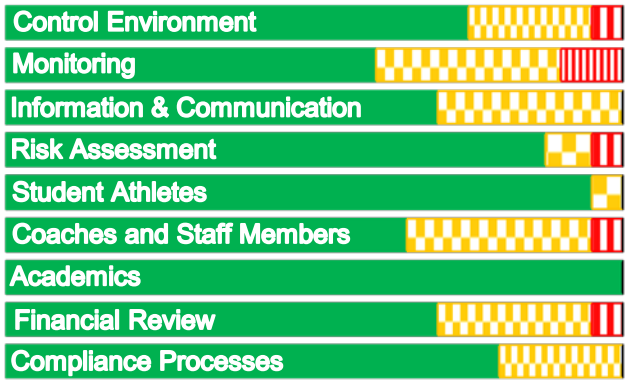
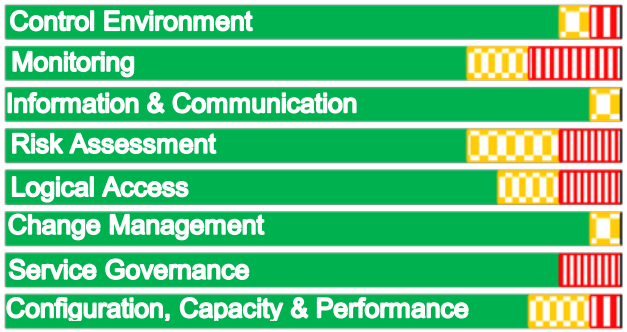


OIT Database Administration (June 2016)



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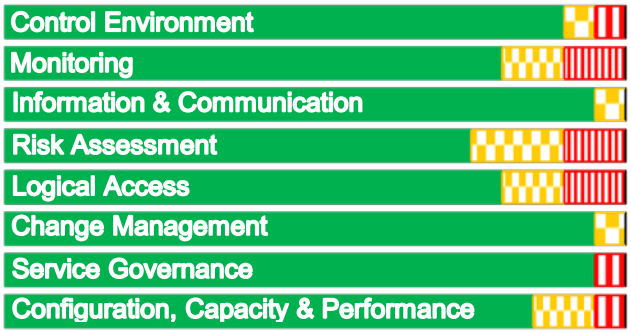
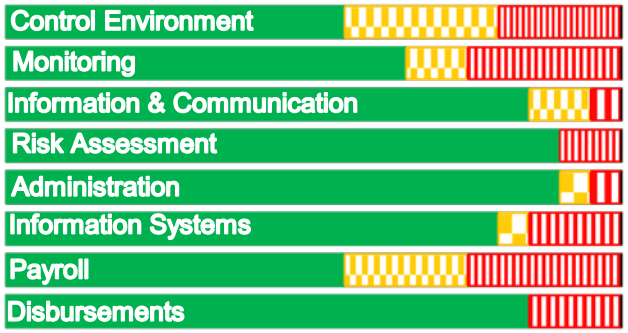


Adequate Control | Significant Control Issue(s) | Critical Control Issue(s)

Original Report Evaluation | Previous Quarter Evaluation | Current Quarter Evaluation

Law School (May 2016)



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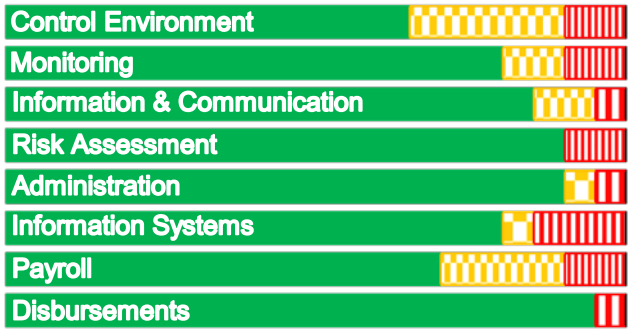
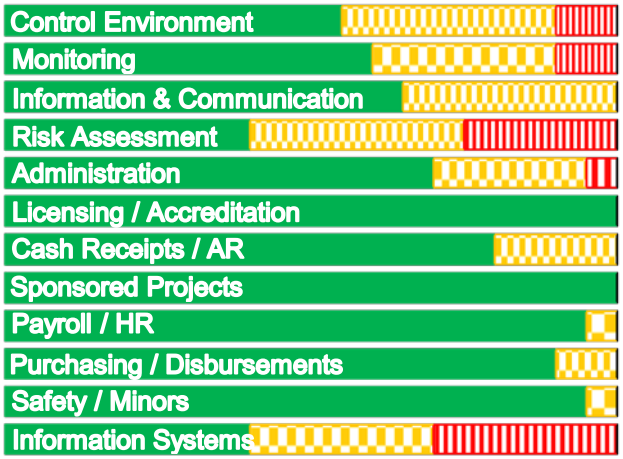


UMD College Ed. & Human Service Professions (May 2016)



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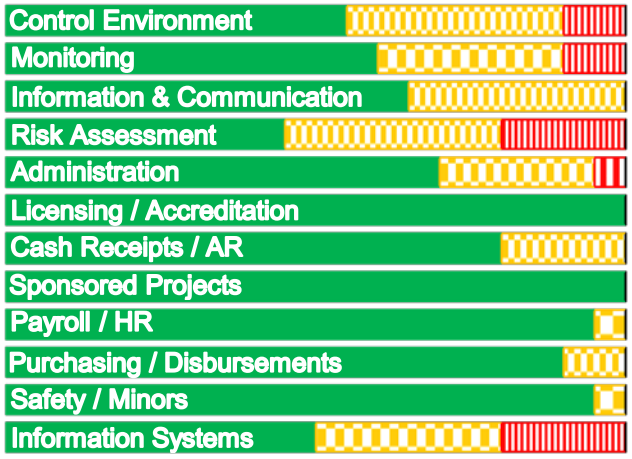
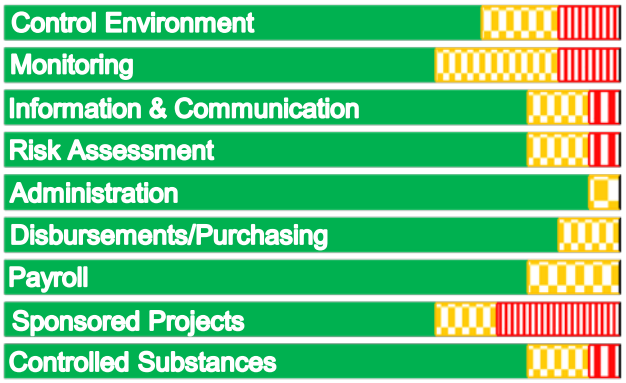


Adequate Control | Significant Control Issue(s) | Critical Control Issue(s)

Original Report Evaluation | Previous Quarter Evaluation | Current Quarter Evaluation

Department of Medicine (June 2016)



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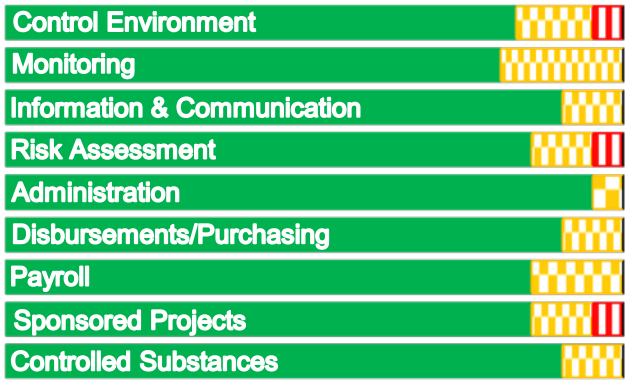
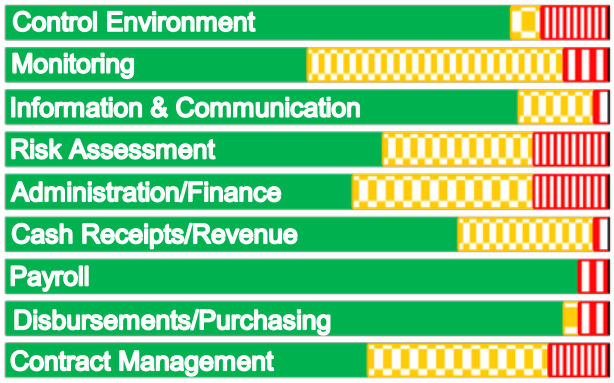


Athletics Financial & Operational Review (June 2016)



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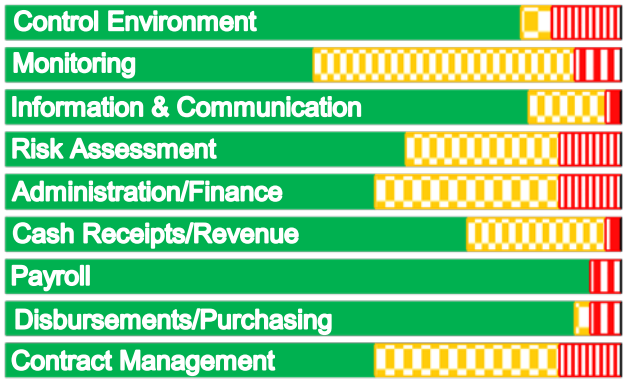
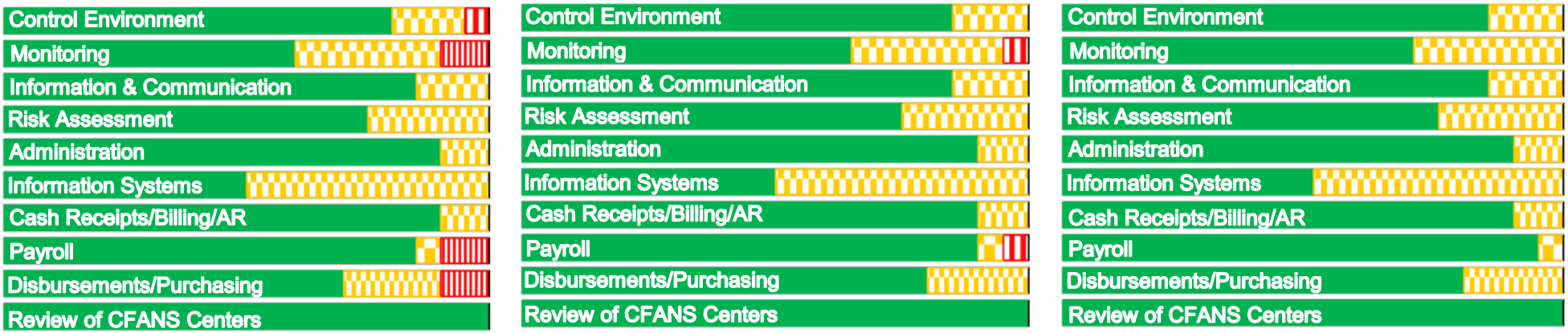


Adequate Control | Significant Control Issue(s) | Critical Control Issue(s)

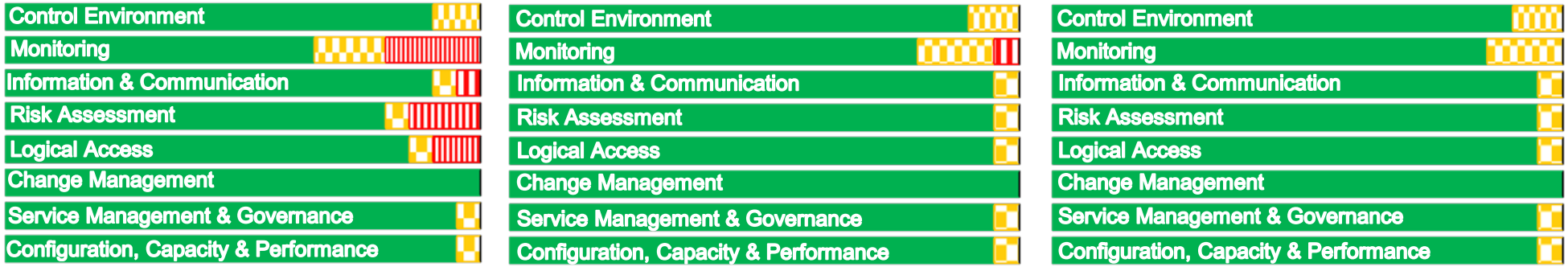
Units with Charts that Fully Implemented their "Essential" Recommendations During the Past Quarter

Original Report Evaluation | Previous Quarter Evaluation | Current Quarter Evaluation

CFANS - Dean's Office (October 2015)



OIT Server Administration (May 2015)



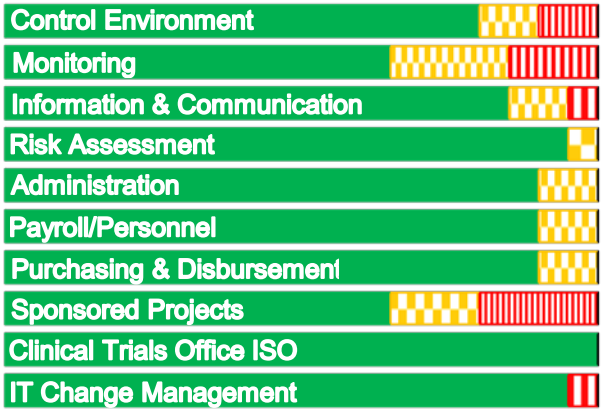
Adequate Control | Significant Control Issue(s) | Critical Control Issue(s)

Original Report Evaluation

Previous Quarter Evaluation

Current Quarter Evaluation

Masonic Cancer Center (June 2016)



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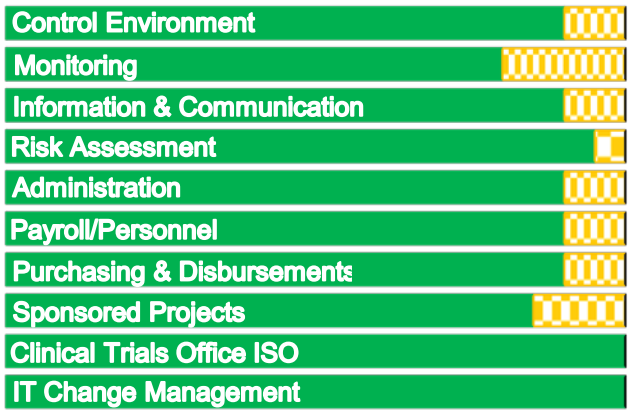
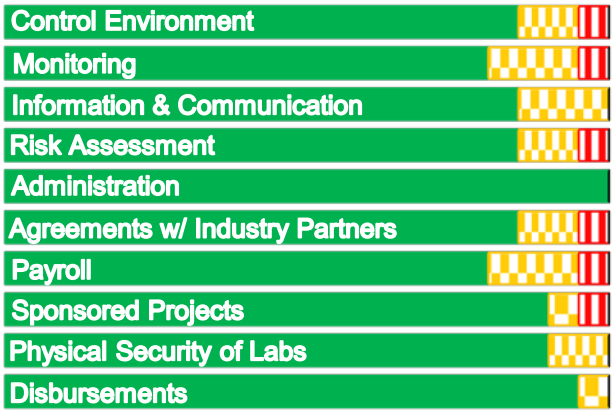


Department of Electical & Computer Engineering (June 2016)



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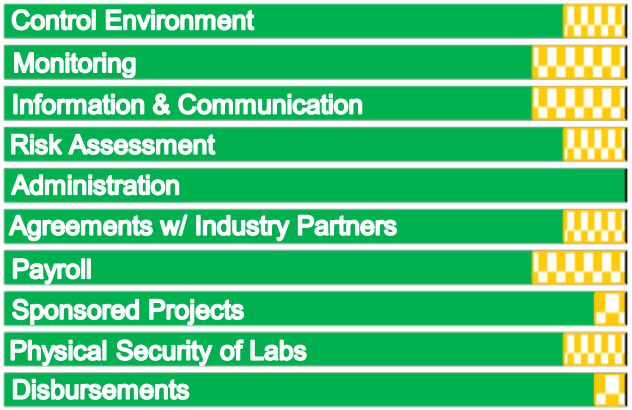


Adequate Control Significant Control Issue(s) Critical Control Issue(s)

Audit Activity Report

Scheduled Audits

- Completed audits of: PCI Compliance & Governance, Procurement Card Process and the Vendor Payment Process. Details are shown on the following charts.

- Began/continued audits of: Community University Health Care Center, Sponsored Transactions and Subawards under Uniform Guidance, Department of Surgery, College of Biological Sciences, Office of Human Resources Operations, PeopleSoft IT General Controls & Governance, Epidemiology & Community Health, School of Dentistry and a Minnesota Vikings closeout.

- Began reviews of the Next Generation Network (NGN) and identity management system upgrade projects.

Non-Scheduled Audits

- Completed a requested audit of UMD tuition waiver processes. Details are shown on the following charts.
- Continued a review of international admissions processes.

Investigations

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

Special Projects

- Performed annual institution-wide testing of UMF-funded gift and endowment accounts.
- Provided consulting services related to University payroll exception testing.
- Provided technology consulting in several areas including on vendor management and IT security.
- Participated in a review of the institutional compliance program.
- Reviewed TCF Stadium scheduling issues associated with Drum Corps International.
- Organized a team to review Google account termination processes and identify potential solutions to compliance concerns.

Other Audit Activities

- Participated in the following:
  - Senior Leadership Group
  - Operational Excellence Leadership Team
  - President's Policy Committee
  - Policy Advisory 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
  - IT Leadership and Operational Excellence Committees
  - Data Storage Guidance and Use Case Categorization Scheme Committees
  - Senior Vice President Finance & Operations Search Committee
  - Standard Operating Procedures Advisory Committee

- Made a presentation to the FinMAC group (a financial advisory committee to the CFO) on the annual audit planning process and current audit trends and issues.

Audit Reports Issued Since June 2016

PCI Compliance and Governance

Report #	1701	Issue Date	Jul-16
# of Essential Recs.	0	Total # of Recs.	2
Overall Assessment	Good	Adequacy of MAP	Satisfactory

University of Minnesota departments that accept payment cards as payment for goods and services are contractually obligated to follow the Payment Card Industry Data Security Standards (PCI DSS). PCI Compliance Program staff in the Controller's Office and University Information Security have established effective governance and control processes to address PCI DSS compliance and other payment card risks. PCI Compliance Program staff have implemented robust oversight mechanisms and taken steps to limit scope and risk. Technical control strategies and oversight is similarly operating effectively. Effectiveness of the University's PCI Compliance Program is further demonstrated by the external Qualified Security Assessor's 2016 report concluding the University is fully compliant with PCI DSS.

Procurement Card Process

Report #	1702	Issue Date	Aug-16
# of Essential Recs.	1	Total # of Recs.	2
Overall Assessment	Good	Adequacy of MAP	Satisfactory

We believe the PCard Office has developed a control environment and a system of internal control that generally addresses most business and compliance risks associated with the operation of the PCard program, which has annual expenditures totaling $64 million. Error rates for most attributes were considered reasonable and not indicative of widespread non-compliance with policy. The PCard Office can continue to stress the need for cardholders and their approvers to reconcile and approve transactions within the 30 days allowed by policy, and to provide complete transaction justifications. There is also an opportunity to encourage cardholders to procure using UMarket Services whenever possible, which will help achieve the best pricing possible on these items.

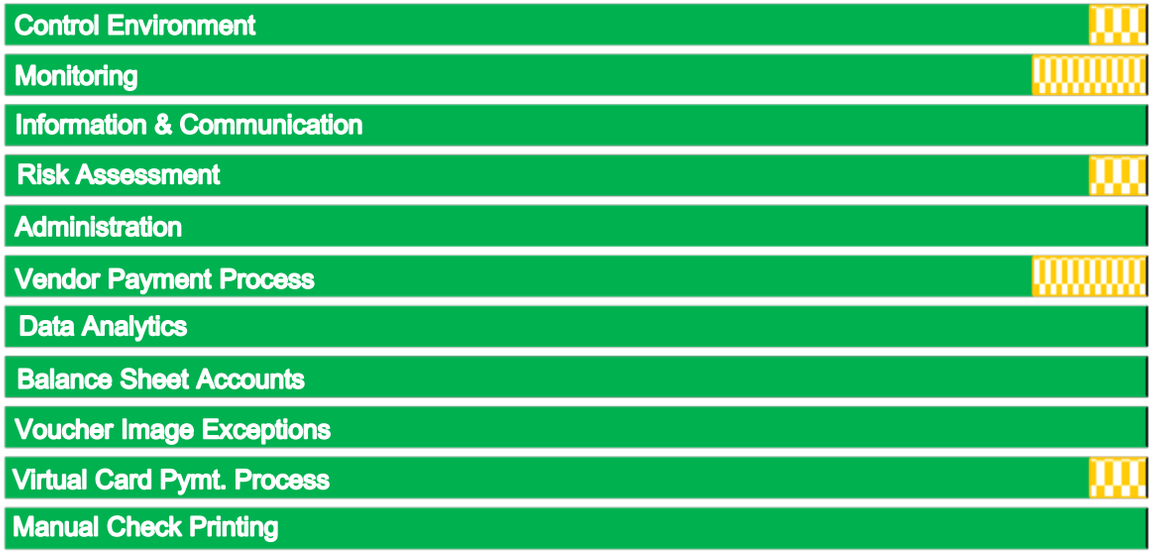
Adequate Control Significant Control Issue(s) Critical Control Issue(s)

UMD Undergraduate Tuition Waivers

Report #	1703	Issue Date	Aug-16
# of Essential Recs.	3	Total # of Recs.	17
Overall Assessment	Needs Improvement	Adequacy of MAP	Satisfactory

A tuition waiver “waives” all or a portion of tuition charged to a student and, unlike scholarships and grants, waivers represent forgone revenue because the University generally does not recoup the amount waived. We believe the control environment and system of internal control for undergraduate tuition waivers at UMD does not sufficiently address the major business and compliance risks. The two issues of greatest concern involve the absence of clear authority over tuition waivers and the lack of strategic management. There are multiple UMD departments involved with tuition waivers and ultimate responsibility for the management and oversight of waivers has not been established. The lack of strategic management of waivers has resulted in UMD expending resources on activities that may not be furthering UMD’s mission, vision and goals.

Vendor Payment Process



Report #	1704	Issue Date	Aug-16
# of Essential Recs.	0	Total # of Recs.	3
Overall Assessment	Good	Adequacy of MAP	Satisfactory

We believe University-wide departmental adherence to policies regarding processing of vendor payment transactions $500 and above is generally good. Disbursement Services, a unit within the Controller's Office, has created a control environment and a system of internal control that addresses most business and compliance risks associated with the operation of the vendor payment process. Control improvement opportunities include strengthening controls over wire transfer payment processing, better oversight of contingent fund accounts (zero balance checking accounts), and improved monitoring processes for virtual card (VCard) payment rebates.

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

BOARD OF REGENTS
DOCKET ITEM SUMMARY

Audit & Compliance **September 8, 2016**

AGENDA ITEM: Update on the Remediation of Intercollegiate Athletics Audit Findings

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

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

PRESENTERS: Michael Volna, Interim Vice President & CFO
Mark Coyle, Director, Intercollegiate Athletics

PURPOSE & KEY POINTS

The purpose of this item is to discuss progress made related to the remediation of findings from the following internal audits of Intercollegiate Athletics (Athletics):

- Athletics Administration – December 2015
- Men's and Women's Basketball – May 2016
- Athletics Finance and Operations – May 2016

A financial oversight group chaired by Interim Vice President Volna has been working with Athletics to ensure that appropriate financial controls are in place; ensure that policies and procedures are understood and adhered to by department personnel; strengthen the culture of financial compliance through training and education; and strengthen processes and procedures related to the procurement of alcohol for events and related hospitality. These are all matters raised in the December 2015 and May 2016 internal audits.

The work of the oversight group has been guided by a work plan developed in December 2015 and adjusted after completion of the May 2016 audits. The plan has nine priority areas of focus:

1. Align Athletics policies with University financial policies.
2. Evaluate and address purchasing audit findings.
3. Evaluate and address purchasing card (P-card) audit findings.
4. Develop and deliver education and training to Athletics staff.
5. Address "pain points" in University financial policies.
6. Evaluate and address contract management audit findings.
7. Implement Elevation, a financial software tool, to better track and manage financial information.
8. Create administrative policy requiring annual financial certification.
9. Review other internal financial controls as appropriate.

In addition, the oversight group has developed an audit action plan scorecard that tracks progress on the specific "significant" and "essential" findings of the December 2015 and May 2016 audits.

BACKGROUND INFORMATION

In December 2015, the Board of Regents received the results of an internal audit of financial management practices within Intercollegiate Athletics related to expenses incurred and/or authorized by senior department officials from 2012-2015.

In February 2016, the committee received an update on the implementation of recommendations related to the December 2015 internal audit and the external review.

In May 2016, the Office of Internal Audit completed a sport-specific audit of men's and women's basketball covering the 2014-15 school year, and completed an audit that included a review and assessment of current financial and operating controls and procedures within Athletics primarily focused on November 2014-October 2015.

The committee's 2016-17 work plan calls for updates on remediation of Athletics audit findings in December 2016 and May 2017 in support of the Board's ongoing oversight.

Update on Remediation of Intercollegiate Athletics Audit Findings

Audit & Compliance Committee
September 8, 2016

UNIVERSITY OF MINNESOTA
Driven to Discover℠

Intercollegiate Athletics Internal Audit History 2015-16

- December 2015 / Athletics Administration
  - financial activities associated with ICA administration, the AD and his staff. Audit timeframe was July 2012-August 2015
- May 2016 / Men's and Women's Basketball
  - operational and compliance sport team audit. Audit timeframe was July 2014-June 2015
- May 2016 / Athletics Finance and Operations
  - operational, financial, and compliance procedures and controls. Audit timeframe was November 2014 to October 2015

Audit Action Plan
"Scorecard"

Detailed information included in docket materials

- December 2015 / Athletics Administration
  - 7 essential / 4 completed, 2 partially implemented, 1 not implemented
- May 2016 / Men's and Women's Basketball
  - 7 essential / 5 completed, 1 partially implemented, 1 not implemented
- June 2016 / Athletics Finance and Operations
  - 7 essential / 1 completed, 4 partially implemented, 2 not implemented

Financial Oversight Committee
President's Charge – December 2015

- Strengthen the culture of compliance; emphasize "tone at the top"
- Ensure that appropriate controls are in place
- Ensure financial policies and procedures are understood and adhered to by Athletics staff
- Focus on high-risk policies and activities
  - Travel, hospitality expenses, employee reimbursements
  - Purchasing and p-card usage
  - Contract management

Financial Oversight Committee Work Plan Status

1. Align Athletics' policies with University financial policies
   - Policies were reviewed for alignment and compliance.
   - Limited exceptions were noted due to unique circumstances dealing with Team Travel and cost-saving measures.
2. Evaluate and address purchasing audit findings
3. Evaluate and address purchasing card (P-card) audit findings
   - Steps to improve adherence to department policies and procedures including a Points of Emphasis document and department-wide training have been completed.
4. Develop and deliver education and training to Athletics' staff
   - Purchasing staff assigned to work with Athletics staff to develop and deliver training
   - Mandatory training completed with coaches, support staff, administrators in August 2016
   - Topics covered: travel, purchasing, expenses
5. Address "pain points" in University financial policies
   - Purchasing staff led a combined Athletics and FinMAC work group to review policy "pain points" from throughout the University
   - Group developed a set of recommendations regarding how to proceed with each "pain point" concern

Work Plan Status (cont'd)

6. Evaluate and address contract management audit findings
   - Athletics Senior Staff members will attend campus Contract Management training in September
   - A draft contract management plan has been developed and will be implemented after training is completed
7. Implement Elevation financial software tool
   - Budget reporting functionality implemented for FY2016-17
   - Budget development functionality scheduled for implementation for FY2017-18
8. Create administrative policy requiring annual financial certification
9. Review other internal financial controls as appropriate
   - Continue to monitor response to, and progress on, audit findings
   - Adjust and adapt committee work plan as needed in the coming year

Expectations

- FY17 Work Plan / Intercollegiate Athletics
  - Guiding Principles
    - Sound fiscal management and a commitment to transparency
    - Implement measurable processes that exceed expectations
    - Proactively engage Internal Audit Office with best practices
- Clearly defined department-wide expectation
  - Individual meetings with senior staff / head coaches
- Culture of being intentional and consistent

BOARD OF REGENTS
DOCKET ITEM SUMMARY

Audit & Compliance **September 8, 2016**

AGENDA ITEM: Update on Human Participant Research Protection Plan

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

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

PRESENTERS: Brian Herman, Vice President for Research

PURPOSE & KEY POINTS

The purpose of this item is to share and discuss progress made on the Board resolution, passed June 2015, related to the Human Participant Research Protection Program implementation plan.

Overall, the work remains on schedule. The implementation teams have completed their reports and moved into the operationalization phase. Progress on operationalization is being monitored. Work areas remain engaged with key faculty stakeholders and work is consulted broadly to ensure engagement and adoption of the changes. Updates are provided below.

Since the committee last heard an update, in June, eight Institutional Review Board (IRB) medical panels have been recruited and will provide more rigorous and timely reviews. Policies and supporting documents under "Human Research Participants Who Have Impaired or Fluctuating Capacity to Consent" have also been released.

The IRB developed new policies and procedures to establish requirements for assessing capacity to consent to research and to promote the protection of potentially vulnerable participants.

HRP-110 "Research Involving Adults with Absent, Diminished, or Fluctuating Capacity to Consent to Participate in Research" establishes requirements for investigators enrolling these types of adults. This includes the requirement that one of the following validated tools be used to assess capacity to consent in research studies: MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR) for greater than minimal risk research; or UCSD Brief Assessment of Capacity to Consent (UBACC) for minimal risk research.

HRP-111: Research Involving Adults under Court Jurisdiction establishes conditions under which potential subjects may not be enrolled in any psychiatric drug, device, or biological trial, including adults under a hold, including those subject to a commitment petition and/or temporarily confined involuntarily under 72-hour emergency holds, "intent to leave" periods, or detainment under a Peace Officer/Health Officer Authority.

Policy HRP-403C reflects two changes to Minnesota law effective August 1, 2016:

1. The first change prohibits investigators from enrolling a patient on an involuntary hold (72-hour emergency admission hold, peace officer transport hold, or court apprehend and hold order) into any clinical drug trial. This change extends IRB policy that has, since 2015, prohibited enrolling patients on an involuntary hold from being enrolled in any psychiatry clinical drug, device, or biological trial.
2. The second change requires investigators in the Department of Psychiatry conducting clinical drug trials to notify the Minnesota Ombudsman for Mental Health and Disabilities within 24 hours of a research participant's death or serious injury. The Ombudsman has authority to recommend actions to the University to prevent a recurrence of deaths; receive and investigate complaints from any source related to an individual's participation in a psychiatric drug trial and recommend actions to the University; and monitor psychiatric drug trials to assure the protection of participants.

An online, interactive course, "Assessing Capacity to Consent to Research," has been developed to support the education and training needs of the research and IRB community in the adoption of the new policies and procedures. The course was vetted by University stakeholders including the Center for Bioethics, Department of Psychiatry, and Paul Appelbaum, MD, co-author of the MacArthur Competence Assessment Tool for Clinical Research.

BACKGROUND INFORMATION

On February 23, 2015, an external review panel issued a report containing 63 recommendations for improving the human subjects protection program at the University. The language of that 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 subjects protection. The external panel's report is available here.

On March 12, 2015, President Kaler charged Brian Herman, Vice President for Research, and Brooks Jackson, Vice President for Health Sciences, with oversight of the implementation of the recommendations of an external review panel by establishing an Implementation Team (Team) of internal and external individuals with the qualifications and expertise to review the recommendations and develop a plan to implement them. At its March 2015 meeting, the Board approved immediate and longer-term action plans to implement the recommendations.

The Team was chaired by Dr. William Tremaine, Professor of Medicine, Mayo Clinic and Director, Mayo Clinic IRB. During the time of the Team's work, two additional reports were made available: 1) a May 5, 2015 draft report from the Office of the Legislative Auditor, 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." Team members considered the information from these reports in their recommendations. Report #2 above is publically available on the Advancing Human Subjects Research website.

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

The report recommended significant and disruptive changes to the University's human participant research protection program. These changes are intended to cultivate a culture of ethics, ensuring

the primacy of the University and each investigator's duty to keep the well-being of patients who become research participants at the center of policies and procedures, while ensuring the institution's commitment to clinical research and the faculty.

Key components of the report were:

- Cultivating a culture of ethics
- Strengthening Institutional Review Board (IRB) membership and review process
- Scientific review
- Post-approval monitoring
- For-cause investigation
- Research with subjects who have impaired or fluctuating capacity to consent
- Department of Psychiatry
- Engaging research subjects
- Education and training of investigators
- Accounting metrics
- Managing Conflicts of Interest
- Community Oversight Board
- External advisor
- Required resources

The Team received over 60 comments to the draft report. The comments reflected 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.

At its June 2015 meeting, the Board reviewed and discussed the final work plan's key recommendations and passed a resolution endorsing the final work plan. The Board also stated it would 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. Those progress reports are online at the Advancing HRP website.

At its September 2015 meeting, the Audit & Compliance Committee received an update about several recommendations from the external review and implementation plan that had been addressed and reported to the Regents and the Legislature over the summer. Those items included:

- Establishment of the Fairview University Research Oversight Committee (FUROC)
- Retaining an external advisor (Dr. David Strauss) from the external advisory panel to assess progress on the original recommendations
- Outsourcing review of Psychiatry clinical trials
- Hiring Compass Point to randomly review 100 psychiatric trials
- IRB meeting changes: quorum, number of meetings, number of protocol reviews per meeting
- Policy change: 72-hour hold practice

The December 2015 Audit & Compliance Committee meeting included updates from Vice President for Research Brian Herman; Professor Steve Miles; and Lynn Zentner, Director of the Office of Internal Compliance.

Continued monthly reporting to the Legislature included updates about:

- Status of IRB Membership, Research Compliance Office and For Cause Investigations final deliverables including review by David Strauss, external reviewer for the implementation.
- Development of four medical IRB rosters and nominees to serve.
- Updates about a more stringent Conflict of Interest policy and broad consultation of the changes.
- A national conference on December 2, 2015, hosted by the University's Consortium on Law and Values entitled "Research with Human Participants."
- Research Compliance Office structure and operations that became effective on October 2, 2015.
- Appointment of a new Community Oversight Board chair, Paul Mattessich.
- Development of new coursework by the Center for Bioethics that includes standards for research with human participants and the hiring of a new education and outreach specialist for researchers and IRB member training and communications.

At the February 2016 meeting, Paul Mattessich, Executive Director of Wilder Research and Chair of the Community Oversight Board, was introduced to the committee and discussed implementation of the new COB board. The following updates were also covered:

- The Clinical and Translational Science Institute (CTSI) continuing its evaluation of the Department of Psychiatry and has begun a gap analysis and curriculum design plan for human participation research training and education at the University in collaboration with the OVPR, IRB, and Center for Bioethics.
- Presented the results of a recent external consultant's review of the Department of Psychiatry. CTSI hired the consultant to assess the status of clinical trials in the department early last fall and assist in developing a management plan. The consultant's final report was received in January and made observations similar to previous reports on this topic. To address those observations, the University has increased monitoring of clinical research in the department, including assisting faculty in understanding and using GCP guidelines, and is moving forward on transferring the management of this clinical research to CTSI.
- HRPP beginning the first phase of implementing an electronic IRB. The eIRB, when fully implemented, will speed up reviews for researchers, add capacity, and ensure proper documentation.
- Continued consultation of the Conflict of Interest policy changes. This policy will be voted on at the April 2016 University Faculty Senate meeting.
- Plans to make the successful December conference entitled "Research with Human Participants" an annual event.
- The Scientific Review submitting their final report and move forward to discontinue departmental review and create a process in the Human Research Protection Program (HRPP) for this review, eliminating real or perceived conflict.
- Recruiting of membership for the Community Oversight Board. The board is diverse with members representing health care providers, patient advocates, the State, the University and the non-profit community.

At the May 2016 meeting, a full list of all the accomplishments since the June 2015 Board resolution was provided. The updates included the following:

Department of Psychiatry

- New department head, Dr. Sophia Vinogradov, starts July 31, 2016 and is already engaging with the University community.
- Department faculty have adopted new policies: requiring Good Clinical Practice (GCP) standards for all studies, implementation of a new checklist to ensure better collaboration with clinical staff, and a requirement that a treating clinician of a potential study participant cannot be involved in consent for a research study.
- The department has endorsed Clinical and Translational Science Institute (CTSI) management of all clinical trials and begun that transition.
- A full-time CTSI research project manager, already embedded in Psychiatry, is working with investigators on all aspects of design and execution of clinical trials.
- New accountability standards require that any problems identified with studies and not quickly corrected by the Principal Investigator are reported to the department head and then, if still not corrected, to the Vice Presidents of Health Sciences and Research.
- The department continues to work with the Center on Bioethics on recruitment and other ethical issues.

Internal Review Board (IRB)

- Reconstituted to form eight medical committees, broadened membership to ensure adequate expertise, and implemented compensation for faculty participants.
- Revised the format of meeting minutes to ensure adequate documentation.
- Reviewed best practices of peer organizations.
- Began implementation of an electronic IRB to ensure better and faster review of study protocols.
- New monitors have been hired through the Post Approval Review function to increase and improve PAR monitoring.
- All psychiatric interventional drug trials were suspended and re-reviewed by an external IRB. Quorum IRB continues as the IRB of record for these trials.
- Implemented a policy stating the University will not recruit individuals or patients on a 72-hour hold.
- An external consulting firm, Compass Point Research, submitted a final report of their independent review of close to 100 IRB protocols for active studies. Overall, the report indicates that the University does not have a systemic issue with the conduct of clinical research.

New Oversight Structure

- Research Compliance Office (RCO) – Effective as of October 2015, RCO has responsibility for conducting for-cause investigations to ensure separation from the IRB.
- Fairview University Research Oversight Committee (FUROC) – This committee is composed of leaders of the University and Fairview Health Services to ensure better communication about and oversight of research in Fairview facilities and involving Fairview patients and staff. The committee is co-chair by Brooks Jackson, Vice President of Health Sciences and Dean of the Medical School, and Beth Thomas, Chief Medical Officer of Fairview.
- Community Oversight Board (COB) – The COB was created to allow greater community input into research involving human participants at the University on ethics, community engagement, policies, communication and dissemination of research finding. The board is chaired by Paul Mattessich of Wilder Research and has a diverse membership representing health care providers, patient advocates, the University, the non-profit community.

- External Advisor – Dr. David Strauss continues reviewing progress with each work team and spent time on campus in March consulting and discussing accomplishments.

Education and Training
- New "best clinical practices" training is in final stages of development and will be required in the Department of Psychiatry starting this summer.
- Needs assessment and gap analysis on Human Research Protections and Ethics training complete
- New model for human research protection education coordination and enforcement approved

Culture
- Convened a national conference in December 2015 entitled, "Research with Human Participants: The National Debates." This will be an annual event and include an educational component.
- Created language describing the University's core ethical commitments. This statement is being discussed and published throughout the University, particularly within clinical and research units.

At the June 2016 meeting, the committee received an update on the following progress:

- The Engaging Research Participant work group is drafting the work area's final report that adopts a systems approach, identifying expectations of researchers in engaging participants and the public as well as evaluating participant and public responses related to research. The recommendations focus on the informed consent process documents and the on-going engagement of research participants. The work group is in the process of finalizing participant contact cards for study coordinators to give to participants and their family members at each visit, and a participant feedback survey that will provide real time feedback and trends about participant's experience in research studies to University leadership, the Community Oversight Board (COB) and the public. Feedback from participants and the public will also help inform education and training for investigators and their study teams. The work group is also finalizing recommendations about the dissemination of research results to participants and the broader public.

- The COB held its second quarterly meeting on May 12, 2016. Key agenda items included the Compass Point Report, the Department of Psychiatry Assessment Report and CTSI Management Plan and the composition of the board.

- Progress continues with changes to the IRB structure and process improvements. IRB member assignments for four of the eight planned biomedical panels have been finalized and will start in July. Additional member orientation meetings and training sessions were held during in May.

A complete list of all the progress to date is available at:
http://research.umn.edu/advancehrp/implementation.html

Status Report:

Implementation of Enhancements to Human Research Protections at the University of Minnesota

David H. Strauss, M.D.
August 2016

At the request of Dr. Brian Herman, Vice President for Research at the University of Minnesota, I offer the following observations and recommendations on the University's response to the February 2015 External Review of its human subjects protections program. This report draws upon discussions with members of the university community during my visit in late March; telephone and in-person meetings with faculty and staff prior to and subsequent to the visit; and review of available draft and final reports and documents related to the University's efforts to fulfill its commitment to human subjects protections.

In response to the recommendations of the External Review, the University has set a course to re-establish and re-invigorate its human research protections program. The call for change has been fully embraced by the University and the effort reflects extraordinary resolve, effective leadership, and teamwork at many levels. Progress to date has been impressive, but the success of Advancing Human Research Protections will be measured over years and will require ongoing commitment and refinement of newly implemented structures, policies and practices.

Background

In July 2014, University's Faculty Senate commissioned an external review to address continuing criticism of the human subjects protections program at the University of Minnesota, including concerns raised by its own faculty and staff. In response, University leadership contracted with the American Association of Accreditation of Human Research Protections Program to hire a team of external reviewers to examine the current state of policies, procedures and practices related to human subjects protections, with special attention to research participants with impaired decision-making capacity.

In February 2015, the external review team provided a report of its findings and recommendations (hereafter, the "the External Review," or "The Report"). The Report was widely critical of University practices, and identified both fundamental shortcomings and missed opportunities requiring attention if the University was to satisfy its critics and achieve its stated goal of establishing a clinical research enterprise that met or surpassed best practices.

In response, in April 2015, the University convened an Implementation Team whose June 2015 work plan "Recommendations of the External Review of the University of Minnesota Human Research" outlined a university-wide effort and an 18-month timeline to remake its human subjects protection program and establish its commitment to high ethical standards in clinical research. To support and guide the

effort under the umbrella term, “Advancing Human Research Protections,” the Office of the Vice President for Research established a standing Research Compliance Advisory Committee (RCAC). The university designed and launched this effort and component processes (e.g. “IRB Renew”) with broad input and representation.

In keeping with its commitment to transparency, all plans, work products and meeting summaries were made available to the public. Descriptions of progress toward fulfilling each of the objectives of the Work Plan are well catalogued in easily accessible documents on web pages dedicated to this now 14-month long effort.

The recommendations of the External Review were numerous, broad in scope, and emphasized six overlapping and interrelated problem areas. These categories form the structure of the report that follows:

I. The involvement by university, medical school, and hospital leadership in human research protections
II. The quality of IRB review
III. Education and training of investigators in research ethics and research subject protections
IV. Policies and practices related to informed consent and the inclusion of research subjects with impairment in consent capacity
V. Research within the Department of Psychiatry
VI. University culture and values

I. The Involvement by University, Medical School, Hospital and Departmental Leadership in Human Research Protection Program

A central conclusion of the External Review was that leadership at the University, the Academic Health Center, and at the department level was not sufficiently engaged in the activities and mission of human research protections. For example, the report noted, "The University and its Medical School do not appear to employ existing lines of reporting to define a hierarchy of accountability for human research ethics [in order to] expand oversight responsibilities beyond the IRB."

Observations:

University leadership has embraced the many recommendations of the External Review with extraordinary resolve and energy. The development, implementation, and success to date of the Advancing Research Protections initiative itself derive from a new and vitally important degree of involvement by leadership.

The creation of a central Research Compliance Office, the development of a Community Oversight Board, and the introduction of a Fairview University Research Oversight Committee (FUROC) represent three important new structures central to the effort.

The March 2016 "Hierarchy of Accountability" specifically defines the larger network of interrelated committees, programs, and reporting relationships focused on human research protections. The "Fairview Research Administration (FRA) Chain of Command" (Appendix) illustrates the integration and coordination of institutional research oversight responsibilities.

The External Review called for the involvement of Fairview staff in "gatekeeping" functions to ensure that clinical interests remain priorities in research in the hospital setting. The FUROC is co-chaired by Fairview's Interim Chief Medical Officer and the VP for Health Sciences, and includes the University's VP for research and the Chief Nursing Executive of M Health, among others. According to a summary of its charge, FUROC will:

> …serve as a place for researchers, staff, and the public to share concerns and to achieve a response or resolution to those concerns. The committee is to monitor the entire spectrum of clinical research across the Fairview Health System to insure…both research and clinical regulatory obligations are met…research protocols are appropriate and

feasible within the concurrent demands of patient care [and] that Fairview staff members have a voice in the conduct of research."

A new practice, under the direction of FUROC, now requires the involvement of leadership and line clinical staff in the process of research protocol development, implementation, and ongoing monitoring. The Clinical Research Study -Fairview Behavioral Service Checklist (Appendix) outlines this requirement and documents its fulfillment. "Climate" assessments are planned and will help leadership gauge the impact of these new oversight efforts.

The Community Oversight Board, with whom I had the opportunity to meet, includes a diversity of expertise, interests and constituencies from within and outside the University. The group demonstrated enormous enthusiasm and recognized its potential to serve both consultative and oversight functions with regard to human research protections and research ethics more broadly. There is evidence of bidirectional communication; the IRB has presented to the COB, and the COB has offered input on the Research Subject Bill of Rights. However, the stated desire by members of the COB to understand their role was the topic of much of the discussion during my meeting with the group. Many members seemed uncertain of their responsibilities, their access to information about research practices, and whether they were to be "responsive or proactive."

The University has taken a valuable step, also referenced in the External Review, to draw upon the strengths of its highly regarded academic programs. Linkages between University compliance functions, the Consortium on Law and Values, and the Center for Bioethics have already enriched activities such as educational programming and the development of a statement of core commitments.

The External Review called for the involvement of department level leadership in research oversight functions. The Departments of Psychiatry and Neurology have been working with the IRB to develop educational programming; the IRB anticipates more widespread participation by the departments in this work. However, the Medical School has yet to specify a role for department chairs in supporting routine compliance activities (or where they sit within the Hierarchy of Accountability).

At the time of my visit in March, some roles and responsibilities within the nascent oversight hierarchy remained only partially defined, as did the relationships and boundaries between others. One member of the RPAC was critical of the purpose and

uncertain of the responsibilities of this steering committee. Elsewhere, concerns were expressed with regard to the relative roles and responsibilities of the Research Compliance Office, the CTSI, and the IRB.

What is not evident from document review and web-browsing, however, but became immediately apparent during my visit to the University, was the degree of involvement by senior leadership of the University and Health Sciences Center, the vast number of faculty and staff of all disciplines engaged in the work of implementation, and the commitment and enthusiasm they brought to the work. The IRB leadership, with whom I had the opportunity to spend several hours, expressed pride in the evolving changes in their operation and optimism about what they hoped to achieve with the additional support and resources made available to them by the University.

Discussion:

Under the direction of University leadership, the University has conceived and crafted an impressive infrastructure with the potential to drive and sustain meaningful progress in human research protection. It is substantially responsive to the External Review.

Rapid change of the sort required of the Work Plan will almost certainly be associated with missteps and require some reanalysis. The need for course corrections and iterative refinements should be anticipated, encouraged, and carefully guided by leadership as it prepares to transition from implementation to maintenance and assessment phase.

The Community Oversight Board can mature to assume multiple roles on behalf of the HRPP, and its membership should work with leadership to define how its relationships within and outside the University can best support and shape the University's vision of ethical research, patient/subject and family engagement, and research advocacy. As a semi-independent body, the COB can provide a non-institutional perspective on policy matters of importance to the University. In its oversight function, it can promote accountability to subject and community interests and influence practice.

The Fairview University Research Oversight Committee bridges a wide gap that existed between clinical care and research functions at Fairview. It supports a vital interaction that can promote joint responsibility between hospital-based clinical functions and University research. While I did not meet with representatives of Fairview, summaries

of FUROC meetings describe a plan to become actively engaged in the review of policies, monitoring findings and event reports. FUROC will periodically assess the effectiveness of Fairview's efforts to promote "gatekeeping" functions by its clinical teams.

The External Review emphasized the value of Departmental accountability for compliance activities, and with some exceptions, this does not appear to be central to the implementation plan. Department heads involved in matters such as setting compensation, evaluating effort, supporting faculty for academic promotion, and otherwise assessing the state of departmental activity, are uniquely positioned to support the University's educational and compliance agenda, and do so in manner that is tailored to the nature of the work of the department and the investigator. Department chairs should be aware of compliance problems within their service area or among their faculty. They can play a valuable role in enforcing IRB rules and identifying "local" solutions to the non-compliant investigator. The external review noted, "the Dean of the medical school could craft policies requiring the departments to develop ethics education requirements and content, build relevant performance metrics into investigator evaluations, and most importantly, hold chairs accountable for human subjects protections within their departments."

II. The Quality of IRB Review

The External Review identified problems with the quality of IRB review and with the value of a department-based scientific review process. The examination of IRB membership rosters and meeting attendance raised concerns about reviewer expertise and workload, and IRB documentation suggested that IRB deliberations lacked necessary substance. The extent of involvement of IRB leadership in investigations of non-compliance was seen as an unnecessary additional burden on the operation.

Observations:

In response to the External Review, the University developed an ambitious plan to reform its IRB operations and IRB review processes. The University engaged internal and external consultants, examined other nationally recognized University programs, and committed significant new funding to support system-wide change.

The IRB leadership team, with whom I had the opportunity to spend considerable time, is a talented and highly professional group with great pride in its work and commitment to excellence in human research protections.

An analysis of the scope and content of the University's human subjects research portfolio was used to estimate demand for review and categories of required reviewer expertise in order to plan for a restructured IRB committee process. Implementation of the plan was slowed, however, by difficulty in recruiting new IRB members; feedback indicated that the planned meeting schedule would place excessive demands on faculty time. With the input of external consultants, the University made a prudent mid-course correction in the design and timeline for the new IRB committee structure. At the 12-month mark, new IRB members have been identified, oriented, and trained. Four of 8 planned panels commenced or will soon commence review.

In the interim, the IRB review process has undergone considerable refinement. Important changes include the addition of meetings so that there is now a single Continuing Review and a single Biomedical IRB meeting each week, a capping of the number of items that can be addressed at any meeting, and a review format that demands a more structured and systematic evaluation of each research proposal.

The University has contracted with Huron consulting, and has begun to make use of the Huron Toolkit that provides forms, templates, and checklists to facilitate review, and supports training of both IRB staff and reviewers on standard operating procedures. For example, a checklist prompts IRB administrators to assess and document whether the required number of reviewers is present and whether reviewers with appropriate expertise are present at the IRB meeting. With this, and with enhanced staffing, IRB professionals plan to conduct a more robust administrative and regulatory pre-review of research, thereby facilitating a more focused committee review.

The University has outsourced IRB Review of industry-sponsored research in the Department of Psychiatry to a highly regarded independent (commercial) review board, Quorum Review.

The University has allocated funds to pay IRB members, augment members' salaries, or offset departmental contributions to salary. Other methods of providing incentives or requirements are currently being examined.

Responsibility for for-cause monitoring has shifted to the RCO. At the time of my last meeting with IRB, the respective roles for the CTSI, the RCO, and the IRB required clarification.

The External Review was critical of the existing department-based scientific review of human subject research protocols: there was little evidence that the process was substantive, and in some departments, it was likely to be influenced by bias or conflicting interests. Also, scientific review was not considered by the IRB in its deliberations. As part of the Work Plan, department-based scientific review has been eliminated and replaced by an online process of review by scientifically qualified IRB members. The process requires two reviewers to make a determination based on two broad questions:

(1) Is the scientific question reasonable?
(2) Will the methods described in the protocol answer that question?

Several "sub-criteria," such as "the research has the potential to provide new and useful knowledge," and "the principal investigator is qualified to conduct the research," are intended to assist in the categorical decision to "Accept" the protocol for IRB review or "Do Not Accept." Both reviewers must "Accept" for the protocol to be forwarded for IRB

submission. No other information about the reviewer's assessment is provided to the IRB. A "Do Not Accept" decision requires the reviewer to solicit additional information from the researcher.

Plans are underway to introduce a new electronic IRB submission tool by Spring 2017.

Discussion:

The University has made a substantial material and intellectual investment in the structure and function of the IRB. Interim measures to increase the number of meetings, limit reviewer work-load, and to better structure deliberations, address key concerns raised by the External Review and represent important accomplishments. New approaches to member training, the addition of members and panels, and the introduction of a toolkit to promote a more effective review process all represent a significant re-making of IRB review.

Ongoing attention to the outcome and effectiveness of these operational improvements is essential; regular measurement of IRB adherence to quality is planned. While the University's effort to remake its IRB process is well underway, success will require ongoing refinement of policies and procedures in response to performance measures. The University plans an annual assessment of IRB operations.

It is not surprising that the recruitment of new IRB members has been slow and difficult. Increased willingness to serve on the IRB may occur as the new cohort of reviewers report back on their experience within an enhanced IRB operation. The University and Academic Health Center should continue to identify financial and academic incentives for IRB participation, and gauge satisfaction among new member in terms of training, workload, and efficiency. Finally, a requirement for research departments to have representation on the IRB in proportion to the size of their research portfolio is not unreasonable.

The University has eliminated department-based scientific review, but it is not clear if this new approach offers advantages over scientific review that is conducted by the IRB itself. It is also not clear, in the new approach, if the IRB is expected to conduct its own assessment of study merit. Approval criteria require an IRB to determine whether "risks to subjects are reasonable in relation to anticipated benefits to subjects, if any, and the importance of the knowledge that may reasonably be expected to result." The categorical determination of merit (Accept vs Do Not Accept) under the current practice will provide the IRB with no meaningful information

about the reviewer's assessment of study benefit. For example, the current method may not serve to address concerns about an industry-sponsored study of a "me too drug" which is scientifically sound, but adds little "new knowledge" and therefore may not justify risks to subjects. Also, absent benchmarks or anchors for decision-making, how will a categorical Accept/Do Not Accept" choice be made? A default mode for all but the most concerning research may well be "Accept." To promote a more substantive review, the University should consider requiring reviewers to comment and rate each criterion and to "Accept with comments." If unchanged, the process should be tracked and its value and validity assessed. Expectations for review of merit by the IRB should be defined in policy.

The implementation of the NIH policy on the use of single IRBs in multicenter research in 2017, like the anticipated publication of a revised Common Rule later this year, will introduce new requirements and place new demands on the development of institutional and IRB policies and procedures. The completion of the implementation timeline and transition to a "maintenance" phase, and the introduction of the electronic IRB submission system at the University will also occur in at the same time; these may well place strain on both the IRB and researcher communities. Advanced planning is warranted.

III. Education and Training of Investigators and Staff

The External Review stated, "The broader educational policies and practices at the University fulfill minimal standards but represent a missed opportunity for a richer and more sophisticated institute-wide approach to investigator training."

Online "ethics training" under the auspices of the Collaborative Institutional Training Initiative (CITI) has become a standard human subjects protection and good clinical practice educational requirement for universities and other clinical research enterprises nationwide. The extent to which CITI provides *effective* training, however, is not known. Given the nature of the problems identified, the External Review suggested that the University would benefit from advanced and specific educational opportunities and requirements, particularly in relation to matters involving informed consent and the inclusion of vulnerable populations in research.

Observations:

The University engaged an external educational consultant to evaluate its human subjects training activities and evaluate these against standards and national norms. Based on this assessment and its priority recommendations, the Education and Training Work Group (Appendix) concluded:

> … that the University of Minnesota strengthen the current knowledge-based human research protection training and work to develop, assess and implement skill and attitude-based training over the next three years. The resulting training program should be comprised of a hybrid of online, discussion, peer learning, case and simulation, problem-solving practice, learning assessment, and demonstration of competence. The training needs to insure the appropriate levels of training for the specific research being performed and that human subjects are appropriately protected. Simultaneously the training must be high quality and the potential burdens for investigators and staff to understand, obtain and remain compliant with the required training should be minimized. Advanced training should be strongly encouraged, supported and rewarded.

The planned introduction of a range of learning formats--"skill and attitude-based" training, "learner assessment," as well as ongoing program evaluation"--reflects a significant commitment to meaningful education in human research protections and will doubtless place the University in the forefront of such efforts.

Plans to develop and pilot advanced training for researchers working with vulnerable individuals and those with diminished capacity, and to pilot consent training programs in the Department of Psychiatry, represent a joint effort by the CTSI, IRB and the Center for Bioethics.

Other enhancements involve: the hiring of an IRB education and outreach specialist; monthly IRB newsletters and HRPP Education and Outreach reports for the research community; course offerings from the Center for Bioethics; day-long conferences on ethics and research protections; video-training opportunities; and new educational toolkits for study coordinators.

Discussion:

CITI training has become the national standard because it is inexpensive, scalable, and trackable. However, most agree it offers little more than "lip-service" to the notion of ethics training, at least there is no data to suggest otherwise. How best to educate and sensitize researchers is ultimately an empirical question. Given the many groups contributing to training initiatives at the University, a central infrastructure or "clearinghouse" for education could offer a promising model for the coordination and study of education and training. The extent to which individual research departments and centers can be assisted in developing their own educational programming should be explored, as should "train-the-trainer" efforts.

Tailoring educational programming to the learning needs of researchers in different disciplines and assessing competencies and skills will represent a leap forward for the University and for the field. However, substantial effort and funding will be required to develop and fully implement the education and training program envisioned in the Work Plan. The University is prudent to focus implementation on priority areas (enhancing the consent process, assessing capacity in vulnerable populations, identifying and minimizing risks in research) with active and iterative modification before larger scale roll-out. This may shift the implementation timeline, but will ultimate prove more effective.

Regardless of quality, educational opportunities such as the March 2016 lecture on consent for study coordinators (also available online) or the 15-week lecture series "Standards for Research with Human Subjects" are not likely to attract the desired

audience and may serve only to “preach to the converted.” The University should mandate training beyond CITI for IRB members and all those involved in human subjects research.

IV. Policies and practices related to informed consent to research and the inclusion of research subjects with impairment in consent capacity

The External Review offered an extensive analysis and a series of recommendations related to the process of informed consent, the assessment of capacity, and safeguards related to the enrollment of research subjects with impaired decision-making.

Observations:

With regard to the inclusion of subjects with impaired consent capacity or those who lack the capacity to consent, the University introduced two important additions to the Policy and procedure manual**,** both dated March 2016. Entitled *Adults Lacking Capacity and/or Adults with Diminished Capacity to Consent* and *Vulnerable Populations* these additions established new standards for IRB review and, therefore, for research protocol design. In August, these policies were superseded by new policies, and associated IRB reviewer Checklists and investigator Standard Operating Procedures (SOPs) were added.

The SOP entitled "Informed Consent Process for Research" provides step-by-step "instructions" on consent for the investigator. While rudimentary, the SOP does establish certain guidelines to foster informed decision-making. For example, 1.1 to 1.3 (below) prompt the investigator to invite the subject's questions and to allow the subject time to consider consent or confer with others before making a decision. Item 1.4 establishes an expectation that subject understanding should be assessed in all circumstances by the researcher.

1.1 Invite and answer the subject/representative's questions.

1.2 Give the subject/representative time to discuss taking part in the research study with family members, friends and other care providers as appropriate.

1.3 Invite and encourage the subject/representative to take the written information home to consider the information and discuss the decision with family members and others before making a decision.

1.4 Ask the subject/representative questions to determine whether all of the following are true, and if not, either continue the explanation or determine that the subject/representative is incapable of consent:

1.4.1 The subject/representative understands the information provided.

1.4.2 The subject/representative does not feel pressured by time or other factors to make a decision.

1.4.3 The subject/representative understands that there is a voluntary choice to make.

1.4.4 The subject/representative is capable of making and communicating an informed choice.

The IRB reviewer checklist entitled “Vulnerable Populations” prompts an IRB reviewer to consider a limited range of “additional safeguards” such as “Exclusion of the population if not required to achieve study objectives” and “Researcher should not have any role in decisions impacting subjects’ status (e.g. institutionalization).”

The policy entitled “Research Involving Adults With Absent, Diminished, or Fluctuating Capacity to Consent to Participate in Research” defines consent capacity and some general categories of disorders in which it may occur. This policy establishes the new requirement to use a standard instrument in the assessment of capacity:

> The IRB recommends that the following validated tools be used to evaluate capacity to consent in research studies that involve adults with absent, diminished, or fluctuating capacity to consent:
>
> - For greater than minimal risk research, the MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR) appropriate to the context of the research.
> - For minimal risk research, a version of the UCSD Brief Assessment of Capacity to Consent (UBACC) appropriate to the context of the research.

This policy references the checklist entitled “Cognitively Impaired Adults” which specifies the IRB’s approval criteria for research that involves adults with absent, diminished, or fluctuating capacity to consent. It also references the SOPs entitled “Legally Authorized Representatives, Children, and Guardians,” “Informed Consent Process for Research,” and “Written Documentation of Consent” for detailed information regarding who can serve as an LAR and the process for obtaining and documenting informed consent from an LAR for subjects unable to consent.

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The same policy establishes a requirement regarding subjects with fluctuating capacity to consent:

> "The IRB expects that investigators include procedures to address fluctuating capacity, where applicable. Where fluctuating capacity to consent is anticipated in a subject population, the protocol must include plans for monitoring capacity for the duration of the study. "

The policy references the Checklist "Cognitively Impaired Adults" for the IRB's approval criteria for research that involves adults with fluctuating capacity to consent and the SOP "Informed Consent Process for Research" for the process for obtaining informed consent from subjects with fluctuating capacity to consent.

The checklist "Cognitively Impaired Adults" establishes approval criteria for research with subjects who "are cognitively impaired," and although not explicitly defined, appears to mean cognitively impaired subjects "who have been judged to lack the capacity to consent." Approval of greater than minimal risk research is only allowable when there is anticipated direct benefit to the subject, and includes additional safeguards, such as "Subjects will be withdrawn if they appear to be unduly distressed."

The Policy Research Involving Adults under Court Jurisdiction specifies:

> "researchers may not recruit or enroll the following persons in any clinical drug trial under Minnesota law (effective August 1, 2016) and/or existing IRB Policy: 1) individuals subject to a commitment petition; and/or 2) individuals temporarily confined involuntarily under: a) 72-hour emergency admission holds; b) "intent to leave" periods; or c) peace officer/health officer authority (formerly "transport hold") or a court apprehend and hold order.

Further,

> "an individual who has had a commitment hearing, and is released by the court before a commitment order is issued, is prohibited from participating in a psychiatric clinical drug trial during the period of a stay of commitment, unless the court specifically authorizes the participation. Investigators wishing to recruit such individuals must provide justification for doing do and a process compliant with the terms of the statute.

In addition, no member of a study team may participate in a decision to rescind or discontinue a patient's involuntary status (as described above) before its expiration, provisionally discharge a committed patient, or rescind a provisional discharge, when the patient is a prospective research subject for a study conducted by the study team.

The SOP "Legally Authorized Representatives, Children, and Guardians" establishes a hierarchy of LARs who may provide consent for an adult determined to lack capacity and other restrictions:

1.5 Unless the IRB has waived the requirement to obtain consent, when research involves adults unable to consent, permission must be obtained from a legally authorized representative. Minnesota law does not specifically address the issue of research participation by incapacitated adults.

1.5.1 Based on legal advice, the IRB follows the Minnesota laws on surrogate consent in health care to determine surrogate consent for research participation, including specifically the law on surrogate consent for treatment of incapacitated patients undergoing in-patient mental health treatment. When research is conducted in Minnesota the following individuals meet this definition in order of priority:

1.5.1.1 Healthcare agent previously appointed by the individual through a health care power of attorney;

1.5.1.2 Spouse;

1.5.1.3 Parents;

1.5.1.4 Adult children; and

1.5.1.5 Adult siblings.

1.5.2 The legally authorized representative may not be a member of the clinical or research staff or an employee or beneficiary of the sponsor of the research project.

1.5.3 Under Minnesota law, an incapacitated adult who has a court appointed guardian or conservator may not receive experimental treatment of any kind unless: 1) a court first approves the treatment through a court order; or 2) the court's guardianship order specifically authorizes the guardian to consent to research participation in addition to medical treatment generally.

1.5.4 For research outside Minnesota, a determination of who is a legally authorized representative is to be made with consultation from legal counsel.

Discussion:

The introduction of these policies on consent and approval criteria is a step forward. How effectively they will be disseminated and applied in the IRB and in the research clinic will depend to a large extent, however, on the quality of new training initiatives. The University should remain active in evaluating the value of such tools and checklists and in assessing the education and training efforts that are underway.

The IRB could develop rules and standards to better guide reviewer decisions. For example, as currently written, it appears to be solely at the reviewer's discretion to require the presence of a witness during consent, or to require the live monitoring of a consent process. The active use of consent observation as a monitoring and educational tool should be encouraged and policy driven.

While the Department of Psychiatry has established a rule preventing clinician researchers from being "involved in the research consent process" when the prospective subject is in their care, it is not clear if this same rule extends to recruitment. In the interest of preserving voluntariness of consent, clinicians should not approach their patients to solicit interest in their studies. The IRB should also consider whether this rule should extend beyond Psychiatry.

V. Research practices within the Department of Psychiatry

The External Review identified a number of system-wide deficiencies in oversight of research that had implications for Psychiatry, such as the *pro forma* departmental scientific review of IRB proposals. Other problems were specific to Psychiatry. Questions about the integrity of two clinical investigators, one of whom was the department head, were at the core of concerns by many faculty, staff members, and external critics. In the aftermath of the Markingson case, and in the context of ongoing criticism of industry sponsored clinical trials in the Psychiatry at the University of Minnesota, too little was done within the department to acknowledge the seriousness of the allegations or to address the department's broader obligations to support human subject protection.

Observations:

Without question much has changed within Psychiatry as a result of the Advancing Human Research Protections initiative.

Following the External Review, Dr. Charles Schulz stepped down as Head of Psychiatry. His departure was a necessary and more than simply symbolic event that was important to efforts to rebuild trust in Psychiatry.

Dr. Mark Paller, Senior Associate Vice President of the Academic Health Center was named Interim Head of Psychiatry and also charged with overseeing the implementation effort as it applied to the department. Under his stewardship, Psychiatry has been affirmatively engaged with the component functions of Advancing Human Research Protections initiative. While implementation is incomplete, the design of new programs, policies, requirements, and practices reflects the thoughtful and willing engagement by Psychiatry leadership, staff and faculty.

Following a nationwide search, Dr. Sophia Vinogradov, formerly Professor and Vice Chair at UCSF, was named Head of Psychiatry. Her own research examines cognitive training in schizophrenia and the neural underpinnings of the disabling cognitive deficits associated with serious mental illness. Dr. Vinogradov has announced plans for a department wide strategic planning initiative, and has signaled her commitment to human research protections, discussed further in the next section, with plans for the development of a consumer advisory board to provide " important viewpoints on

ethical, compassionate, and consumer-relevant approaches to all of the department's activities."

Dr. Stephen Olson is no longer actively involved in clinical trials. Should he seek permission to conduct research again, his request will be subject to review and his work will be subject to special educational, supervisory, and monitoring requirements outlined in the Work Plan.

As noted, as an interim measure, the University has outsourced the review of industry-sponsored research in Psychiatry to the Quorum IRB. The CTSI has assumed the management of the conduct of all clinical trials in Psychiatry.

An ambitious plan for competency-based training (Appendix, Department of Psychiatry Final Report) in informed consent has/or is soon to be piloted in Psychiatry. The goal of the Good Clinical Practices: the Informed Consent Process is to train staff to:

> Confidently, ethically, and humanely carry out all tasks appropriate to their roles within the research team in the informed consent process for regular and special populations of participants according to the FDA 21CFR50.25 and 45CFR46.111, ICH GCP principles and Good Clinical Practice guidelines, Minnesota Law, and University of Minnesota guidelines.

To "mitigate issues of therapeutic misconception," the Department of Psychiatry has developed and implemented the **"**Dual Role Consenting Policy," (Appendix) which is also cross-referenced in IRB policy "Research Involving Adults With Absent, Diminished, or Fluctuating Capacity to Consent to Participate in Research." The policy prohibits clinicians who are treating patients from "being involved in the consent process" when they are also the study's investigator. The policy also requires patients to be given an opportunity to confer with another clinician about treatment options when choosing whether to take part in research. Beyond simply addressing patients' tendency to overestimate the clinical benefit of research involvement ("the therapeutic misconception"), this policy addresses the clinician-investigator's conflicting interests in serving the best interest of the patient and fulfilling the needs of the research. It also recognizes that patients may have difficulty declining research participation when it is offered/suggested by their caregiver.

The "Clinical Research Study Checklist Fairview Behavioral Health Services" seeks to promote the involvement of clinical staff in gatekeeping functions. The purpose of this

checklist is to “provide a process so that leadership and clinical staff can provide input into how clinical research is developed and performed on the Fairview Behavioral Health Services.”

Discussion:

The Department of Psychiatry, in concert with other components of AHRP, has taken important steps to address a number of problems identified by the External Review. The introduction of new policies regarding consent and capacity, and especially the involvement of Fairview clinical staff in gatekeeping functions, represents genuine progress. The successful recruitment of a new Department Head offers opportunities for the credible engagement by leadership in setting new expectations and new standards for the ethical conduct of research. While some have expressed frustration with the pace of change, for the first time, the Department has completed the necessary groundwork in policy to foster improvement in research protections.

Much of the work of implementation is now beginning, and the key challenge will involve evaluating the effectiveness and sustainability of newly introduced requirements and making necessary refinements.

The External Review recognized the need for greater IRB expertise in the review of research with vulnerable populations. Psychiatry may choose to play a more central role in setting standards for the ethical conduct of research by insuring that Psychiatry is well-represented on the IRB and by working with the IRB to develop such standards, as it has done with the “Dual Role” policy.

New policies and guidelines can be developed to ensure that the rights and welfare of individual research participants are not treated as secondary to the interests of research and researchers. The commitment to protect psychiatric patients requires an understanding that some patients with serious mentally illness are not able to protect their own interests through the process of consent, because of cognitive impairment, because research offers care not otherwise accessible, or because they have, or may perceive that they have, little or no freedom to exercise choice. This is not to say that psychiatric patients cannot choose, either on their own, or with input from others, to participate in research and assume certain risks in the pursuit of personal benefit or to benefit science. But protecting psychiatric subjects requires expert understanding of subjects’ susceptibility to risks associated with experimental therapies, transitions to

and from experimental therapy, and drug free states, among others. Finally, protecting research subjects who are "vulnerable to coercion or undue influence," under-educated, and have limited access to healthcare, also means researchers must recognize that there may be a tension between what is best for the patient and what best serves research. Importantly, this conflict exists even when the investigator is not the treating clinician.

Even when prospective subjects are judged to have "capacity" to consent, they may be unable to fully protect their interests by making a careful and informed choice about study enrollment. An institution may provide additional protections by setting ethical standards in policy or in practice. For example, an IRB may determine in policy that patients who are stable and tolerating their current medication regimen should not be enrolled in research that entails discontinuing that medication, absent compelling justification. An IRB may request that an investigator exclude prospective subjects from participation in an experimental drug trial if they have never received standard and available treatment for the disorder, again absent compelling justification. Such "paternalism" recognizes the limits of informed consent.

Another related but distinct concern is the fact that current consent policy appears to be silent on the credentials required of staff responsible for discussing and documenting consent or making a capacity determination. Further, will (or how will) the department seek to validate the capacity determinations that result from the use of the McCAT-CR? What standards of care and monitoring should apply to transitions to and from protocol-based treatment? How will the department leadership respond to non-compliance?

The Department head and ultimately the IRB will need to make a determination about whether Dr. Olson, or for that matter any investigator, may serve as an investigator on a human subjects research protocol. Perhaps more important than this decision is whether the program for human subjects protections, as it operates within the Department, is setting necessary standards for the ethical conduct of research.

VI. University Culture and Values

The External Review faulted the University of Minnesota for its past failure to cultivate a culture that promoted the ethical conduct of research, and advised it to "signal a change in its culture of human subjects research by creating an expectation of excellence, demanding accountability, and more effectively engaging the community." As referenced in earlier sections, the creation of the Community Oversight Board and the Research Compliance Office, like the development of the Hierarchy of Accountability and Statement of Core Commitments, demonstrate an affirmative effort by the University to create structures and define values that serve its commitment to human research protections.

The ambitious campaign to communicate these values to University constituents and stakeholders similarly provides meaningful evidence of progress. The "Communicators Toolkit" for example, includes the Statement of Core Commitments in posters and flyers and digital formats, and a" Speak Up, It Matters" poster encourages feedback from research subjects. The use of a research participant contact card is intended to encourage research subjects to ask questions or lodge complaints; it also represents an innovative practice that underscores the importance of subject engagement. It is not surprising that Research Ethics now occupies prominent place on the home page of the Office of the Vice President for Research. But the emphasis on research ethics in the Medical School blog describing the recently appointed head of Psychiatry reflects the new messaging strategy:

> Dr. Vinogradov is the right leader to move reforms forward; to implement the highest standards of ethical research; and to build a new culture of trust and cooperation as the department works to develop innovative state-of-the-art programs of care for patients, and to conduct important scientific investigations that will lead to better outcomes for those with mental illness.
>
> ‘‘One of my first steps as the new Department Head will be to build on the work of the implementation team by creating a 'consumer advisory group' consisting of people with lived experiences of mental illness and other key stakeholders from the community, such as family members, advocates, and community providers," said Dr. Vinogradov. "I will count on this advisory group to provide me important viewpoints on ethical, compassionate, and consumer-relevant approaches to all of the department's activities.

The proposal to gather data to assess and track "culture" by employing an empirically validated instrument, the Survey of Organization Research Climate, represents a unique and potentially valuable method of measuring attitudinal change in response to interventions and to benchmark these findings against other institutions.

Certainly, the External Review became part of a national dialogue in the human research protections community. Dr. Herman's willingness to participate in a panel discussion at PRIM&Rs annual meeting in 2015 demonstrated the University's willingness to discuss the challenges it has faced and offer guidance to others.

Discussion:

The University has responded to the letter and spirit of the recommendations of the External Review and has undertaken a broad-based effort to affirm and communicate its commitment to human research protections, to accountability, and to community engagement.

While the benefits of Advancing Human Research will accrue over time with experience and as the new processes and functions evolve, there is impressive forward movement at present.

The considerable accomplishments of the many participants in AHRP, their drive, dedication and creativity, should be a source of pride throughout the University.

Education and Training of Investigators and Research Team Members:

Final Report
June 30, 2016

David Ingbar, M.D., Co-Chair
Timothy Schacker, M.D., Co-Chair

Appendix 1: Needs Assessment and Gap Analysis by Janet Shanedling, PhD, Education Manager

Executive Summary

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 or fluctuating capacity to consent. In response to an independent assessment of the University of Minnesota's Human Research Protection program, President Eric Kaler charged the Vice President for Research (Brian Herman) and Vice President for the Health Sciences (Brooks Jackson) to create an implementation team to review and implement the recommendations of the external reviews. The implementation team developed a work plan, a key component of which addresses the education and training of investigators.

This report comprises the results of a Needs Assessment/Gap Analysis conducted by an independent consultant, Janet Shanedling, PhD, and concludes with recommendations for enhancing human research protection (HRP) training and education at the University of Minnesota.

To ascertain the current environment within which the University provides human research protection education and training to investigators and research personnel, ***the needs assessment process included***:

- Online review of federal and accreditation (AAHRPP) training requirements and policies, and a review of National Clinical and Translational Science reports and documents pertaining to current GCP and research competency initiatives
- Survey of University of Minnesota websites and resources documenting current HRP and ethics training requirements and resources
- Interviews and discussions with University of Minnesota personnel involved in HRP education and training from multiple U of M offices and academic units
- Review and consideration of the recommendations and commitments in the work plan, *Implementing the Recommendations of the External Review of the University of Minnesota Human Research Protection Program* and *CTSI Recommendations for Integration of Clinical Research Studies in the Department of Psychiatry into the University of Minnesota CTSI.*
- Online exploration of HRP training resources and requirements from eight other universities, and interviews with HRP leaders at four of those institutions.

Based upon ***the review of federal and AAHRPP policies and requirements as well as current University HRP and research ethics training and education practices***, the University does offer the required training framework and is satisfactorily addressing 'areas of need' for recertification. However, in question (at the University of Minnesota and other institutions) is whether almost completely online, knowledge-based education is sufficient to ensure that investigators and research personnel develop and can apply the appropriate skills and attitudes at the point of actual human participant research studies in a competent and ethical manner. Does completion of CITI modules actually result in the ethical and skilled behaviors that should characterize high quality research with human participants? In addition, metrics, monitoring, and evaluation of the *results* of training that would contribute to responding to such a question do not appear to be in place currently at the University.

The ***review of websites and interviews with HRP leadership at other institutions*** suggests quite clearly that the HRP and ethics training at the University of Minnesota has much in common with programs at other leading universities, for example:

- Collaborative Institutional Training Initiative (CITI) learning modules serve as the backbone of its HRP program

- The Responsible Conduct of Research program is often a locally-developed offering
- With the exception of IND/IDE research, good clinical practice training is generally offered as an option for investigators or as part of recertification
- HRP renewal training is generally required every three – four years, and is typically a repetition of the same CITI modules originally completed
- Training across the institutions is predominantly online and knowledge-based, though a few of the institutions surveyed do require attendance at in-person training events.

The institutions surveyed included: Duke University/Duke Medicine, Emory University, Harvard University, Johns Hopkins University, UCSF, University of Michigan, Washington University, University of Pennsylvania, . All except for one of the institutions surveyed offer HRP and RCR training through enterprise learning management systems (LMS), which also track and provide reporting and audits of training completion. In most cases, the LMS is integrated with the institutions eIRB system.

Two of the institutions developed and mandated Clinical Research coordinator training that involves in-person workshops and ongoing recertification, including renewal of GCP training.

Other institutions are waiting to learn about the national decision from NCATS regarding the requirement for all study personnel involved in interventional human subject research to complete GCP training.

Interviews with University of Minnesota research personnel suggested needs to go beyond the current national requirements in the following high level areas:
- Address advanced training needs for research with vulnerable individuals and/or those with diminished or fluctuating capacity to consent
- Update and clarify the University's human research protection training and education policies
- Upgrade and establish a clear and supported HRP Education and Training infrastructure
- Engage departments and centers to create and participate in a university-wide 'community' supporting a 'Culture of Ethics in Research'
- Ensure consistent, accessible, and transparent ongoing communication about HRP education and training across the university.

A series of ***priority recommendations*** are based upon the data and input summarized above. Details and descriptions of tasks supporting each recommendation are included in the final section of this report, some of which may already be underway within the HRPP/IRB, CTSI, and/or other research units.
1. Define a transparent **UMN infrastructure to manage HRP education for investigators and the research workforce**
2. Decide upon and implement a **central human research protection education, training, and communication unit**, to work with HRP subject matter experts University-wide, supported by enterprise commitment and funding
3. As part of the Community Engagement initiative, engage patients and prospective research participants in the design and development of training programs for investigators and the research workforce
4. Focus initial training development and implementation on:
    a. Advanced training for **research with vulnerable individuals and those with diminished capacity to consent**
    b. **Upgraded initial and recurrent training in ethics and the conduct of human research**

    c. Build on current efforts to engage U of M colleges, departments, and centers to create a university-wide community supporting the development of a **Culture of Ethics for Human Participant Research**
    d. Plan to pilot training programs in the **Department of Psychiatry**
5. Create a web-based, comprehensive learning platform—using current and recently implemented enterprise systems—to manage the functions of learning programs, including resource cataloging, registration, tracking, reporting, and prompting of research personnel for ongoing training requirements.
6. Over the next 3 years, develop, pilot and implement a competency-based curriculum plan that develops knowledge, skills, and attitudes and includes learner assessment as well as ongoing program evaluation (perhaps a systematic review and update of activities every two – three years).

Recommendations: University of Minnesota HRP Education and Training

At a high level, priority need for changes exist in the following high-level areas:

1. Define a transparent **UMN infrastructure to manage HRP education for investigators and the research workforce**.
2. Decide upon and implement a **central HRP education, training, and communication unit**, to work with HRP subject matter experts University-wide, supported by enterprise commitment and funding
3. As part of the Community Engagement initiative, engage patients and prospective research participants in the development and delivery of training programs for investigators and the research workforce
4. Focus initial training development and implementation on:
    a. Advanced training for **research with vulnerable individuals and those with diminished capacity to consent**
    b. **Upgrade initial and recurrent training in ethics and the conduct of human research**
    c. Build on current efforts to engage U of M colleges, departments, and centers to create a **Culture of Ethics for Human Participant Research**
    d. Plan to pilot programs in the **Department of Psychiatry**
5. Create a web=based comprehensive learning platform—using current and recently implemented enterprise systems—to manage the functions of learning program, including resource cataloging, registration, tracking, reporting, and prompting for ongoing training requirements.
6. Over the next 3 years, develop, pilot and implement a competency-based curriculum plan that develops knowledge, skills, and attitudes and includes learner assessment as well as ongoing program evaluation (perhaps a systematic review and update of activities every two – three years).

The purpose of this section is to outline high-level recommendations for addressing these areas. The recommendations in this section largely represent the conclusions and opinions of Janet Shandeling, PhD, the curriculum and instructional designer authoring the Needs Assessment & Gap Analysis report, with some input from HRP leadership engaged with this initiative.) Specific details (e.g., tasks, roles and responsibilities, specific deliverables, and timeframes) could be included in a subsequent curriculum plan based upon review, and finalization of this report's recommendations.

The following priority recommendations are organized into high-level categories. Recommendations are drawn from and integrate all of the sources of data summarized in this report:

- Federal requirements and policies, certification requirements, and national initiatives
- Current U of M HRP training requirements and resources
- HRP educational requirements at other universities
- Action commitments made in response to the U of M HRP External Review
- Input from research leaders at the U of M and at other universities.

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Priority Recommendations

	Recommendations
1. Define a transparent UMN infrastructure to manage HRP education for investigators and the research workforce	a. Define and agree upon the HRP roles and responsibilities for all aspects of human research protection enterprise-wide, including: Center for Bioethics, Community, CTSI, Fairview, HRPP/IRB, OVPR/RCO, and Schools/Centers/Departments University-wide b. Establish a transparent, collaborative cross-unit executive HRP Educational Advisory Group with defined Responsibilities Accountability, Support, Consultation, and Information Network (RASCI) among the HRP executive leaders. c. Assign that cross-departmental infrastructure group the initial responsibility to review and decide upon University of Minnesota **policies and mandates** regarding: • Basic HRP training for investigators, CRCs, research staff, trainees and IRB members regarding content (e.g., should GCP training be included?), format (e.g., is CITI training sufficient or should learner assessment/ demonstration of basic competencies be included) • Advanced HRP training for investigators, CRCs, research staff, and IRB members with a focus on 'high risk' research, for example, with vulnerable individuals and/or individuals with diminished decision-making capacity, international research, research with biospecimens, etc. • Content, format (e.g., online + in-person electives) and frequency for continuing renewal of HRP training for investigators, CRCs, research staff, and IRB members • Requirements for and tracking of advanced level training for investigators and research teams for serious and/or continuing noncompliance • A mandated system and responsibilities for ensuring basic and renewal training of research teams is complete, particularly for vulnerable populations research, for all personnel involved in a study. This should align with protocol review and remediation for noncompliance, and specify timing of training in relationship to the date of protocol submission to the IRB. d. Determine the locus for decision-making regarding the planning, purchase of and/or instructional design and development of HRP, RCR, and advanced training; recertification training; and ongoing Culture of Ethics U of M offerings. (See Recommendation 2 regarding an HRP Education and Training Unit.) e. Address policies and mandates regarding training for all U of M clinical research coordinators, including challenges faced when reporting solely to investigators (as in c. above) f. Ensure a financial model that provides training and support to all investigators and research teams without cost being a barrier to access and insuring compliance without excessive time requirements that dis-incent clinical research.

	Recommendations
2. Establish a central human research protection education, training, and communications unit	a. Create and resource a U of M HRP Education Specialist/Director (and necessary staff) to lead a centralized unit (based upon determination of 1d above) and work with U of M subject matter experts and existing resources to: • Develop HRP curriculum sourcing, development, learning assessments, training dissemination, program evaluation and QA, and ongoing updates. (IRB member training should be coordinated with these efforts but may be developed and managed separately.) • Carry out of guidelines for basic and advanced research compliance and human subjects protection training, under oversight from the Educational Advisory Board • Serve as the U of M liaison with national efforts such as the NCATS GCP initiative and ECRPTQ Researcher Competencies initiative, and suggest how to integrate into the U of M curriculum as those move forward • Collaborate on or manage the development and implementation of U of M Culture of Ethics forums, podcasts, webinars, etc. in collaboration with all other U of M units engaged in HRP leadership and management • Work with other institutions and instructional design consultants to source and/or develop learning programs to meet the goals of the U of M HRP curriculum plan that will include knowledge, skills, and attitudes for HRP • Ensure that timely, accessible, and clear communications regarding policies, training offerings, new regulations are created and disseminated to the research community • Monitor the changing national policies and 'state of the art' and externally available training resources, bringing advances and recommendations to the HRP Educational Advisory Group b. Either within or affiliated with the Education and Training unit, assign clear responsibility to a Communications specialist who will be responsible for developing and maintaining a comprehensive, easily accessible HRP website (e.g., *humanresearch.umn.e*du), creating and aligning regular and continuous communications in other media formats (e.g., newsletters, updates), and ensuring two-way communication with all of the U of M research audiences (community participants, investigators, coordinators and research staff, IRB members, faculty, etc.) This position will require appropriate staff resources, including information technology support. • Through a central Human Research Protection website, provide access to individualized training self-assessments, training reports, training offerings, CITI, and regular updates of U of M HRP offerings and other communications media, making access to all information about human participant research highly accessible and transparent for the research community. This should include pro-active automatic notifications of faculty and staff and should be linked closely to the IRB website. • Use the website to provide overviews and centralized access via the U of M learning management system (LMS) to all U of M and other training materials, including CITI, the CRC Orientation, Clinical Research Methodologies modules, etc. • Provide links on the website to consultation and support services, for example, from the IRB.

	Recommendations
2. Establish a central human research protection education, training, and communications unit (cont'd)	c. Within that HRP Education and Training Unit, strongly consider the creation of a new **position of Human Research Procedures, Policies, and Ethics Education Coordinator** linking to Center for Biomedical Ethics. (Depending upon the individual skill sets and time, It might be possible to consolidate this position with the 2a leadership position) This individual would ensure that required and optional training is available and current and easily accessible to the research community. • When determined and developed, this position would coordinate and administer interdepartmental forums, WebEx-based presentations, podcasts, or other U of M Culture of Ethics offerings • Manage updates to all existing training and launch new offerings. • Work with NIH and other training grants to help fulfill requirements for HRP and RCR training compliance • Serve as the liaison with OVPR units responsible training documentation and reporting systems to continuously monitor that all training offerings are being appropriately tracked and reported on transparently (including RCR, HIPAA, GCP, CITI, advanced training) d. Develop the option of offering Continuing Education credit for advanced and recertification training, including a system to approve, track and credit HRP CE 'one-of-a-kind' activities offered at UMN or elsewhere (conferences, etc) e. Collaborate with the IRB leadership to support, as needed, the design of training that can be integrated into the Protocol and Study design module being developed in collaboration with Huron Consulting.
3. Engage patients and prospective research participants in the development and delivery of training programs for investigators and the research worforce	a. Gather input and feedback from patients and families regarding their priorities and areas of concern with U of M human research protection (as part of this Needs Assessment Process) b. Within the Education and Training curriculum development process, engage community members/research participants and U of M community content experts as some of the 'content experts' in the development of HRP training for researchers as well as training for research participants c. Develop and implement learning materials (HRPP/IRB) for legally authorized representatives (LAR) to explain the LAR role, authority, and considerations for making decisions.
4. Focus initial training development and implementation on a) vulnerable research populations, b) ethics and conduct of human research, c) creating a U of M Culture of Ethics, and d) piloting all programs in the Department of Psychiatry	a. **Training for Research with Vulnerable Individuals and/or Those with Diminished Capacity to Consent** • Develop advanced training (required and recommended) on ***consenting*** for investigators and research staff in collaboration with content experts from HRPP/IRB, CTSI, Center for Bioethics, patients and families from the community, Fairview psychiatrists, U of M psychiatry and psychology faculty, etc. This will include development, pilot testing (if necessary) and/or implementation of competency based training. ○ Have the Educational Advisory Group consider a requirement that all researchers who consent in greater than minimal risk studies be qualified through demonstration of competencies to do so. ○ Develop template consent documents and processes with easily accessible examples and practice cases • As tools are developed/sourced for assessing participants' capacity to consent and for monitoring ongoing capacity, develop and implement experiential training on their use • Adapt the learning programs to provide specialized training for an IRB panel (who will be charged with evaluating all research with these populations) on the unique needs of research with individuals with impaired or fluctuating capacity to consent or who belong to vulnerable populations.

	Recommendations
4. Focus initial training development and implementation on a) vulnerable research populations, b) ethics and conduct of human research, c) creating a U of M Culture of Ethics, and d) piloting all programs in the Department of Psychiatry (cont'd)	b. **Augment Training on the Ethics and Conduct of Human Research** • Develop and pilot test/source a cross-training (or even team-based training?), competency-based curriculum for investigators, clinical staff, and IRB members on the ethics, mechanics, and importance of research in collaboration with experts from HRPP/IRB, CTSI, Center for Bioethics • Include as topics for increased knowledge, skills, and attitudes: GCP, reporting adverse events, protocol deviations, source documentation, documenting informed consent, inclusion/exclusion, safety monitoring, etc. • Review the RCR basic program and integrate into a comprehensive curriculum with advanced and ongoing mandated and elective options o Consider in the future requiring a demonstration of ability to apply the knowledge learned in skill-based cases and simulations and learning assessments, particularly for non-compliance remediation • (Where is training on OnCore and REDCap offered?) c. **Engage U of M colleges, departments and centers to create a U of M Culture of Ethics** • Enhance the availability of and access to a transparent centralized HRP website and regularly disseminated university-wide HRP updates, newsletters, presentations, podcasts, etc. • Engage the University-wide research community in learning about and adapting the national Enhancing Clinical Research Professionals' Training and Qualifications (ECRPTQ) competencies and NCATS' GCP training framework as those are approved and adapted nationally. Update the community as standards evolve. • Hold campus conversations and forums across the university, including Research Grand Rounds that provide for peer-to-peer learning, highlighting what works and what are the challenges in human participant research • Develop required and recommended advanced and refresher training modalities to be promoted and/or implemented by academic units in faculty, investigator, and research staff meetings. • Develop training materials and train facilitators and moderators ('train-the-trainers') to offer opportunities for discussions and peer-to-peer learning at department faculty meetings, Research Grand Rounds, college forums, or research team events on topics such as: vulnerable populations research; university policies related to study monitoring; scientific review; and new and evolving regulatory requirements. Offer CE credit as appropriate. • Develop annual updates (perhaps in online format and/or in-person forums) regarding new regulations and policies, audit findings, best practices, etc. Consider collaborating on this with other institutions. Offer CE credit. d. **Plan to Pilot All New Training (4a and b) in the Department of Psychiatry** • Use feedback from pilot usage in Psychiatry research to finalize new training offerings prior to dissemination University-wide.

	Recommendations
5. Develop an integrated learning platform	a. Identify an easily accessible, transparent, welcoming Learning Management System (LMS) through which all investigators, CRCs, research staff, IRB members, and research participants can access all HRP learning materials. Ensure that that system: • Integrates with the University's upcoming eIRB system being developed with Huron Consulting • Is easily accessible through the central HRP Education and Training website • Provides a clear self-assessment for determining what training each individual research professional requires initially and as they become involved in additional research activities • Provides access to CITI as well as U of M online learning modules and courses (and links to external resources) • Provides easy registration for other U of M forums, Research Grand Rounds, conferences • Provides access to a wide variety of training materials in various formats such as synchronous and asynchronous webinars, podcasts, research papers, presentations • Notifies faculty and staff of required training, upcoming deadlines, compliance status and other action items • Manages CE if/when offered • Documents and provides certificates of all online and in-person training that is completed b. Integrate/enhance U of M reporting on all HRP training to provide accessible and clear reporting to users, departments, IRB, SPA, and a University-wide monitoring and quality assurance system • Build into that system prompts for all research professionals and their departments regarding upcoming training recertification requirements (similar to REPA) • Ensure that completion of all CITI modules (required and recommended) can be captured and reported upon by that system.
6. Develop over time a competency-based curriculum plan that includes learner assessment and metrics for program evaluation	a. Based upon the top priorities accepted and committed to from this needs assessment, develop a plan outlining the tasks, responsibilities, timeframes, and budget for developing, piloting, and finalizing the priority training programs identified and agreed to from report. Include wherever appropriate: • Learning that addressing knowledge, skills, and attitudes • Experiential and interactive learning formats • Modular learning materials that can integrated and re-used for a variety of learner audiences and purposes) • Learning assessments and demonstration of competencies • Metrics and process for program evaluation and ongoing quality assurance. ○ As one metric, benchmark the U of M's training against peer institutions to ensure our HRPP training meets or exceeds the norm (p. 17, External Review Work Plan)

	Recommendations
6. Develop a competency-based curriculum plan that includes learner assessment and metrics for program evaluation (cont'd)	b. Following review and finalization of the previous priority recommendations, build into the curriculum plan goals and objectives for addressing some secondary priorities: • Review currently-required CITI courses and determine the most appropriate for basic, advanced, and non-compliance training, particularly in relation to a competency-based, hybrid training programs • Identify other internal and external high quality resources for training and for knowledge or competency assessment • Develop modules and/or hybrid advanced programs on international research, research with biospecimens, research involving the use of medical records in clinical environments, and other topics • Completion of a hybrid curriculum for ***clinical research coordinators***: ○ Build upon the almost-complete competency framework developed by CTSI in conjunction with Mayo ○ Integrate the current online curriculum ○ Secure a pool of AHC-wide mentors available to support CRCs, particularly those in small studies, and adapt the Optimizing the Practice of Mentoring course for those mentors, as needed ○ Develop and include an experiential- and case-based module on 'Challenges of Research Management' (or some such term). Address the challenges that CRCs can face when questioning ethical conduct of research that may differ from the perspective of their investigator/boss. Consider offering this as a 'team-based' course, and including all members of the research team—including investigators. • Create a module/hybrid program for investigators on 'How to Do Clinical Research' similar to the CRC course, 'Navigating Research.' That course could contain an interactive flow chart of the research process with call-outs explaining and giving examples of each step within the scope of the whole process. Use it as 'just-in-time' training for investigators at the point of need, and demonstrate how changes made in one step (e.g., change to a protocol) can affect others. Use case examples.

Recommendations: Conclusion

The section, 3.3.1.3 Conclusion, of the Final Report of the External Review states that ". . . it is essential that individuals at all levels of the human research protections program be knowledgeable about the ethical principles, as well as the specific regulatory, policy, and procedural requirements related to human subjects research. . . It is critical that training in human subjects protections not fall prey to the decision to 'right-size' educational requirements in the wake of ongoing institutional efforts to reduce the administrative burden placed on researchers. . . Advanced level training should allow for in-depth exploration of specific topics in human subjects protections." We recommend that the University of Minnesota strengthen the current knowledge-based human research protection training and work to develop, assess and implement skill and attitude-based training over the next three years. The resulting training program should be comprised of a hybrid of online, discussion, peer-learning, case and simulation, problem-solving practice, learning assessment, and demonstration of competence. The training needs to insure the appropriate levels of training for the specific research being performed and that human subjects are appropriately protected. Simultaneously the training must be high quality and the potential burdens for investigators and staff to understand, obtain and remain compliant with the required training should be minimized. Advanced training should be strongly encouraged, supported and rewarded.

Appendix 1

Education and Training of Investigators and Research Team Members: Needs Assessment and Gap Analysis

Final Report
July 5, 2016

Submitted by Janet Shanedling, PhD
Education Manager

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Executive Summary

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 or fluctuating capacity to consent. In response to an independent assessment of the University of Minnesota's Human Research Protection program, President Eric Kaler charged the Vice President for Research (Brian Herman) and Vice President for the Health Sciences (Brooks Jackson) to create an implementation team to review and implement the recommendations of the external reviews. The implementation team developed a work plan, a key component of which addresses the education and training of investigators.

This report comprises the results of a Needs Assessment/Gap Analysis conducted by an independent consultant, Janet Shanedling, PhD, and concludes with recommendations for enhancing human research protection (HRP) training and education at the University of Minnesota.

To ascertain the current environment within which the University provides human research protection education and training to investigators and research personnel, ***the needs assessment process included***:

- Online review of federal and accreditation (AAHRPP) training requirements and policies, and a review of National Clinical and Translational Science reports and documents pertaining to current GCP and research competency initiatives
- Survey of University of Minnesota websites and resources documenting current HRP and ethics training requirements and resources
- Interviews and discussions with University of Minnesota personnel involved in HRP education and training from multiple U of M offices and academic units
- Review and consideration of the recommendations and commitments in the work plan, *Implementing the Recommendations of the External Review of the University of Minnesota Human Research Protection Program* and *CTSI Recommendations for Integration of Clinical Research Studies in the Department of Psychiatry into the University of Minnesota CTSI.*
- Online exploration of HRP training resources and requirements from eight other universities, and interviews with HRP leaders at four of those institutions.

Based upon ***the review of federal and AAHRPP policies and requirements as well as current University HRP and research ethics training and education practices***, the University does offer the required training framework and is satisfactorily addressing 'areas of need' for recertification. However, in question (at the University of Minnesota and other institutions) is whether almost completely online, knowledge-based education is sufficient to ensure that investigators and research personnel develop and can apply the appropriate skills and attitudes at the point of actual human participant research studies in a competent and ethical manner. Does completion of CITI modules actually result in the ethical and skilled behaviors that should characterize high quality research with human participants? In addition, metrics, monitoring, and evaluation of the *results* of training that would contribute to responding to such a question do not appear to be in place currently at the University.

The ***review of websites and interviews with HRP leadership at other institutions*** suggests quite clearly that the HRP and ethics training at the University of Minnesota has much in common with programs at other leading universities, for example:

- Collaborative Institutional Training Initiative (CITI) learning modules serve as the backbone of its HRP program

- The Responsible Conduct of Research program is often a locally-developed offering
- With the exception of IND/IDE research, good clinical practice training is generally offered as an option for investigators or as part of recertification
- HRP renewal training is generally required every three – four years, and is typically a repetition of the same CITI modules originally completed
- Training across the institutions is predominantly online and knowledge-based, though a few of the institutions surveyed do require attendance at in-person training events.

The institutions surveyed included: Duke University/Duke Medicine, Emory University, Harvard University, Johns Hopkins University, UCSF, University of Michigan, Washington University, University of Pennsylvania, . All except for one of the institutions surveyed offer HRP and RCR training through enterprise learning management systems (LMS), which also track and provide reporting and audits of training completion. In most cases, the LMS is integrated with the institutions eIRB system.

Two of the institutions developed and mandated Clinical Research coordinator training that involves in-person workshops and ongoing recertification, including renewal of GCP training.

Other institutions are waiting to learn about the national decision from NCATS regarding the requirement for all study personnel involved in interventional human subject research to complete GCP training.

Interviews with University of Minnesota research personnel suggested needs to go beyond the current national requirements in the following high level areas:
- Address advanced training needs for research with vulnerable individuals and/or those with diminished or fluctuating capacity to consent
- Update and clarify the University's human research protection training and education policies
- Upgrade and establish a clear and supported HRP Education and Training infrastructure
- Engage departments and centers to create and participate in a university-wide 'community' supporting a 'Culture of Ethics in Research'
- Ensure consistent, accessible, and transparent ongoing communication about HRP education and training across the university.

A series of ***priority recommendations*** are based upon the data and input summarized above. Details and descriptions of tasks supporting each recommendation are included in the final section of this report, some of which may already be underway within the HRPP/IRB, CTSI, and/or other research units.
1. Define a transparent **UMN infrastructure to manage HRP education for investigators and the research workforce**
2. Decide upon and implement a **central human research protection education, training, and communication unit**, to work with HRP subject matter experts University-wide, supported by enterprise commitment and funding
3. As part of the Community Engagement initiative, engage patients and prospective research participants in the design and development of training programs for investigators and the research workforce
4. Focus initial training development and implementation on:
    a. Advanced training for **research with vulnerable individuals and those with diminished capacity to consent**
    b. **Upgraded initial and recurrent training in ethics and the conduct of human research**

   c. Build on current efforts to engage U of M colleges, departments, and centers to create a university-wide community supporting the development of a **Culture of Ethics for Human Participant Research**
   d. Plan to pilot training programs in the **Department of Psychiatry**
5. Create a web-based, comprehensive learning platform—using current and recently implemented enterprise systems—to manage the functions of learning programs, including resource cataloging, registration, tracking, reporting, and prompting of research personnel for ongoing training requirements.
6. Over the next 3 years, develop, pilot, and implement a competency-based curriculum plan that develops knowledge, skills, and attitudes and includes learner assessment as well as ongoing program evaluation (perhaps a systematic review and update of activities every two – three years).

Background and Goals of the Needs Assessment

In response to an independent assessment of the University of Minnesota's Human Research Protection program, President Eric Kaler charged the Vice President for Research (Brian Herman) and Vice President for the Health Sciences (Brooks Jackson) to create an implementation team to review and implement the recommendations of the external reviews. The implementation team developed a work plan, a key component of which addresses the education and training of investigators by stipulating:

- A new position of Human Research Procedures, Policies, and Ethics Education Coordinator
- Establishing guidelines and expectations for basic and advanced research compliance and research participant protection training
- Ensuring that required and optional training modules are available and kept current
- Specific attention be given to advanced training in the use of research participants with limited or fluctuating capacity to consent
- Collaborative development of training by the HRPP, CTSI, Center for Bioethics, other U of M resources, and community members (including research participants).

A curriculum and instructional design consultant was hired to address the action items in the Education and Training of Investigators section of the work plan, specifically to complete a comprehensive Needs Assessment/Gap Analysis and develop a curriculum plan to address the needs or gaps identified.

Based upon the recommendations and action items of the Implementation Team's work plan as well as input from University leadership involved in human research training, the ***goals*** of the needs assessment were defined as:

1. Evaluate existing learning programs and materials (initially against regulatory standards, and with plans toward nationally-defined competencies) at the University of Minnesota and at other leading research institutions.

2. Identify training gaps, especially in ethics and research with vulnerable populations

3. Review and define mandatory basic and refresher training for investigators, needed areas for elective training, and potential required training in critical areas

4. Plan for integrated and coordinated training for investigators and workforce, including the implementation of a tool for individuals to easily self-assess and identify their research training requirements

5. Explore whether research learning competencies/target behaviors and metrics for assessing learning have been defined, and the possibility of adopting those for use at the University of Minnesota

6. As needed to cover gaps, define the needed curriculum development creation and implementation plan that outlines the development and acquisition of learning programs in the form of online, seminars, or printed materials, including small- and large-group discussion sessions:
    a. Plan to develop and implement a self-assessment tool for individual researchers to determine required and recommended training (ensuring alignment with the new IRB tool being developed by IRB/Huron Consulting with a possible focus on protocol development?)

b. Ensure that going forward the curriculum is engaging and interactive, using mixed methods in addition to lecture and online, including possibilities of train-the-trainer models, *modules adaptable and accessible for various types of research learners, etc.*
c. Develop a plan for regular updating and communication about the curriculum for and with the research community, including monitoring, reporting, and evaluation of the University's training efforts.
d. Analyze current tracking tools and plan to ensure that they automatically track and report on all training required and completed, including communication regarding recertification training needed. This process needs to be user friendly for the investigators.
e. Determine the extent to which metrics and learning assessment should be enhanced in order to demonstrate clear learning and capability of application from training to actual research. {Note: It was determined that this is not really being done, apart from multiple choice questions in CITI – see the design document for the Informed Consent course for more details.}

7. Clearly define key responsibility roles—particularly decision-making—among U of M offices involved in AHRP (RCO, CTSI, HRPP-IRB, Center for Bioethics) for ongoing training management, development, and delivery, as well as policy-making.

A set of Assumptions related to carrying out the needs assessment were developed prior to beginning the needs assessment process and were vetted with the identified stakeholders. Those assumptions used in development of this report are listed below:

1. The **scope** of this needs assessment and curriculum plan involves human research protection training for biomedical and social/behavioral research workforce. Training requirements pertaining to HIPAA, COI, Environmental Health and Safety, and protecting animal subjects are outside the scope of this analysis.

2. To support the accomplishment of this educational resources gap analysis and ensure its alignment with other AHRP initiatives, the **Stakeholder Group** will be comprised of representatives from HRPP, RCO, CTSI, Center for Bioethics, SPA, and appropriate Fairview representation. Other input from the schools and departments and community will be solicited as needed. Recommendations from the stakeholders will be forwarded for final decisions/approval to T. Schacker, D. Ingbar, and ultimately B. Jackson and B. Herman.

3. The **audiences** for whom we are defining training gaps include: investigators/co-investigators, key personnel (including graduate and undergraduate students, research assistants, study coordinators, faculty advisors, research fellows, etc.), IRB members, and department heads.

4. This gap analysis needs to **coordinate with similar needs** across other research compliance areas (e.g., animal research, environmental health and safety, etc.), specifically in areas of infrastructure such as an LMS or tracking system that can serve all areas.

5. While the U of M HRPP training does address the nine key areas defined by NIH in 2009 (built upon the 2000 OHR Objectives), we should **define University of Minnesota standards** (whether those areas or the 2015 Competency Domains and Statements from the NCATs work, or other) against which to evaluate the University's current offerings and determine needs for the future. For the

purposes of this gap analysis, we will initially generate a plan that ensures that the U of M AHRP program meets the minimum regulatory requirements. Recommendations will be included in the gap analysis report and curriculum plan to subsequently implement ongoing standards or competencies that may result in moving the University toward being an exemplary program.

6. The programs established need to fulfill current requirements and should be designed to be 'state of the art,' but at the same time need to be designed and implemented in ways that facilitate high quality, safe research while minimizing non-essential required burdens on investigation.

Overview of the Process

The University's President Kaler charged the Vice President of Research, Brian Herman, and the Vice President for the Health Sciences, Brooks Jackson, to oversee the AHRP team implementing the recommendations of the external reviews. David Ingbar, MD, Associate Director, Research Education, Training, and Career Development (CTSI-Ed) and Tim Schacker, MD, Associate Director, Clinical Translational Research Services, are the faculty co-leaders of the component addressing the Education and Training of Investigators, and thus, the Needs Assessment process. The following individuals have served as Stakeholders and reviewers of the process and deliverables for the Needs Assessment and Curriculum Plan.

- Debra Dykhuis, Executive Director, Human Research Protection Program
- Lisa Johnson, Assistant Director, Clinical and Translational Research Services, Clinical and Translational Science Institute
- Lisa Warren, Ass't Vice President, Office of the VP of Research
- Michelle Lamere, Assistant Director for Education Programs, CTSI
- Mickey Eder, Associate Director, Community Engagement to Advance Research and Community Health
- Pamela Webb, Associate Vice President for Research Administration
- Sarah Waldemar, Director, Research Education and Oversight, Office of the VP of Research
- Steven Miles, Professor, Center for Bioethics and Department of Medicine

Additional reviewers for the Needs Assessment and Curriculum Plan are being identified to represent Fairview and the Community.

The curriculum/instructional designer completed the following tasks as part of the Needs Assessment:

- ***Reviewed federal, accreditation, and NCATS reports and documents pertaining to HRP training requirements:***
    - HRP training requirements for biomedical and social/behavioral research from federal agencies and national organizations including: CDC, DOD, FDA, HHS/OHRP, NIH, and SOCRA
    - Accreditation standards and the University of Minnesota 2015 Site Visit Report from the Association for the Accreditation of Human Research Protection Programs (AAHRPP)
    - Documentation and reports from the Enhancing Clinical Research Professionals' Training and Qualifications (ECRPTQ) work force (for the National Center for Advancing Translational Sciences (NCATS)) that included recommendations for Good Clinical Practice (GCP) training, Competency Domains as well as Competency Statements for Research Professionals, Competency Assessments, and Catalog of training programs/links currently available nationally.
- ***Surveyed University of Minnesota resources to document current training requirements, resources, processes, perceived needs, and recommendations:***
    - Explored U of M websites and documentation not only for HRP training requirements but also to experience how clear and transparent the information is for researchers to locate
    - Interviewed and communicated with 15 U of M personnel from HRPP/IRB, Department of Medicine, School of Public Health, CTSI Populations and Community Engagement, Research Compliance Office/OVPR, Pediatrics, Center for Bioethics, and other CTSI units

- Considered the previous data and input with the work plan entitled: *Implementing the Recommendations of the External Review of the University of Minnesota Human Research Protection Program* as well as the *CTSI Recommendations for Integration of Clinical Research Studies in the Department of Psychiatry into the University of Minnesota CTSI.*

- ***Surveyed HRP resources from eight other universities to document their current training requirements, resources, processes, and perceived needs:***
  - Explored websites at Duke University, University of Pennsylvania, Johns Hopkins University, Harvard University, University of Michigan, UCSF, Emory University, and Washington University
  - Interviewed IRB Directors, research and training managers, and a VP for Research, Regulatory & Compliance Oversight at University of Michigan, Johns Hopkins University, Emory University, and University of Pennsylvania.

- ***Concluded with a series of recommendations and tasks that integrate the priority needs and gaps identified from the data and input gathered.***

Requirements, Policies, and Initiatives for Human Research Protection

This section provides a summary of what was learned about:

1. Federal requirements pertaining to human research protection training
2. AAHRPP certification requirements
3. University of Minnesota HRP training requirements
4. Current initiatives from NCATS regarding recommendations for GCP training and for establishment of competencies and assessments for research professionals.

1. Federal Requirements for Biomedical and Social/Behavioral HRP Education and Training

Agency	Human Subject Research Investigators: Training Requirements
CDC	• Scientific Ethics Training Basic Course (choice of): ○ CITI RCR course (Biomedical or Social/Behavioral) ○ NIH Protecting Human Research Participants ○ FHI360 Research Ethics Training ○ CITI GCP Course: Advanced/Special Requirements for PIs, supervisors, or administers of biomedical research with drugs, devices, biologics • The CDC Human Research Protections Policy (recertified July 2015), stipulates: Prior to serving as investigators, they must 1) certify HRPO-approved education in research ethics and human research regulations and obtain certification of competency. 2. Maintain competency in research ethics and human research regulations and certify at least once every 3 years.
DOD	Section 5, Education and Training, of DoD Directive (DoDD) 3216.02 states under paragraph (d): "When assessing whether to support or collaborate with a non-DoD institution for research involving human subjects, the DoD Components should evaluate the non-DoD institution's education and training policies to ensure the personnel are qualified to perform the research. The rigor of the evaluation should be appropriate for the complexity and risk of the research."
FDA	. . . the regulations require that sponsors select investigators who are qualified by training and experience as appropriate experts to investigate the drug. The regulations do not specify the minimum requirements nor do the regulations specify what qualifications an investigator must have in order to be considered qualified by training and experience to conduct a clinical investigation. Sponsors have discretion in determining what qualifications, training, and experience will be needed, ***based on the general recognition that this would include familiarity with human subject protection (HSP) regulations (i.e., 21 CFR Parts 50 and 56) and practices as well as good clinical practice (GCP) regulations (see 21 CFR Part 312) and standards (e.g., ICH E6) for the conduct of clinical studies.)***
HHS/OHRP	The HHS regulations for protecting human research participants (45CFR, part 46) don't specify required training for investigators of human subjects research. However, institutions conducting HHS-supported human subjects research must comply with HHS regulations. Therefore, OHRP recommends that institutions and their designated IRBs ensure that investigators ***maintain continuing knowledge to comply with: relevant ethical principles, relevant federal regulations, written IRB procedures, OHRP guidance, other applicable guidance, state and local laws, institutional policies for the protection of human subjects***. In addition, the OHRP recommends that investigators complete training ***before*** conducting human subjects research.

Agency	Training Requirements
NIH	For NIH-awarded human subjects research: • Key personnel must be trained. Investigators who conduct studies with human specimens, tissues, or data that do not involve human subjects "do not need to fulfill the education requirement." • The NIH does not endorse any specific programs to fulfill the educational requirement for the protection of human subjects nor the frequency of training. • ***RCR*** training is 'integral' to all research training programs; Individuals should be responsible for their own RCR instruction that they should take at their various career stages. • ***Instructional Components*** *for "all trainees, fellows, participants, and scholars receiving support through any NIH training, career development award…, research education grant, and dissertation research grant":* ○ ***Substantial face-to-face discussions among participants; a combination of didactic and small-group discussions (e.g., case studies***); and participation of research training faculty in instruction is highly encouraged. "…Online instruction is not considered adequate as the sole means of instruction." ○ The following ***topics*** are "most acceptable": ***1) Conflict of interest, 2) Policies regarding human subjects. . ., 3) Mentor/mentee responsibilities and relationships, 4) Collaborative research, 5) Peer review, 6) Data acquisition, managing, sharing, and ownership, 7) Research misconduct, 8) Responsible authorship and publication, 9) Scientific responsibilities to society, ethical issues in biomedical research, and environmental and societal impacts of scientific research*** ○ Instruction should involve substantive contact hours between the … participants and the participating faculty. Acceptable programs generally involve at least ***eight contact hours*** ○ ***RCR reflection and training should occur throughout a scientist's career*** and be appropriate to the particular career stage(s) of the individual(s)—undergraduate, post-baccalaureate, predoctoral, postdoctoral, and faculty levels. "Instruction must be undertaken at least once during each career stage, and at a frequency of no less than once every four years." • ***Compliance***: "It is expected that course attendance is monitored and that a certificate or documentation of participation is available upon course completion." NIH expects institutions to maintain sufficient records to demonstrate that NIH-supported trainees, fellows, and scholars have received the required instruction.

Summary: Federal Requirements for Biomedical and Social/Behavioral HRP Training

Other than the Centers for Disease Control, none of the federal agencies surveyed mandate specific training programs for investigators leading research with human participants, instead, relying on the supported institution to ensure that investigators are appropriately educated. The agencies generally recommend that such training ensure that investigators are familiar with the following before conducting human subjects research:

- Human subject protection regulations and practices (federal, state, and local)
- Relevant ethical principles
- Written IRB procedures and institutional HRP policies.

In addition, the FDA 'generally recognizes' the need for familiarity with good clinical practice regulations and standards. The NIH cites that responsible conduct of research training is 'integral' to investigator preparation, and identifies nine topic areas. Furthermore, they stipulate that online training (such as CITI) is not adequate within their grant framework, but should be accompanied by face-to-face discussion and application, that it should include a minimum of eight contact hours, and that

investigators should participate in training at each stage of their career, in periods no longer than four years apart.

2. Association for the Accreditation of Human Research Protection Programs (AAHRPP) Standards Pertinent to HRP Education and Training

As the accrediting organization for institutions to demonstrate adherence to rigorous standards for ethics, quality, and protection for human research, AAHRPP certification represents important guidelines for the University's human research protection program.

AAHRPP Standard I-1 contains elements that contribute to an institution's systematic and comprehensive human research protection program for all research participants, and outlines methods that ensure that individuals conducting research at the institution are knowledgeable about and follow human research protection policies and procedures. Two elements within that standard pertain specifically to human research protection training and education.

- ***Element I.1.E.*** The Organization has an education program that contributes to the improvement of the qualifications and expertise of individuals responsible for protecting the rights and welfare of research participants
- ***Element I.4.B.*** The Organization conducts activities designed to enhance understanding of human research by participants, prospective participants, or their communities, when appropriate. These activities are evaluated on a regular basis for improvement.

AAHRPP Standard III-1 … Researchers and research staff adhere to ethical principles and standards appropriate for their discipline. In designing and conducting research studies, researchers and research staff have the protection of the rights and welfare of research participants as a primary concern. Specifically:

- ***Element III.2.A.*** Researchers and research staff are qualified by training and experience for their research roles, including knowledge of applicable laws, regulations, codes, and guidance; relevant professional standards; and the organization's policies and procedures regarding the protection of research participants.

To meet these elements, the following are required:

- **Element I.1.E**.
    - Written list of education activities for human subjects research teams
    - Policies and procedures including education requirements and timeframes, methods to monitor education requirements, continuing education and timeframes, corrective action that is taken if education requirements are not fulfilled
    - Education plans and records documenting the above.
- **Element I.4.B.**
    - Policies, procedures, and plans for enhancing the understanding of participants, prospective participants, and communities
    - Policies and procedures for evaluating outreach activities
    - Pamphlets, web sites, events, educational programs, evaluation reports, and QI plans to document the above.
- **Element III.2.1.**
    - Policies and procedures describing metrics/evidence for researchers and research staff to demonstrate competence in research roles and responsibilities

- Demonstration of researcher and research staff's knowledge of laws, regulations, codes, guidance, and institutional policies and procedures that govern their research.

AAHRPP Reaccreditation

In the June 2015 accreditation report, a number of standards were cited as 'areas of concern.' The HRPP/IRB and CTSI have put into a place an implementation plan to address those areas of concern. The plan is being submitted in June 2016. Among the areas of concern are some pertinent to the education/training elements noted above, specifically:

- Element 1.4.B.: Needed process to evaluate and improve U of M's outreach activities to prospective participants and the community to enhance their understanding of research
- Element 1.4.B.: Define education and monitoring that will be integrated into the enhanced community engagement and participant outreach plans.
- Domain II Standards for Institutional Review Board or Ethics Committee: Changes to SOPs and planning for education/training of IRB members is being managed by the U of M HRPP/IRB.

The HRPP has submitted two implementation progress reports (November 2015 and February 2016) to AAHRPP for reaccreditation. The progress reports highlight the HRPP's progress, including progress and development of education and outreach activities.

The HRPP hired an Education and Outreach Specialist, developed new basic and advanced training offerings for IRB members, staff, and the research community in collaboration with departments and experts. An internal (IRB members and staff) and external (research workforce) newsletter was launched in fall 2015 highlighting important regulatory updates, IRB news, and educational content. Work is underway to relaunch the IRB website as a one-stop resource for the research community as it relates to human research protections.

In addition, the specialist launched monthly education reporting that includes information about training activities, results from training feedback surveys, and additional education and outreach activities underway or completed. Monthly reports are shared with HRPP leadership, the Executive IRB Committee, IRB members, and HRPP staff.

Training required for IRB members has been defined to include:

- Attendance at one orientation session facilitated by HRPP leadership
- E-ROC, Ethical Research Oversight Course (formerly the Ethical Oversight of Human Subjects Research online course), is a four and a half hour, online course that presents an in-depth exploration of the function and purpose of institutional review boards (IRBs) through an interactive, realistic interface. The course addresses the roles of IRB members who tackle the challenging, ethical, and regulatory issues of human subjects research.
- IRB Membership Training (Online Moodle Course): An advanced online course that includes units on research integrity and IRB review, vulnerable populations, and evaluation of several case studies. This online course was developed and will be maintained by Courtney Jarboe and HRPP staff to ensure that training includes local context issues.
- Mock IRB Committee meetings: An opportunity to learn about the committee review process and develop relationships with IRB colleagues

In addition, all IRB committee meetings and bi-weekly HRPP staff meetings include an educational agenda item (basic or advanced) facilitated by the Education and Outreach Specialist.

Summary: AAHRPP Requirements

The University of Minnesota is addressing AAHRPP concerns, with resubmittal of implementation plans in place by June 2016.

3. Enhancing Clinical Research Professionals' Training and Qualification (ECRPTQ)

Sponsored by the National Center for Advancing Translational Sciences (NCATS), the ECRPTQ project seeks 'to improve the efficiency, safety and quality of clinical research, as well as reduce redundant training requirements.'

Phase I—GCP Training: The first phase of the project engaged representatives from each CTSA hub in 2014 to compose recommendations for addressing Good Clinical Practice (GCP) standards and training. Consensus on recommendations for GCP training was reached by individuals from all 62 CTSA hubs, after which they were forwarded to NCATS for endorsement. A summary of those recommendations includes:

- **Who:** All study personnel engaged in a drug, device, biologic, and/or behavioral intervention study that meets the new NIH definition* of a clinical trial should receive GCP training.
  * *A research study in which one or more human subjects are prospectively assigned to one or more interventions… to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.* (Summary Report and Consequent Recommendations for GCP Training Expectations for CTSA Consortium Hubs, 11/25/2014) 'Engagement' in a clinical trial was defined as "any clinical research professional involved in the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of a clinical trial." In the early phase of adoption, this would include research investigators and clinical research coordinators formally listed as members of the study team. (Subsequent discussion may endorse training for all team members in future phases of implementation.)
- **What:** GCP content taught should be at a baseline level, and be offered at a methodology selected by each CTSA site. The selection of a training platform will be informed by the CTSA hubs. Minimum criteria for International Conference on Harmonisation GCP training include: GCP Overview, the Principles of ICH GCP, and investigator responsibilities. Research personnel should complete GCP training at a minimum of every three years. CTSA hubs will be expected to track GCP training completion, reporting to their CTSA hub and NCATS.
- **Metrics**: No consensus was reached on exact metrics to be tracked and reported; therefore, a working group was assigned the task of addressing determination of metrics.

Phase II—Competency Domains and Statements: The aim of the second phase of work for the ECRPTQ initiative is to identify the minimal competencies necessary for research personnel to execute safe, high quality, and efficient clinical trials and develop a training approach that will teach and assess those competencies. In September 2015, the ECRPTQ working groups agreed upon eight competency domain areas, for which specific competency statements (for both biomedical and social/behavioral research), assessments, training resources, and current training gaps are being identified. The competency domains that have been forwarded to NCATS for acceptance are:

1. Scientific Concepts and Research Design

2. Ethical and Participant Safety Considerations
3. Investigational Products Development and Regulation
4. Clinical Trials Operations (GCPs)
5. Study and Site Management
6. Data Management and Informatics
7. Leadership, Professionalism, and Team Science
8. Communication.

Summary: ECRPTQ Initiatives

The Enhancing Clinical Research Professionals' Training and Qualifications initiative supported by the National Center for Advancing Translational Science is actively in the process of defining both GCP training standards for research professionals as well as competencies to be demonstrated by investigators, research coordinators, and possibly, all research team personnel. The results of NCATS' review of those recommendations is likely to be announced in the near future.

Conclusion: Requirements, Policies, and Initiatives for Human Research Protection

A determination of the training needs of University of Minnesota personnel engaged in all roles of research with human participants must be based upon standards of behavior as well as content and topic areas determined to be essential to high-quality, ethical performance of human subject research. Today, nationally-defined NIH and OHRP topic areas, AAHRPP certification standards, and (soon) national consensus on ECRPTQ domains and competencies can serve as frameworks against which the University of Minnesota can build and continuously evaluate its training programs. Ideally, those standards would be defined by evidence-based measures and 'best practices.' And ideally, assessment of research personnel's competence at applying the knowledge they have learned in those training programs would be an essential component for ensuring implementation of safe and effective human subject research at the University.

Current University of Minnesota HRP Training Requirements and Resources

This section addresses the HRP education/training requirements, resources and tracking/reports for University of Minnesota investigators and co-investigators, key personnel, and the research workforce. (Education and training of IRB members is being addressed under the auspices of the U of M HRPP/IRB.)

1. HRP Training Requirements

Principal Investigators

Prior to Submitting Protocol for any U of M Research	Human Subjects Research	NIH-Sponsored Research	NSF/USDA/NIFA-Sponsored Research	Research on Drugs or Devices
RCR Core Curriculum (41xx) based on discipline. Research integrity topics: social and professional responsibilities; reporting misconduct; mentoring; authorship; plagiarism; peer review; fiscal responsibilities; intellectual property; research data management. (6 – 8 hours) **Or:** **Standards for Research with Human Participants (BTHX5000; RC6150)** * Three lectures from the semester-long course fulfill RCR requirements: Standards for Publication; Data Integrity/ Confidentiality; Research Misconduct* **And:** Additional courses in topics specific to the research (e.g., COI, Environmental Health & Safety, HIPAA)	**CITI Basic Training Module** (review every 3 years). Biomedical Research Basic Course includes: 1. Belmont Report 2. History and Ethics of Human Subjects Research 3. Basic IRB Regulations and Review Process 4. Informed Consent 5. Social and Behavioral Research for Biomedical Researchers 6. Populations in Research Requiring Additional Considerations and/or Protections 7. Conflicts of Interest in Research Involving Human Subjects 8. University of Minnesota ***Supplemental Modules***: • Avoiding Group Harms • Records-Based Research • Vulnerable Subjects (Prisoners) • Vulnerable Subjects (Children) • Vulnerable Subjects (Pregnant Women, Human Fetuses, and Neonates)	Applicants to NIH Research Training Grants, Individual Fellowship Awards, Career Development Awards, Research Education Grants, Dissertation Research Grants must complete and document: • **RCR core curriculum** • Applicants must "also seek opportunities for formal and informal training that is in-person, ongoing, relevant to their own disciplines, and appropriate to their career stage. Applicants are required to provide detailed descriptions of these activities as part of their applications for funding and reports."	• PIs, co-PIs, and others in upper management positions on these projects must complete the University's **RCR core curriculum** **Or:** • **Research Ethics Training** ○ **(CITI curriculum – 14 modules + 3 Supplemental**) **Or:** ○ **Approved U of M courses and seminars** that include core topics: ○ Authorship and plagiarism ○ Data/research integrity ○ Reporting misconduct	**IND or IDE Training** (**CITI course entitled: GCP for Clinical Trials with Investigational Drugs and Biologics**.) Topics: 1. International Conference on Harmonisation: GCP Requirements 2. Investigator's Responsibilities & GCP 3. Informed Consent 4. Safety Management 5. Investigational Product (Drug) Management 6. Audits, Inspections, and Monitoring of Drug Studies 7. Sponsor Responsibilities and GCP This is a U of M requirement for all sponsors, investigators, and sponsor-investigators on drug or device investigational research.

Research Personnel

If you are staff on: And are a:	**Sponsored Project on Human Subjects Research: Required Training**	**NIH Sponsored Project: Required Training**	**NSF/USDA/NIFA Sponsored Project: Required Training**	**Research on Drugs or Devices: Required Training**
Clinical Research Coordinator	**CITI Basic Training Module**		**Research Ethics Training (CITI Curriculum)**	
Graduate Student	**CITI Basic Training Module**		**Research Ethics course, seminar, or activity from approved list** (Appendix A)	
Post-Doctoral Fellow	**CITI Basic Training Module**		**Research Ethics Training (CITI Curriculum)**	
Clinical Staff /Lab Personnel	**CITI Basic Training Module**		**Research Ethics Training (CITI Curriculum)**	
Undergraduate Student			**Research Ethics Training (CITI Curriculum)** **or:** Course, seminar, or activity from approved list (Appendix A)	

Research Coordinator Training Recommendations or Requirements (if CTSI affiliated CRC)

CTSI-Recommended Orientation for Clinical Research Coordinators	1. U of M New Employee Orientation (in person sessions) 2. HIPAA & Privacy 3. Human Subjects' Protection Training 4. NERS (as required) 5. Research 101 for Clinical Research Coordinators 6. Bloodborne Pathogens 7. CPR Training (in person) 8. Clinical Trials Budgeting Overview	9. Good Clinical Practice in Clinical Research (U of M online course) 10. Hazardous Material Shipping 11. Navigating Research at the University of Minnesota 12. Participant Recruitment & Retention 13. Research Ethics 14. Role of CRC Certification 15. Time and Study Collection System (TASCS) 16. 15. University of Minnesota and Fairview Research Policies

Other CTSI Career Development, Education, and Training Activities (Current and Planned)

Current	Planned
• Bi-weekly Clinical Research Professional Development Seminar (staff) • Monthly Career Development Seminar (faculty, staff, students) • Clinical Research Professional Development Advisory Group (staff) • Specialized training re: research for CSC clinical staff (staff)	• Practice-Oriented research Training (PORT)—conversion/adoption of UMich program. Likely content: Research design, securing funding, research conduct, presenting findings and writing manuscripts, study feasibility, research ethics (faculty) • Blended learning foundational training and orientation for research professionals (will build on existing CRC modules) and complementary preceptor program. Goals are to ensure staff has knowledge and skills to implement high-quality, ethical research; recruit and train a more diverse workforce, and share with other CTSA hubs. (staff) • Community Engagement Studios (with CEARCH) to advance education and training for community and researchers (faculty) • (In development): Informed Consent training modules and workshop (hybrid program) to be piloted in Psychiatry (faculty, staff)

2. Additional Resources for Research Training

Additional training opportunities are available at the University, offered by the University of Minnesota, professional organizations, and other institutions. Some can be found at http://www.research.umn.edu/irb/advanced.html. In addition, HRPP offers training sessions by request to help support researchers and research personnel with the IRB process.

Training Recordings

- Keep Calm & Carry On: Preparing for FDA Inspections of Clinical Investigators
- Information Session on the Notice of Proposed Rulemaking (NPRM)
- HIPAA & Research

Introduction to Clinical Research Methodologies

These stand-alone, interactive modules were authored by research experts at the University of Minnesota. The authors of the modules are indicated in parenthesis following each course title.
(Note that the links found at the website indicated are in the process of being updated and replaced by the new modules listed below, which are available at: www.18education.umn.edu:

- Basic Statistics for Clinical Research (John Connett, PhD, Professor, Division of Biostatistics, SPH)
- Critical Appraisal of Observational Studies (Jim Pacala, MD, MS, Professor & Associate Head, Dept. of Family Medicine and Community Health)
- Ethics in Clinical Research (Debra DeBruin, PhD, Associate Professor, Center for Bioethics)
- Good Clinical Practice in Clinical Research: An Introduction (contains a graded exam at the end) (Debra Dykhuis, Executive Director, HRPP)
- Integrating Research Into Clinical Environments (Debra Dykhuis, Executive Director, HRPP; Moira Keene, MA, CIP; Mark Paller, MD)
- Introduction to Biomedical Health Informatics (Connie Delaney, PhD, RN, Dean, SON)
- Introduction to Clinical Trials (Jim Neaton, PhD, Professor, Division of Biostatistics, SPH)
- Introduction to Epidemiologic Methods (Russell Luepker, MD, Professor, Epidemiology and Community Health, SPH)
- Translational Research: An Overview (Mark Paller, MD, MS, Sr. Associate Dean for Research and Medicine, Medical School)

Online Ethics Center Training Modules

Published by the National Academy of Engineering, the modules below also provide readings on each of the following topics:

- Responsible Collection, Retention, Sharing, and Interpretation of Data
- Special Issues in Conducting Human Genetic Research
- Ethical Challenges in Research with Human Biological Materials
- Ethics of Research on Vulnerable Populations
- Ethics of Research with Subjects Who Have Dementia

- Ethics of Research with Children
- Ethics of Research with Human Subjects Who are Mentally Ill

U of M Courses to Meet NSF and USDA/NIFA Ethics Training Requirements
To meet this requirement, students enrolled in 'specific degree programs,' can complete one or more for-credit or non-credit courses (See Appendix A) including seminars or activities on umn.edu core topics:

- Authorship and Plagiarism
- Data/Research Integrity
- Reporting Misconduct.

Center for Bioethics Courses
The Center for Bioethics offers the course, ***Standards for Research with Human Participants***, which can be taken for credit or in 'a la carte' format, in which learners are welcome to attend the lectures of most interest to them. That course is focused on understanding the regulations (e.g., use of IRBs, consent, international) from the federal, state, and University. The Center's ***Research Ethics*** course can be taken for credit or for continuing education credit as well.

3. Tracking and Reporting

- ***Research Education Reports*** accessed through the OVPR Research Reporting Center show RCR and Human Subjects training that have been completed, both online as well as approved University courses.
- UM Reports show an employee's or student's entire history of completed training (RCR, HIPAA, Organizational Effectiveness, etc.)
- ULearn Transcripts display an employee's or student's courses that they have taken through ULearn only
- A direct feed from CITI has been established so that all training completed under a University x.500 address is fed into the ULearn system and is ultimately available in either the ULearn transcripts or UM Reports.

Conclusion: Current University of Minnesota HRP Training Requirements and Resources

Based upon University websites and from interviews with OVPR/RCO, HRPP, and CTSI personnel, the University does offer the required training framework to meet current federal guidelines for human subjects research, including requirements from specific agencies (e.g., NIH, NSP). A tracking system (or three) is in place for tracking and reporting most training completion. Questions that are apparent from this initial overview include:

1. Beyond the honor system of reporting training completion on application forms, how do IRB reviewers ascertain currency of training of investigators and research teams identified on protocols?
2. How is renewal of training tracked and reinforced, and through what infrastructure?

3. What type of in-person training is provided to meet NIH RCR training grant requirements, and how is that administered and monitored?
4. How much and which specific advanced or additional training should be required for investigators and/or staff doing research with vulnerable populations, international studies, biospecimens, and/or other research beyond that covered by core courses? How should requirements be implemented and monitored?
5. What advanced training options are available and typically offered in noncompliance situations? For whom? How is that administered and tracked?
6. What metrics are in place to ensure that investigators can ***apply*** at the point of need in their research what they have covered in online courses?
7. What evaluation metrics are in place and being used to continuously monitor the quality of the University's HRP training programs?
8. How can the entire HRP education and training system be developed into a highly accessible, transparent, and welcoming system for all investigators and research personnel?

HRP Educational Requirements at Other Universities

In order to learn about human research protection education and training at other universities, the author of this report explored the websites of eight other universities known for excellence in research, and interviewed leaders at the IRBs and/or offices of the vice president of research at four of those. A summary of the training programs and requirements derived from that exploration follows. (Appendix B contains one 'best practice' example from Emory University of a role-based website clearly showing HRP training requirements.)

	Prior to Submitting Research Protocol or RCR Training	CITI ?	Human Subjects Research	CITI?	Training Registration & Tracking	Comments
Duke University & Duke Medicine	• ***Postdoctoral Fellows***: 4-hour RCR Orientation or 5-Session course (for NIH Training Grants • ***PhD Students:*** 12-hour RCR Orientation + 2-hours RCR Forums + 4-hour course • ***Graduate Students***: 4-hour RCR Orientation course		***Investigators and key personnel, Postdoctoral fellows, PhD students, CRCs and Clinical Staff*** • History & Ethical Principles (Duke ORS Initial Certification) • Human Subject Protection Training (8 modules) • Duke Human Research Training (instructor-led or online) (Duke Medicine)		• Duke Human Research Training is delivered through the Duke LMS • Other courses are tracked	• Duke ORS requires 1 CE credit each year for 2 years following initial certification • Duke Medicine requires CITI modules every 3 years • Duke's Office of Clinical Research (DOCR) provides services and training to support Investigators, Coordinator
Emory University	**Investigators:** • Online RCR Training offered as a 'resource for those interested in obtaining training on RCR…' • ***Key Concepts in Clinical Research for Investigators***, **required** to cover Emory-specific content. • To meet NIH in-person requirements, Office of Compliance offers monthly in-person case studies based on issues that have arisen regarding RCR.		• ***All key research personnel must complete:*** Online Training: Protection of Human Subjects in Research		Investigators, fellows, residents, students, and research staff can document all training (online and in-person) using the Emory Learning Management System (ELMS)	• They are the largest commercial IRB in the world • CITI HRP training and Key Concepts in Clinical Research renewed every 3 years • 12 AMA PRA CE credits offered for **Key Concepts** course • IRB does not require RCR and GCP training. They are waiting to hear about the NCATS initiative.

	Prior to Submitting Research Protocol or RCR Training	CITI ?	Human Subjects Research	CITI?	Training Registration & Tracking	Comments
Emory University (cont'd)	**Residents and Fellows:** • ***RCR online and in-person*** training if associated with NIH or NSF grants. • ***Key Concepts in Clinical Research for Investigators*** (every 3 years; 12 AMA PRA credits) • ***Online Introduction to Clinical Research at Emory*** (every 3 years; 7 AMA PRA credits) **Clinical Research Coordinators:** • ***2-day Classroom Intro to Clinical Research at Emory*** (every 3 years; 14 AMA PRA credits)	□	•		•	• New coordinators are mandated by the University to attend a 3-day, Emory-developed program. Completion is verified by the IRB. Any CRC who consents participants must attend. They may adopt the CITI GCP course for CRCs with a couple Emory-specific modules. • Renewal for CRCs, residents, and fellows is the CITI course.

Harvard University	Harvard's RCR course meets the NIH requirement for all trainees and fellows receiving support from NIH ... Graduate students, post-doctoral fellows, and junior faculty members must attend a minimum of 6 lectures and complete all case studies. "This course is separate from CITI Training, encompassing far more than strictly Human Subjects Research, and must be completed in person per NIH requirements. (Renewal: each career stage or every 4 years)		**Required Ethics Training***
			• **CITI Online Training** or:
			• **NIH Certification Online Training** or:
			• **Committee on the Use of Human Subjects undergraduate training**
			* Required for anyone working directly with human subjects, data, including PIs, Co-Investigators, and NIH-defined 'Key Personnel.'
			
			Renewal: Every 3 years:
			• ***CITI Refresher Course*** or:
			• ***3 QI education sessions***
				□
				
				□
					• Training certification (except for NIH online course) is tracked in the eIRB submission system, ESTR.	• CITI Ethics Training for social/behavioral research includes 10 required modules + 5 electives. (Did not find Biomedical Research requirement.)
						• Office of Human Research Administration offers
						  ○ Monthly IRB Clinics
						  ○ QI Program Monthly Education Series
						  ○ Small-group In-Services
						  ○ One-on-One Study Staff Orientation

	Prior to Submitting Research Protocol or RCR Training	CITI ?	Human Subjects Research	CITI?	Training Registration & Tracking	Comments
Johns Hopkins University	All faculty, postdoctoral trainees, and staff engaged in research at JHU SOM are required to complete RCR training every 4 years. Three required components: • Complete **RCR CITI Online Course** (7 modules) • Attend **2 Dean's Research Integrity Lecture**s Series (8 offered each year with interactive discussion and panels led by faculty; CME credit offered) • Attend **one Department/Division Meeting** at which an RCR topic is discussed. RCR Program components satisfy the NIH and NSF guidelines for responsible conduct of research.		**IRB Compliance Training for Human Subjects Research** (Required for PIs and Study team members): • **Basic Human Subjects Research Course** (CITI online) • **Conflict of Interest and Commitment** (online) • **HIPAA** (online) • **Clinical Research Billing and Clinical Research Management Systems** (online and live training) **Research Ethics Workshops About Responsibilities and Duties of Scientists (REWards)** (PIs and Fellows must attend 2 workshops.) **PI Recertification** will include 4 required online modules + 1 in-person activity. **Study team members** recertify within 3 years of initial HSR compliance training, and then every 3 years		The University's 'mylearning' system and CITI are used to track training completion. The electronic IRB submission system has training data within it, and might be future system for tracking.	• IRB for Medicine and Nursing reports up to the Vice Dean of Clinical Research of Medicine. Public Health has a separate IRB. • As of March, 2016, PIs will be required to complete HSR recertification training every 3 years. • PI recertification training includes 4 required CITI modules (GCP, Informed Consent, Research with Vulnerable Subjects, RCR) + in-person workshops. • Study team recertification requires 4 online CITI modules + 2 elective online modules. • Continuing education credit is not offered.

	Prior to Submitting Research Protocol or RCR Training	CITI ?	Human Subjects Research	CITI?	Training Registration & Tracking	Comments
UCSF	• Required by the University of California Office of the President: **Compliance & Conflict of Interest for Research (COIR)** (every 2 years). Satisfies NIH and UC requirements. And: • Required by UCSF Office of Ethics and Compliance: ○ UCOP General Ethics and Compliance Briefing (PowerPoint) ○ UCOP Sexual Harassment Prevention (web page) ○ Responsible Conduct of Research Training (Undefined. Link on 'Required Training' page leads to NSF site.)		PIs and key study personnel must complete CITI training (required). • 5 core modules + 2 elective modules required (2 – 4 hours) • Renewal every 3 years by completing 3 modules of your choice **GCP Training** (valid 4 years) • Basic course is optional for the HRPP (CITI) though may be required by departments • ***Optional Modules GCP Course*** (13 modules): for research personnel conducting drug, device or biologic studies (4 hours)	▯ ▯ ▯	Retain CITI certificates in individual files and provide copy to administrative team.	• "Trainings are required as part of the conduct of one's research. The [UCSF] Ethics & Compliance office is leading efforts to ***reduce, combine, streamline, and optimize the number and presentation of required courses."*** • CME/CE credit available for GCP courses. • CRC training is 'recommended,' and includes print-based, classroom, and online materials. • UCSF Training in Clinical Research program offers: ○ Summer Workshop ○ Advanced Certificate ○ Master's in Clinical Research ○ Certificate in Imple-mentation/Translation Science

	Prior to Submitting Research Protocol or RCR Training	CITI ?	Human Subjects Research	CITI?	Training Registration & Tracking	Comments
University of Michigan	Investigators on a project proposal must complete the **Program for Education and Evaluation in Responsible Research and Scholarship (PEERRS)** (every 3 years): • Conflict of Interest • Research Practice Foundations • Research Administration		PEERRS Training is required for anyone listed as a study team member on a human subject study application. Renewal: 3 years. For Biomedical & Health Sciences: • Belmont Report & CITI Course Intro • History & Ethical Principles • Basic IRB Regulations & Review Process • Informed Consent • Research with Protected Populations-Vulnerable Subjects PEERRS is now integrating with CITI so that people have options between the two.		myLINC, the University's online Learning and Information Center	• The U-M Office of Research develops PEERRS courses. Human Subjects courses are adapted from CITI. • U-M has 4 IRB offices reporting up through an IRB council, recommending policy to the VP of Research. Council includes CTSA • Training is 'weak link' and understaffed. • Refresher course system isn't good because it's just repetition. • NSF requirements and remediation programs are pushed down to the departments • Practice Oriented Research Training (PORT): didactic & experiential mentored research training program for clinicians
Washington University	Program for the Ethical and Responsible Conduct of Science and Scholarship (PERCSS). This is a voluntary web-based and/or online program to the Washington University research community: 8 online modules: • Intro to Ethical and Responsible Research • Authorship & Publication • Collaborative Research • Conflict of Interest • Data Ownership & Mgmt • Mentor-Trainee Relationships • Peer Review • Research Integrity		Human Subjects Education (CITI) (The Research Gateway system assigns modules appropriate to the type of research)		The Research Gateway is Washington University's online resource for faculty and staff to access research-related resources, tools, forms, and applications to propose, perform, manage, and close research projects.	• HRP Office offers education programs that include: ○ Lectures & presentations ○ Open-access publication of conferences and discussions on HRPP best practices ○ Videos and podcasts on HSP protection and IRB review ○ Consultations ○ FDA regulation and oversight guidance

	Prior to Submitting Research Protocol or RCR Training	CITI ?	Human Subjects Research	CITI?	Training Registration & Tracking	Comments
University of Pennsylvania	For anyone mandated through NIH or NSF grants: The CITI RCR Course covers the nine instructional areas related to ethics and practice of research endorsed by **NIH** and the Office of Research Integrity. It fulfills the **NSF** requirement for RCR training and supplements the face-to-face instruction that NIH requires." (4 – 6 hours)		The CITI Human Subjects Protection Course ethical principles underlying the federal regulations governing human subjects, outlines the rules for conducting research with various populations of human subjects, and covers IRB procedures. Completion of a Human Subject Protection Course is required by the Penn IRB for participation on an approved protocol. No ongoing training requirements		Penn Profiler, the University's web-based assessment tool, enables University constituents to self-identify most of their required research- and financial-related training needs. The Penn Profiler survey must be completed annually by all University personnel. Knowledge Link, Penn's learning management system (LMS), provides access to classroom and on-line training. It is the primary repository for administrative, compliance and certification training, along with professional development courses. Knowledge Link training is integrated with the University's compliance training survey, Penn Profiler.	***All Clinical Research (CR) staff are required*** to complete the 2-day Clinical Research Coordinator training offered by OCR within 6 months of their start date. This requirement includes the following research staff: Clinical Research Nurse, Clinical Research Coordinator, Clinical Research Nurse Coordinator, and Clinical Research Assistant. CR Certification Program Topics: • Research infrastructure at Penn • Best standards of practice and regulatory requirements for CRCs and methods to achieve them • Practical suggestions, tips, and resources • Comprehensive training in GCP for investigator-initiated, industry-sponsored, and grant-funded research

Conclusion: HRP Educational Requirements at Other Universities

From explorations of university websites as well as interviews with personnel at IRB and offices of vice presidents of research at eight other universities, it appears that those universities—both public and private—provide and require HRP training and education in much the same manner as does the University of Minnesota. Some of the key findings from this exploration include the following:

1. The Collaborative Institutional Training Initiative (CITI) training is the 'standard' used among universities for providing online training on human subjects research topics, good clinical practice, and research ethics. All of the universities in this sampling subscribed to CITI for HRP and/or RCR training.
2. While the number of and specific CITI courses vary amongst the Universities, it appears that the nine categories of NIH responsible conduct of research (see 12 of this report) guide training content for general research training.
3. All of the Universities—with the exception of Washington University—have developed their own training programs for general research or responsible conduct of research training. Some integrate or adapt CITI training in those programs.
4. Human Subjects Research training, however, is universally offered in online (CITI) format by all universities. (Johns Hopkins supplements this training with a requirement for investigators and fellows to attend two in-person REWards workshops.)
5. With the exception of requirements for IND/IDE research, Good Clinical Practice training may be offered for investigators either as optional (e.g., UCSF) or as part of recertification. (The Emory informant mentioned that their IRB doesn't require RCR and GCP training, though they are interested in following the NCATS GCP training initiative.)
6. Six of the eight universities surveyed require recertification training for investigators on responsible conduct of research, ranging from every two – four years.
7. All of the universities researched—with the exception of University of Pennsylvania and Washington University—require recertification of investigators conducting research with human participants every 3 – 4 years. Typically, the training is a repetition of or additional CITI modules. Some institutions, including Duke, Harvard, and Johns Hopkins, also require in-person training as part of the renewal process.
8. Only a few institutions provide CE credit for RCR, recertification, and/or GCP training.
9. Emory University and University of Pennsylvania have developed and mandated Clinical Research Coordinator training that involves in-person workshops and ongoing recertification, including renewal of GCP training.
10. With the exception of UCSF, it appears that all of the universities researched use enterprise learning management systems for registration and tracking of RCR and HRP training. In most cases, the learning management system is/will soon be integrated with the institution's eIRB system.
11. In general, a question arises from this exploration of the extent to which all of the training content covered at the University of Minnesota as well as the other Universities (including CITI) is 'knowledge' based (e.g., regulations, policies, roles and responsibilities) vs. attention to developing and demonstrating skills and attitudes for implementing ethical, conscientious, and team-based participant-focused human research.

Needs and Perspectives

The purpose of this section is to gather and summarize—in light of the federal and accreditation HRP requirements and current status of HRP training at the University of Minnesota—input about the primary gaps that the University must address in order to ensure satisfactory compliance and exemplary performance of investigators and research teams conducting research with human participants. The identification of gaps and needs will be derived from:

- *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: Final Report (February 23, 2015)*
- *Implementing the Recommendations of the External Review of the University of Minnesota Human Research Protection Program: Work Plan (June 11, 2015)*
- *CTSI Recommendations for Integration of Clinical Research Studies in the Department of Psychiatry into the University of Minnesota Clinical and Translational Science Institute (CTSI) (February 11, 2016)*
- Input from interviews with University of Minnesota research personnel
- Input from interviews with IRB and research leadership at other universities.

Attempts to interview research participants and their families in focus groups were pursued for the purpose of listening to the experiences and preferences of patients and families regarding interactions with research teams that can contribute to their understanding of their research role, the protection mechanisms in place, input and feedback mechanisms available to and preferred by them, and resources for addressing challenges they may encounter during research. However, in spite of significant effort to set up these focus groups, this component could not be accomplished within the time span of generating this report.

1. Action Commitments in Response to the External Review

The report of the External Review (February 2015), the Work Plan response (June 2015), and the CTSI Recommendations for the Department of Psychiatry (February 2016) contain a number of commitments to change regarding the education and training of investigators and individuals engaged in research with human participants at the University of Minnesota. Listed below are the
External Review recommendations included in the Implementation Work Plan that specifically pertain to education and training.

3.3.1 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 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 Evaluate whether additional mandatory training requirements, comparable to the new mandatory training for sponsor-investigators (which includes GCP), 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 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 request.

3.3.5 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 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 Consider ways to involve the University's Center for Bioethics in the educational programs on the ethics of research and the University's HRPP

3.3.8 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 Upgrade and professionalize education in, among other subjects, the responsible conduct of research and research ethics.

The Management Plan for the Department of Psychiatry contained additional recommendations pertinent to HRP education and training:

IV. Faculty members/investigators participate in a competency-based training program for research staff in the UMN CTSI. Key areas are likely to include: clinical research requirements for conducting studies; Good Clinical Practices; reporting of adverse events; protocol deviations; source documentation; documentation of informed consent; inclusion/exclusion; criteria assessment prior to consenting; and safety monitoring

VIII. Develop a quality assurance (QA) program. Training development is likely a necessary component to support such a program, when implemented.

2. Input from Interviews with University of Minnesota Research Personnel

Discussion and interviews were conducted in January – February 2016 with the following University of Minnesota research personnel representing various leadership roles and responsibilities within the University.

Amanda Galster	Research Support Manager, Pediatrics, MS
Brenda Prich	Research Support Manager, CTSI
Corinne Komor	Administrative Manager, Biomedical Engineering
Courtney Jarboe	Education & Outreach Coordinator, HRPP/IRB, OVPR
David March	Assistant Director, RCO, OVPR
Debra Dykhuis	Director, HRPP/IRB, OVPR
Karen Cook	Research Support Manager, CTSI
Leslie Kennedy	Grants/Contracts Manager, Department of Medicine, MS
Megan Hoffman	Workforce Development Program Manager, CTSI
Michelle Hintz	Research Project Specialist, Department of Medicine, MS
Mickey Eder	Associate Director, Community Engagement to Advance Research and Community Health, CTSI
Russell Luepker	Professor, Public Health Epi & Community Health, SPH
Sandra Wells	Research Project Specialist, CTSI
Sarah Waldemar	Director, Research Accountability and Education, RCO, OVPR
Steven Miles	Professor, Center for Bioethics, Department of Medicine, MS

Discussions and interviews with University of Minnesota personnel generally addressed the following questions, as appropriate to the role of the individual being interviewed.

1. What training is currently required in your school or department in addition to University requirements for human research protection training?
2. What HRP resources and curriculum is being offered in your academic unit?
3. What is working well?
4. What needs or issues have arisen?
5. What particular issues have arisen pertaining to research with vulnerable populations or research with individuals with diminished capacity to consent?
6. What recommendations do you have?

A summary of a) current HRP training requirements and resources, b) needs and issues, and c) ideas and recommendations from these discussions and interviews follows. In most cases, these are summaries of comments, rather than direct quotations. (Exact quotations are indicated by quotation marks.) If multiple interviewees had similar comments, they are listed together. Some of the comments reflect individual perceptions, which may not be completely accurate.

Current HRP Training Requirements and Resources within U of M Academic Units

- "We do a poor job of ensuring that PIs and CRCs are adequately trained."
- The Department of Medicine has developed its own internal QA procedures for chart review for research, and have their own training.
- The School of Public Health doesn't do anything specific or unique for training, above and beyond the University requirements. The School relies on the IRB for certifications for training both nationally and internationally.
- The Center for Bioethics offers the ***Standards for Research with Human Participants*** and ***Research Ethics*** courses. These are offered for credit or for CE credit. The Research Ethics course is also offered in the School of Public Health. The Standards for Research course is purposely offered as 'a la carte' lectures so that individuals with specific research needs can obtain information about federal regulations, state laws, University policies and other information pertinent to their area of research.
- In the Department of Medicine, some effort is made to train trainees on training grants, but nothing extra is really required outside of the institutional guidelines. {Note: While this perception was expressed, there is a joint working group of T32 P.I.s in the Department of Medicine that has a required dedicated monthly RCR conference and that includes faculty participation from each T32 grant. It is led by Greg Vercellotti MD, with administrative support from Barbara Porwitt.}
- People often don't know what the requirements are for doing human subjects research. In 2000, the Medical School held a 2-day event on HRP, ethics, RCR at the Radisson for faculty. Some haven't done any training since.
- There're no teeth to the three-year recertification. Only from sponsors. Whether it's bench or blood-drawing research, there's no more training, unless it's a clinical trial with a human interface.
- The Responsible Conduct of Research course is a good resource. We make it available for our faculty who receive any kind of funding, and require it for the research staff. This makes them feel they have institutional support.
- The training that the investigators we work with receive is what's required by the IRB. But, we aren't sure it is sufficient to keep subjects safe.
- The Clinical Research Methodologies modules (ctsieducation.umn.edu) contain a lot of information that would be useful for investigators and research teams.
- Only two faculty in Bioengineering are currently engaged in human participant research, which is mostly NIH-funded. The school and departments have no special requirements for human participant research.

- **Tracking and Reporting Training:**
  - Within the department, we don't track training. We assume that investigators will do what's needed. Departments don't have time to check on faculty and track their training, so it's pretty ad hoc on human subjects training and certificates.
  - The UM Reports training record is hard to read, so we just use CITI certificates if needed.
  - There's no way for the department to know or require additional training, say for vulnerable populations. Only the user sees this. It's probably not transmitted to the University systems and is probably not visible to the IRB or SPA if they look you up.
  - The CITI gradebook listing of many refresher courses completed by one of the interviewees contains the following standardized disclaimer: "Note: Your completed gradebook is provided for your general interest and suggested reading only! You do not receive "extra credit" for completing them. They do not show up on any completion reports. They will be credited in a grade book if you subsequently enroll in a course that includes them."

- Clarify if and how SPA and/or the IRB connects funding to protocols submitted to training needs. How does HRPP/IRB check to see what CITI training individuals have completed?

- **Coordinator Training:**
  - If new coordinators are hired there's no required training. It seems that CTSI has a lot of materials, but it's not available or else no one knows where to find it. {Note: This perception is not universally correct, but likely depends upon the hiring unit.}
  - There's currently no mandate in our department for coordinator training. "We need to get to that and track it so that supervisors can see what's been done and use it in performance reviews annually."
  - CRCs may complete CRC training, but not all staff do. And CRCs and staff may or may not attend the regular training sessions. It's not a high priority.
- **Format:**
  - The Departments of Medicine and Pediatrics don't offer in-person training on human research topics, nor is CME provided for research training.
  - Online learning is preferred to in-person. However, the value of in-person learning is the conversation, and the opportunity to instill in investigators and research teams that, no matter what cost or risk, we always need to do the right thing.
- **Additional Training**
  - In Medicine, no special training is being done for research with vulnerable populations, for example, for research with the elderly.
  - Pediatrics research relies on CITI training. If you identify research with children in CITI, it directs you to complete additional modules.

Needs and Issues (University of Minnesota)

- Investigators want to do the right thing, but don't know what/how to run a research project, particularly junior investigators. A good example is how to write a protocol. There's a push to conduct research, but the conflict is a lack of tools to create research that can get the results through the plan/protocol developed.
- RCR is fine as a core concept. However, researchers wander beyond it, for example, into international research where they must understand international standards pertaining to data safety and monitoring, or diverse research that requires community consultation or dealing with biospecimens. That's not included in RCR.
- What's important is for investigators to know what they need and when they need it—so they get the training at the right point of readiness. #2: The University isn't consistent about what's required and for whom. Or where to go to find out.
- The three-year refresher is not consistently enforced; if you aren't actively doing research, people don't do it.
- CTSI Research Support services doesn't have any special resources regarding working with vulnerable populations, and feel there's a need to educate research teams about such research.
- For some Medical School grants, practice facilitators conduct government-funded research throughout the state. They visit clinics, and—although not necessarily reading through patient records—they gather experimental (de-identified) data. Some of those data could be identifiable. What training is required?

- The MS in Clinical Research involves learners from pharmacy, lab medicine, dentistry, and other professions. They need more training. CTSI provides some, but it is too expensive. Training may be reverting back to the 'do it yourself' model.
- We need a training program for international research.
- When individuals are hired in the middle of a study, the names of the new research staff typically aren't shared with the IRB (they aren't key personnel). However, those new staff members need to be trained.
- Investigators need mentors, sometimes from the larger academic unit. Do we have a mentor pool?
- We have a cultural issue, which is not one of collaboration. For example, Coordinators report to investigators, and many don't participate in the monthly Coordinator meetings because it's a cultural challenge to do so.
- **Training Formats**
  - We need in-person training because investigators don't remember what was in CITI training.
  - Good papers and tools to use and follow for helping research teams work with vulnerable populations
  - In-person training for working with vulnerable populations is a big need.
- **Research Coordinators**
  - We need to encourage research coordinators to complete the CTSI modules. They are great for baseline, but we also need to supplement them with in-person training, mentoring, and reinforcement.
  - We should explore who are possible mentors outside our specialty division for new coordinators.

Ideas and Recommendations of Interviewed Individuals (University of Minnesota)

Research with Vulnerable Individuals or Those with Diminished Capacity to Consent

- Create a training program on Consenting (for all research populations and for special populations)
- The specialized CITI modules are probably sufficient for vulnerable populations, though they may be lacking in addressing vulnerable adults with mental health challenges (e.g., dementia and others)
- The goal is to address consent as a process; have it carry through multiple visits over time. Devise a few questions to ascertain the understanding participants have about the research. Make a commitment to help them understand, and educate them.
- Create learning resources on consent, including a link to a consent form template with examples of completed ones
- Use case simulations and skill-based training so that research teams can demonstrate competence.

Update Human Research Protection Training and Education Policies

- Mandate Coordinator training, and use it for annual reviews. #2: Require the CRC modules; no one can be enrolled in a study until the research team has completed the training.
- Implement an infrastructure in which research staff members are not supervised by investigators. That will allow Coordinators to experience less pressure (e.g., for job security), and have options to connect with others in the event they have concerns about the conduct of their research study. {Note: This may not be realistic given the likelihood that the faculty or unit responsible for paying salaries is not likely to completely relinquish supervision.}

- Ensure that investigators and faculty have time to complete REPAs and get them tracked. Add more 'teeth' to the REPA process, perhaps by having protocols put on HOLD or some consequence to ensure they are completed.
- The mandate needs to come from the institutional level. We don't need a variance at the departmental level, especially since researchers work across departments. For example, all Coordinators have the same training or skill set. Could this be mandated even at the AHC level? Should we do the same for investigators?
- Require ***GCP training*** for anyone doing any investigational trial.
- Who is the holder of the requirements for ***GCP training*** through CITI? It would be useful to clarify who is the source of requirements. And what the requirements are.
- What if we had ***GCP training*** month/quarter each year for investigators? Like REPA. It would make sense that at certain times, you do certain things. Easier to keep track, and it could the 'season for refresher courses.'

HRP Education and Training Infrastructure

- We need more infrastructure to support education and training, and more resources to serve the Ethics support needs. Ongoing funding must be a part of this.
- Encourage the VP of the Health Sciences to mandate that no grant funding will be accepted unless all staff have been trained.
- Resources all need to be in one place and easy to find.
- We need to make it easier to find the training requirements. "Here's where you need to go to find out what training you need. Every three years, this is the requirement…" Which modules will satisfy which components of research. (This isn't easy to find on the CITI website.)
- The IRB needs a more complete infrastructure to support human subjects research. Expand it vastly not only for protocol review, but also for prospective and retrospective Ethics review and education. Putting compliance in a separate office is a good idea.
- Could we have a 'Recertification Time' like we do for REPA? For example, if you are on the REPA list and you are engaged in human subjects research, could the requirement add in the CITI modules?
- Establish an Education Council to determine training and curricula for the University and Gillette for all aspects of research.
- Create a Director or Associate Director of Ethics Education, someone who would keep up-to-date on national and international changes in regulations and update training programs accordingly.
- The IRB could offer consultation services for investigators, including a) quick protocol review and identification of red flags, b) review and assistance with institutional requirements, including those from Fairview, c) methodology, including review of scientific design, d) writing support, etc.
- We need to agree on a common IRB for multi-center studies. Ours is too slow for industry-sponsored studies. Consider the multi-IRB structure at the University of Michigan.
- We need a One-Stop-Shop to find training and information at CTSI, HRPP/IRB, and Center for Bioethics.

- ***Content and Format***
  - Need online resources as well as handy guidance documents at point of need on topics such as:
    - Writing a protocol
    - Tools for thinking about the feasibility of a project (e.g., do you have the population? dedicated staff? feasibility assessment?)
    - Investigator responsibilities

        - Sponsor and investigator responsibilities regarding IND and FDA studies
        - Consent process, including screening before consent.
        - Consenting people with diminished capacity
    - Create a module (similar to the Navigating Research module for Coordinators) that has a flow plan of the clinical research timeline and milestones (CTSI Research Services has a model for this.) Use it as a tool to show the scope of a whole project, the effect of changes to a protocol, and include case examples.
    - Use existing resources currently offered through CTSI such as the Clinical Research Methodologies modules (ctsieducation.umn.edu) or the Clinical Research Coordinator Training program.
    - Develop programs for investigators and students who do international research to learn to apply the same ethical standards as they do here, and be familiar with the regulations that apply in other countries.
    - Create training for working with medical records.
    - Case simulations and skill-based training so that research teams can demonstrate competence.
    - Don't train investigators on how to be investigators, but train them on some of the consequences of mismanagement of research

- **Tracking and Reporting Training**
    - Develop a system to confirm that individuals working with children or vulnerable populations have completed applicable training and that it has been recorded and reported.
    - Include 'additional training' for specific types of research in the training reports, and ensure that they are accessible to the IRB, SPA, and departments.
    - Wherever training is tracked, make it transparent for everyone to read and understand.
    - Implement a method to track if someone is out of scope three years after completing training.

- ***Learning Assessment***
    - Ensure that training is competency-based.
    - Core competencies for coordinators would be of great benefit, and we could document them.
    - Consider using the Onboarding Tool that CTSI is creating for CRCs with Mayo

Engagement of Departments and Centers to Create a Culture of Ethics in Research

- Create ***Grand Rounds for Research***, led by faculty, particularly junior faculty. Provide CE credit. Consider it an elective for recertification or basic training.
- ***Research Grand Rounds*** would fill the need for in-person discussions and Q&A. It could be used as opportunities to discuss relevant examples, questions, and issues that need to be shared. For example, do a debrief and report on FDA audits for clinical trials for business and industry. That might be interesting even to those who aren't involved (yet). Talk also about topics such as informed consent. Involve multiple departments and other schools.

Ongoing Communicating and Training

- Investigators need consistent prompting, which should also be copied to department heads. Give investigators a three-month heads-up on what training is due. Maybe add reminders at 60 days, 30 days, two weeks.

3. Input from Interviews with IRB and Research Leaders at Other Universities

Email invitations for online interviews were sent in January 2016 to Associate VPs or Deans of Research at eight other universities. Subsequent correspondence and referrals resulted in scheduled interviews with research leadership at four universities:

Anthony Keyes	Director, Research Staff Compliance, Education, and Training Institute for Clinical and Translational Research, Johns Hopkins University
Janelle Maddox-Regis	Training Manager, SOM clinical Investigations with Human Subjects Johns Hopkins University
Lois Brako	Ass't VP for Research, Regulatory & Compliance Oversight, University of Michigan
Rebecca Rouselle	Director, Emory University IRB
Tracy Ziolek	Director, University of Pennsylvania IRB

Interviews generally addressed the following questions:

1. What human subjects research training is required for investigators, coordinators, and others on the research team?
2. What is the University infrastructure regarding HRP, specifically interaction with schools and programs?
3. How do you manage tracking, reporting, and alerts for recertification?
4. What works well?
5. What are your challenges and opportunities for improvement?

A good deal of the input from the interviews has been integrated in the earlier section, HRP Educational Requirements at Other Universities. However, other pertinent comments and input provided by one or more of those interviewed is provided below.

Training Requirements at Other Universities

- Investigators have a 'self-policing' approach based on what they individually need. "If you compliantly conduct research, and we never hear from you, it's no issue." PIs can take whatever training they decide they need. Most of our training occurs when an issue arises. We don't want to 'rock the boat' for the majority, so we focus on providing individual corrective action when needed. "We are too big to require more training for everyone."
- No ongoing training requirements for the research community. However, we've recently developed a new document of Responsibilities for Research Investigators. The investigators need to confirm that they have reviewed that document each year.
- At one site, investigators and study teams doing research with vulnerable populations must complete recertification training that includes: GCP, RCR, Informed Consent, Vulnerable Subjects modules, plus two electives. Everyone on the study must do the training.

University Infrastructure

- At the University of Pennsylvania, the Office of Clinical Research in the Perelman School of Medicine has now taken the lead in compliance monitoring, clinical operations and support (including developing training for investigators and staff), and INDs/IDEs.
- Most coordinators who consent subjects report to investigators. Some—such as those in the Cancer Center—have regulatory offices and report centrally.
- Our IRB manages Biomedical and Social/Behavioral training. We are adding more requirements for renewal. We also provide annual updates on new policies and a module on common audit findings.

Tracking, Reporting, and Alerts

- The IRB requires up-front and ongoing training, and checks CITI training at initial funding and recertification milestones. They review and require all members of the research team to renew training, and don't leave this up to the investigators. Investigators must confirm online that everyone on their team has been trained.

What Works Well

- We have a library of online training programs with PowerPoint/Voice-overs. We are working to increase this (but are too busy).
- We are starting to adopt the CITI Coordinator course with GCP and are adding a couple University-specific modules.
- The IRB collected and ran a report to see who was out of compliance, then gave everyone a year to complete required training. Now, the IRB will not review new applications unless everyone is up-to-date on HSR training.

Challenges and Opportunities for Improvement

- We don't require GCP training now, but are waiting to hear more about the NCATS initiative.
- Our refresher course system is not good. People just repeat what they've already done, and they hate it. We need new programs.
- Training is our weak link. We only have one person to manage it, so no capacity to continuously update or change training content.
- We need to share more nationally, and have workshops/webinars that can be shared.
- Washington University is a leading model in offering papers, podcasts, and conferences through their Human Research Protection Office.

Conclusion: Needs and Perspectives

Clearly, the University of Minnesota needs to take some steps—and has committed to doing so—to improve education and training for investigators and the research staff who are engaged in research with human participants. From the results of and response to the External Review, and from interviews with research leadership in Minnesota and across the country, it appears that the University of Minnesota faces very similar challenges to both the public and private universities surveyed. The following section synthesizes the needs identified throughout this report, and makes recommendations for addressing those needs and gaps in the U of M human research protection program.

Recommendations: University of Minnesota HRP Education and Training

At a high level, priority need for changes exist in the following high-level areas:

1. Define a transparent **UMN infrastructure to manage HRP education for investigators and the research workforce**.
2. Decide upon and implement a **central HRP education, training, and communication unit**, to work with HRP subject matter experts University-wide, supported by enterprise commitment and funding
3. As part of the Community Engagement initiative, engage patients and prospective research participants in the development and delivery of training programs for investigators and the research workforce
4. Focus initial training development and implementation on:
    a. Advanced training for **research with vulnerable individuals and those with diminished capacity to consent**
    b. **Upgrade initial and recurrent training in ethics and the conduct of human research**
    c. Build on current efforts to engage U of M colleges, departments, and centers to create a **Culture of Ethics for Human Participant Research**
    d. Plan to pilot programs in the **Department of Psychiatry**
5. Create a web-based, comprehensive learning platform—using current and recently implemented enterprise systems—to manage the functions of learning program, including resource cataloging, registration, tracking, reporting, and prompting for ongoing training requirements.
6. Over the next 3 years, develop, pilot, and implement a competency-based curriculum plan that develops knowledge, skills, and attitudes and includes learner assessment as well as ongoing program evaluation (perhaps a systematic review and update of activities every two – three years).

The purpose of this section is to outline high-level recommendations for addressing these areas. The recommendations in this section largely represent the conclusions and opinions of Janet Shanedling, PhD, the curriculum and instructional designer authoring the Needs Assessment & Gap Analysis report, with some input from HRP leadership engaged with this initiative. Specific details (e.g., tasks, roles and responsibilities, specific deliverables, and timeframes) could be included in a subsequent curriculum plan based upon review and finalization of the recommendations in this report.

The following priority recommendations are organized into high-level categories. Recommendations are drawn from and integrate all of the sources of data summarized in this report:

- Federal requirements and policies, certification requirements, and national initiatives
- Current U of M HRP training requirements and resources
- HRP educational requirements at other universities
- Action commitments made in response to the U of M HRP External Review
- Input from research leaders at the U of M and at other universities.

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Priority Recommendations

	Recommendations
1. Define a transparent UMN infrastructure to manage HRP education for investigators and the research workforce	a. Define and agree upon the HRP roles and responsibilities for all aspects of human research protection enterprise-wide, including: Center for Bioethics, Community, CTSI, Fairview, HRPP/IRB, OVPR/RCO, and Schools/Centers/Departments University-wide b. Establish a transparent, collaborative cross-unit executive HRP Educational Advisory Group with defined Responsibilities Accountability, Support, Consultation, and Information Network (RASCI) among the HRP executive leaders. c. Assign that cross-departmental infrastructure group the initial responsibility to review and decide upon University of Minnesota **policies and mandates** regarding: • Basic HRP training for investigators, CRCs, research staff, trainees, and IRB members regarding content (e.g., should GCP training be included?), format (e.g., is CITI training sufficient or should learner assessment/ demonstration of basic competencies be included) • Advanced HRP training for investigators, CRCs, research staff, and IRB members with a focus on 'high risk' research, for example, with vulnerable individuals and/or individuals with diminished decision-making capacity, international research, research with biospecimens, etc. • Content, format (e.g., online + in-person electives) and frequency for continuing renewal of HRP training for investigators, CRCs, research staff, and IRB members • Requirements for and tracking of advanced level training for investigators and research teams for serious and/or continuing noncompliance • A mandated system and responsibilities for ensuring basic and renewal training of research teams is complete, particularly for vulnerable populations research, for all personnel involved in a study. This should align with protocol review and remediation for noncompliance, and specify timing of training in relationship to the date of protocol submission to the IRB. d. Determine the locus for decision-making regarding the planning, purchase of and/or instructional design and development of HRP, RCR, and advanced training; recertification training; and ongoing Culture of Ethics U of M offerings. (See Recommendation 2 regarding an HRP Education and Training Unit.) e. Address policies and mandates regarding training for all U of M clinical research coordinators, including challenges faced when reporting solely to investigators (as in c. above) f. Ensure a financial model that provides training and support to all investigators and research teams without cost being a barrier to access, and ensure compliance without excessive time requirements that disincent clinical research.

	Recommendations
2. Establish a central human research protection education, training, and communications unit	a. Create and resource a U of M HRP Education Specialist/Director (and necessary staff) to lead a centralized unit (based upon determination of 1d above) and work with U of M subject matter experts and existing resources to: • Develop HRP curriculum sourcing, development, learning assessments, training dissemination, program evaluation and QA, and ongoing updates. (IRB member training should be coordinated with these efforts but may be developed and managed separately.) • Carry out of guidelines for basic and advanced research compliance and human subjects protection training, under oversight from the Educational Advisory Board • Serve as the U of M liaison with national efforts such as the NCATS GCP initiative and ECRPTQ Researcher Competencies initiative, and suggest how to integrate into the U of M curriculum as those move forward • Collaborate on or manage the development and implementation of U of M Culture of Ethics forums, podcasts, webinars, etc. in collaboration with all other U of M units engaged in HRP leadership and management • Work with other institutions and instructional design consultants to source and/or develop learning programs to meet the goals of the U of M HRP curriculum plan that will include knowledge, skills, and attitudes for HRP • Ensure that timely, accessible, and clear communications regarding policies, training offerings, new regulations are created and disseminated to the research community • Monitor the changing national policies and 'state of the art' and externally available training resources, bringing advances and recommendations to the HRP Educational Advisory Group. b. Either within or affiliated with the Education and Training unit, assign clear responsibility to a Communications specialist who will be responsible for developing and maintaining a comprehensive, easily accessible HRP website (e.g., *humanresearch.umn.e*du), creating and aligning regular and continuous communications in other media formats (e.g., newsletters, updates), and ensuring two-way communication with all of the U of M research audiences (community participants, investigators, coordinators and research staff, IRB members, faculty, etc.). This position will require appropriate staff resources, including information technology support. • Through a central Human Research Protection website, provide access to individualized training self-assessments, training reports, training offerings, CITI, and regular updates of U of M HRP offerings and other communications media, making access to all information about human participant research highly accessible and transparent for the research community. This should include pro-active automatic notifications of faculty and staff, and should be linked closely to the IRB website. • Use the website to provide overviews and centralized access via the U of M learning management system (LMS) to all U of M and other training materials, including CITI, the CRC Orientation, Clinical Research Methodologies modules, etc. • Provide links on the website to consultation and support services, for example, from the IRB.

	Recommendations
2. Establish a central human research protection education, training, and communications unit (cont'd)	c. Within that HRP Education and Training Unit, strongly consider the creation of a new **position of Human Research Procedures, Policies, and Ethics Education Coordinator** linking to Center for Biomedical Ethics. (Depending upon the individual skill sets and time, It might be possible to consolidate this position with the 2a leadership position.) This individual would ensure that required and optional training is available and current and easily accessible to the research community. • When determined and developed, this position would coordinate and administer interdepartmental forums, WebEx-based presentations, podcasts, or other U of M Culture of Ethics offerings • Manage updates to all existing training and launch new offerings. • Work with NIH and other training grants to help fulfill requirements for HRP and RCR training compliance • Serve as the liaison with OVPR units responsible training documentation and reporting systems to continuously monitor that all training offerings are being appropriately tracked and reported on transparently (including RCR, HIPAA, GCP, CITI, advanced training) d. Develop the option of offering Continuing Education credit for advanced and recertification training, including a system to approve, track and credit HRP CE 'one-of-a-kind' activities offered at UMN or elsewhere (conferences, etc) e. Collaborate with the IRB leadership to support, as needed, the design of training that can be integrated into the Protocol and Study design module being developed in collaboration with Huron Consulting.
3. Engage patients and prospective research participants in the development and delivery of training programs for investigators and the research worforce	a. Gather input and feedback from patients and families regarding their priorities and areas of concern with U of M human research protection (as part of this Needs Assessment Process) b. Within the Education and Training curriculum development process, engage community members/research participants and U of M community content experts as some of the 'content experts' in the development of HRP training for researchers as well as training for research participants c. Develop and implement learning materials (HRPP/IRB) for legally authorized representatives (LAR) to explain the LAR role, authority, and considerations for making decisions.

	Recommendations
4. Focus initial training development and implementation on a) vulnerable research populations, b) ethics and conduct of human research, c) creating a U of M Culture of Ethics, and d) piloting all programs in the Department of Psychiatry	a. **Training for Research with Vulnerable Individuals and/or Those with Diminished Capacity to Consent** • Develop competency-based advanced training (required and recommended offerings) on ***consenting*** for investigators and research staff in collaboration with content experts from HRPP/IRB, CTSI, Center for Bioethics, patients and families from the community, Fairview psychiatrists, U of M psychiatry and psychology faculty, etc. This will include development, pilot testing (if necessary), and/or implementation of competency-based training. o Have the Educational Advisory Group consider a requirement that all researchers who consent in greater than minimal risk studies be qualified through demonstration of competencies to do so. o Develop template consent documents and processes with easily accessible examples and practice cases • As tools are developed/sourced for assessing participants' capacity to consent and for monitoring ongoing capacity, develop and implement experiential training on their use • Adapt the learning programs to provide specialized training for an IRB panel (who will be charged with evaluating all research with these populations) on the unique needs of research with individuals with impaired or fluctuating capacity to consent or who belong to vulnerable populations. **b. Augment Training on the Ethics and Conduct of Human Research** • Develop and pilot-test/source a cross-training (or even team-based training?), competency-based curriculum for investigators, clinical staff, and IRB members on the ethics, mechanics, and importance of research in collaboration with experts from HRPP/IRB, CTSI, Center for Bioethics • Include as topics for increased knowledge, skills, and attitudes: GCP, reporting adverse events, protocol deviations, source documentation, documenting informed consent, inclusion/exclusion, safety monitoring, etc. • Review the RCR basic program and integrate into a comprehensive curriculum with advanced and ongoing mandated and elective options o Consider in the future requiring a demonstration of ability to apply the knowledge learned in skill-based cases and simulations and learning assessments, particularly for non-compliance remediation • (Where is training on OnCore and REDCap offered?)

	Recommendations
4. Focus initial training development and implementation on a) vulnerable research populations, b) ethics and conduct of human research, c) creating a U of M Culture of Ethics, and d) piloting all programs in the Department of Psychiatry (cont'd)	**c. Engage U of M colleges, departments and centers to create a U of M Culture of Ethics** • Enhance the availability of and access to a transparent centralized HRP website and regularly disseminated university-wide HRP updates, newsletters, presentations, podcasts, etc. • Engage the University-wide research community in learning about and adapting the national Enhancing Clinical Research Professionals' Training and Qualifications (ECRPTQ) competencies and NCATS' GCP training framework as those are approved and adapted nationally. Update the community as standards evolve. • Hold campus conversations and forums across the university, including Research Grand Rounds that provide for peer-to-peer learning, highlighting what works and what are the challenges in human participant research • Develop required and recommended advanced and refresher training modalities to be promoted and/or implemented by academic units in faculty, investigator, and research staff meetings. • Develop training materials and train facilitators and moderators ('train-the-trainers') to offer opportunities for discussions and peer-to-peer learning at department faculty meetings, Research Grand Rounds, college forums, or research team events on topics such as vulnerable populations research; university policies related to study monitoring; scientific review; and new and evolving regulatory requirements. Offer CE credit as appropriate. • Develop annual updates (perhaps in online format and/or in-person forums) regarding new regulations and policies, audit findings, best practices, etc. Consider collaborating on this with other institutions. Offer CE credit. d. **Plan to Pilot All New Training (4a and b) in the Department of Psychiatry** • Use feedback from pilot usage in Psychiatry research to finalize new training offerings prior to dissemination University-wide.
5. Develop an integrated learning platform	a. Identify an easily accessible, transparent, welcoming Learning Management System (LMS) through which all investigators, CRCs, research staff, IRB members, and research participants can access all HRP learning materials. Ensure that that system: • Integrates with the University's upcoming eIRB system being developed with Huron Consulting • Is easily accessible through the central HRP Education and Training website • Provides a clear self-assessment for determining what training each individual research professional requires initially and as they become involved in additional research activities • Provides access to CITI as well as U of M online learning modules and courses (and links to external resources) • Provides easy registration for other U of M forums, Research Grand Rounds, conferences • Provides access to a wide variety of training materials in various formats such as synchronous and asynchronous webinars, podcasts, research papers, presentations • Notifies faculty and staff of required training, upcoming deadlines, compliance status, and other action items • Manages CE if/when offered • Documents and provides certificates of all online and in-person training that is completed

	Recommendations
	b. Integrate/enhance U of M reporting on all HRP training to provide accessible and clear reporting to users, departments, IRB, SPA, and a University-wide monitoring and quality assurance system • Build into that system prompts for all research professionals and their departments regarding upcoming training recertification requirements (similar to REPA) • Ensure that completion of all CITI modules (required and recommended) can be captured and reported upon by that system.
6. Develop over time a competency-based curriculum plan that includes learner assessment and metrics for program evaluation	• Based upon the top priorities accepted and committed to from this needs assessment, develop a plan outlining the tasks, responsibilities, timeframes, and budget for developing, piloting, and finalizing the priority training programs identified and agreed to from report. Include wherever appropriate: • Learning that addressing knowledge, skills, and attitudes • Experiential and interactive learning formats • Modular learning materials that can integrated and re-used for a variety of learner audiences and purposes) • Learning assessments and demonstration of competencies • Metrics and process for program evaluation and ongoing quality assurance. o As one metric, benchmark the U of M's training against peer institutions to ensure our HRPP training meets or exceeds the norm (p. 17, External Review Work Plan) b. Following review and finalization of the previous priority recommendations, build into the curriculum plan goals and objectives for addressing some secondary priorities: • Review currently-required CITI courses and determine the most appropriate for basic, advanced, and non-compliance training, particularly in relation to a competency-based, hybrid training programs • Idnetify other internal and external high quality resources for training, and for knowledge and competency assessment • Develop modules and/or hybrid advanced programs on international research, research with biospecimens, research involving the use of medical records in clinical environments, and other topics • Completion of a hybrid curriculum for ***clinical research coordinators***: o Build upon the almost-complete competency framework developed by CTSI in conjunction with Mayo o Integrate the current online curriculum o Secure a pool of AHC-wide mentors available to support CRCs, particularly those in small studies, and adapt the Optimizing the Practice of Mentoring course for those mentors, as needed o Develop and include an experiential- and case-based module on 'Challenges of Research Management' (or some such term). Address the challenges that CRCs can face when questioning ethical conduct of research that may differ from the perspective of their investigator/boss. Consider offering this as a 'team-based' course, and including all members of the research team—including investigators.

	Recommendations
6. Develop a competency-based curriculum plan that includes learner assessment and metrics for program evaluation (cont'd)	• Create a module/hybrid program for investigators on 'How to Do Clinical Research' similar to the CRC course, 'Navigating Research.' That course could contain an interactive flow chart of the research process with call-outs explaining and giving examples of each step within the scope of the whole process. Use it as 'just-in-time' training for investigators at the point of need, and demonstrate how changes made in one step (e.g., change to a protocol) can affect others. Use case examples.

Recommendations: Conclusion

The section, 3.3.1.3 Conclusion, of the Final Report of the External Review states that ". . . it is essential that individuals at all levels of the human research protections program be knowledgeable about the ethical principles, as well as the specific regulatory, policy, and procedural requirements related to human subjects research. . . It is critical that training in human subjects protections not fall prey to the decision to 'right-size' educational requirements in the wake of ongoing institutional efforts to reduce the administrative burden placed on researchers. . . Advanced level training should allow for in-depth exploration of specific topics in human subjects protections." We recommend that the University of Minnesota strengthen the current knowledge-based human research protection training and work to develop, assess and implement skill and attitude-based training over the next three years. The resulting training program should be comprised of a hybrid of online, discussion, peer-learning, case and simulation, problem-solving practice, learning assessment, and demonstration of competence. Training programs need to ensure the appropriate levels of training for the specific research being performed and that human subjects are appropriately protected. Simultaneously, the training must be of high quality, and the potential burdens for investigators and staff to understand, obtain and remain compliant with the required training should be minimized. Advanced training should be strongly encouraged, supported, and rewarded.

Approved For-Credit Courses

All of the below courses satisfy the NSF and USDA-NIFA ethics training requirements. If you have completed and passed an approved course, you have satisfied the requirement and no further action is required.

Twin Cities campus

All of the following are graduate courses, unless otherwise noted.

ANSC 8134 - Ethical Conduct of Animal Research
APEC 8901 - Graduate Seminar - Applied Economics
APEC 8902 - Graduate Seminar - Applied Economics *APSC 8123* - Research Ethics in the Plant and Environmental Sciences
BBE 8001 - Graduate Seminar - Bioproducts and Biosystems Science, Engineering & Management; Natural Resources Science & Management
BBE 8002 - Graduate Seminar - Bioproducts and Biosystems Science, Engineering & Management; Natural Resources Science & Management
BICB 8401 - Ethics in Bioinformatics and Computational Biology
BIOC 8401 - Ethics, Public Policy and Careers in Molecular and Cellular Biology
BTHX 5000 - Standards for Research with Human Participants: A Lecture Series for Researchers (undergrad)
BTHX 8000 - Standards for Research with Human Participants: A Lecture Series for Researchers
CBIO 8001 - Conservation Biology Seminar
CE 8581 - Research and Professional Ethics in Water Resources and Environmental Sciences
CHEM 8066 - Professional Conduct of Chemical Research
CI 8133 - Research Methods in Curriculum and Instruction
CMB 8134 - Ethical Conduct of Animal Research
DES 8181 – Research Ethics
DHA 8181 - Ethics and Research
EE 8925 - Ethics and Professional Conduct in EE
ENT 5920 - Special Lectures in Entomology
ENT 8061 - Scientific Communication and Ethics
ESCI 8001 - Introductory Graduate Seminar in Earth Sciences
FR 8107 - Seminar: Forest Resources
FSCN 8318 - Current Issues in Food Science
N7100 – DNP Seminar I: Project Planning
N7101 – DNP Seminar II
*NSc 832*1 - Career Skills and Understanding Responsibilities as a Neuroscientist
NURS 8181 - Protection of Research Subjects
NUTR 8621 - Presentation Skills
OLPD 5080/8095 - Surviving in the Research World (grad/undergrad)
OLPD 5087 – Masters Research Seminar
PBS 8123 - Research Ethics in the Plant and Environmental Sciences
PHYS 5980 - Introduction to Research Seminar
PLPA 8123 - Research Ethics in the Plant and Environmental Sciences
PSY 4994V - Honor's Research Practicum (undergrad)
PSY 5993 - Research Laboratory in Psychology (grad/undergrad)
PSY 8542 - Ethics in Psychology
PSY 8993 - Research Methods in Industrial and Organizational Psychology
PubH 6348 – Writing Research Grants
SOIL 8123 - Research Ethics in the Plant and Environmental Sciences
STAT 8801 - Statistical Consulting
VMED 8134 - Ethical Conduct of Animal Research
WRS 8581 - Research and Professional Ethics in Water Resources and Environmental Sciences

For-credit, Duluth campus

All of the following are graduate courses, unless otherwise noted.

CS 8993 - Seminar *CSD 5100* - Research Methods in Communication Disorders *EDUC 8020* - Doctoral Seminar *EMGT 4110* - Engineering Professionalism and Practice (undergrad) *GEOL 8200* - Professional Issues in Geological Sciences	*IBS 8099* - The Biological Practitioner *MBA 8111* - Business, Government and Society *MED 5085* - Medical Research Ethics, Responsible Conduct of Research (undergrad/grad) *PHYS 5090* - Physics Seminar (undergrad/grad) *SW 8102* - Advanced Research *WRS 8581* - Research and Professional Ethics

Approved Non-Credit Activities

All of the below courses satisfy the NSF and USDA-NIFA requirements. If you have completed one of the below non-credit activities, you must fill out and submit a completion form to fulfill the ethics requirement.

Ecology, Evolution and Behavior: Ethics in Research and Scholarship Seminar Series (grad)
Mechanical Engineering: Research Ethics and Professional Practice (grad)
Electrical and Computer Engineering: Ethics and Professional Conduct in Electrical Engineering (grad)
Chemical Engineering & Materials Science: Ethics in Science & Engineering
Biomedical Engineering: Ethics in Science & Engineering
Biomedical Engineering Graduate Program Orientation
UMD Chemistry and Biochemistry: Ethics and Responsible Conduct of Research
Computer Science and Engineering: Ethics and the Computer Science Graduate Student

Emory: Training for Clinical Research Staff

Click on the name of the role to review content information.

Investigators (PI, Co-I, Sub-I)

Mandatory courses

*Investigators include PIs, Co-Is, Sub-Is, and residents/fellows/nurses functioning in the role of an investigator.

Courses	Description	CMEs?	Renewal	Who to contact about the course?
Collaborative Institutional Training Initiative (CITI)	An on-line course facilitated in CITI and offered by the University of Miami in collaboration with Emory University Institutional Review Board (IRB). The course is web-based and required prior to submitting research protocols for review and approval for all Key Personnel listed on the Emory IRB submission, regardless of their position.	No	Yes, every 3 years.	Emory's IRB at IRB@emory.edu or 404-712-0720. For course details and registration information, please review the CITI Training page athttp://www.irb.emory.edu/training/courses/citi.html.
Conflict of Interest (COI)	An on-line course facilitated in eCOI and offered by the Office of Conflict of Interest (COI) for faculty and staff to certify that they have received information about Emory's policies and the federal regulations on Objectivity in Research.	No	Yes, every 4 years.	Emory's COI at COI-Office@listserv.cc.emory.edu or 404-712-0046. For course details and registration, please review these COI User Guide.
Key Concepts in Clinical Research for Investigators	An on-line facilitated by ELMS for Emory Investigators conducting clinical trials at Emory per the NIH definition. The course aims to move beyond the required CITI modules and provide Investigators with useful, Emory-specific content.	Yes *12 AMA PRA Category 1 Credits™ are issued as continuing credits when requested.*	Yes, every 3 years.	Emory's OCR at OCR@Emory.edu or 404-778-4960. For course details and registration, please review the Key Concepts User Guide to navigate ELMS and print certificate of completion.

Department of Psychiatry

Final Report

Dr. Mark Paller, Interim Head, Department of Psychiatry

June 30, 2016

The Department of Psychiatry has been a key focus of the University's work to Advance Human Research Protections. Over the past year of this work, the faculty and staff in the department have embraced the change and improvements proposed and have gone above and beyond what has been requested of them. They have embraced a new culture of transparency and collaboration and have been working with the Clinical Translational Science Institute to institute Good Clinical Practices. They have welcomed additional monitoring and project management support of trials and passed several new policies to enhance the ethics and quality of their work. The Department's research council has also had several meetings with the Center for Bioethics to discuss consent and other issues.

The Department's culture has already begun to shift under new leadership, and the faculty look forward to the new permanent head starting this summer. Dr. Sophia Vinogradov is an accomplished researcher, clinician and leader and will help move the work of the faculty and staff forward. She has already begun meeting with stakeholders in the department and the community and will be a major step forward for our work in this important area.

This report will share specifically the accomplishments made in response to the Implementation Team report, approved by the Regents on June 12, 2015. Following that approval Dr. Mark Paller was charged by President Kaler to led the implementation of the recommendations for the Department of Psychiatry.

In order to address the ongoing criticism of the department's culture and practices, the Implementation Team focused on:

- CTSI management of interventional drug and device trials in the Department of Psychiatry
- Education and training for investigators and research staff
- Training for investigators and research staff specific to clinical research with individuals who have impaired or fluctuating capacity to consent
- A specific IRB panel with specialized training on the unique needs of vulnerable individuals
- Climate assessment
- Enhancing a culture of mutual trust between clinical care and research
- Enhanced research training and oversight of two investigators

CTSI Management

As of July 1, 2016 CTSI will manage human participant trials in the Department of Psychiatry. CTSI has already been working with investigators and staff for several months, and the team feels that there has been a great deal of progress in understanding and implementing Good Clinical Practices.

CTSI is currently searching for both a Psychiatry Department Clinical Research manager and a Regulatory Specialist for the department, individuals who will be responsible for overseeing the management of human subject research for the department. Until the positions are filled, CTSI's Lead Clinical Research Advisor and one of the Regulatory Specialists from CTSI's Research Services team will support Psychiatry research and student personnel. In addition, CTSI monitors are starting to monitor additional studies in the Psychiatry research portfolio. (full plan attached) CTSI has engaged new head Dr. Sophia Vinogradov in this work.

Kelvin Lim, Vice Chair for Research, is co-owner, along with Susan Craddock of the Center for Bioethics, of a new course being developed by CTSI entitled Good Clinical Practices: The Informed Consent Process. This training will begin as a pilot in Psychiatry in late August. (description attached)

In addition, investigators in the department have started moving their trials to the OnCore Clinical Trials Management system, and CTSI's Clinical Trials Financial Services team is providing financial management for Psychiatry trials. Faculty are supportive of, and fully engaged in, the transition to CTSI oversight.

Education and Training

The Department will take part in all training required by the new AHRP Education Advisory Group which will be run by and report to OVPR. The Department also plans to participate in that group as requested.

Impaired or fluctuating consent

The Department is working closely with HRPP to implement new policies and training in this area and is serving as a pilot to test the new tools being proposed in the proposed new policy.

IRB panels

The Department has faculty participating in the IRB, in addition to the expertise in this area from outside the University. The department responded to a request from the IRB last year with recommendations for several new members of the IRB.

Climate Assessment

In response to concerns that there was an unproductive and potentially hostile climate between the clinical staff and researchers within behavioral health, several recommendations have been made regarding the assessment and improvement of the culture in the behavioral health unit.

The IRB in 2015 did an investigation into concerns expressed about psychiatric research which has been called the Oakes report. That report found a level of mistrust and misunderstanding between clinical

staff and researchers, but no specific examples of non-compliance. A follow-up climate assessment will be conducted by Fairview Research Services with oversight from FUROC.

In addition, Dr. Vinogradov is undertaking a comprehensive strategic planning process for the Department and its clinical partners within University of Minnesota Physicians, University of Minnesota Health, and Fairview Health Services. Part of this process will be a comprehensive environmental assessment for the department and clinical units.

Culture of inclusion

The Department took very seriously the need to improve communication and collaboration with clinical staff at Fairview. In November 2015 they convened a joint Fairview Behavioral Health and UMN Department of Psychiatry committee to develop policies and procedures for systematically obtaining clinical staff input on psychiatry clinical research projects prior to IRB submission and again following IRB approval. The checklist (attached) has been implemented to a positive response and may possibly be used for other areas of research as well. Monitoring compliance with this process will be the responsibility of the Clinical Research Manager.

Two Investigators

The external review focused specifically on two researchers in the Department of Psychiatry who have received ongoing criticism. The implementation team recommended that they received supervision, coaching and advanced training in human participant protections. The team also recommended more enhanced monitoring for clinical research protocols they participate in and that they attend the OVPR symposium on human research participant ethics.

One of those researchers has retired and is no longer a member of the department or University faculty. The other is not currently participating in research but fully understands the requirements if he chooses to reengage (memo attached). He did attend the ethics conference in December 2015.

Additional information

The Department has instituted a new policy to mitigate issues of therapeutic misconception. Going forward, an investigator who is also a treating physician should not be involved in the consenting process (memo attached). It is important to note that this change was not required by the University but is something the Department chose to do, with the support of the Medical School and the University.

Conclusion

The culture and practices in the Department of Psychiatry have and are continuing to improve. The faculty and staff have embraced change and will continue to participate in new required and recommended processes in order to maintain the highest levels of ethics and research. The steps recommended by the Implementation Team are complete or near it, however, maintaining high standards will be ongoing work for the department, the Medical School and the University.

Department of Psychiatry Human Research
Management Plan for July 1, 2016

Personnel Assigned: CTSI will assign 2.0 FTE to Psychiatry effective July 1, 2016

- Anne Hopper, CTSI's Lead Clinical Research Advisor, will be in the Psychiatry department 20 hours a week, until the time that the Psychiatry Clinical Research Manager is hired/on board.
- A Regulatory Specialist (TBA), will be in the Psychiatry department 20 hours per week, until the time that the Regulatory Specialist for Psychiatry is hired/on board.
- A Clinical Research Associate (aka Monitor) will begin monitoring all research involving humans, following the attached monitoring plan (see page 4-5).
- Jennifer Maas, RN, a Clinical Research Preceptor, will begin in-person clinical research training and education on August 1, 2016, increasing the FTE effort from the original 2.0 FTE assigned. Group in-person sessions are open to both investigators and research staff, while the individualized training/education is targeted to the research staff.

Management Activities:

- CTSI's Workforce Manager is in contact with the Human Research team for Psychiatry to ensure a complete listing of all staff in the of Psychiatry who support human research.
- A departmental email account to support research management has been established (psychrsh@umn.edu) and all studies will be required to submit an Add/Change personnel form to the IRB no later than Friday, July 8, 2016, adding psychrsh@umn.edu as a correspondent on the study.
- Working with investigators and study teams, a listing of all active Psychiatry human research studies (excluding studies in data analysis only) will be confirmed (between July 1-8) and beginning the week of July 11, project status update meetings will be conducted by the CTSI team, on an every other week basis. A representative from each study will be required to attend these weekly meetings and report the current status of the study.
    - Data items updated weekly include:
        - Status (new, enrolling, closed to enrollment, hold, etc.)
        - Regulatory/IRB updates (including any upcoming monitoring visits)
        - Overall study issues/concerns if any
        - Recruitment updates
        - Anticipated start
        - Anticipated close
        - Enrollment goal
        - # consented
        - # screen fail
        - # randomized
        - # completed
        - Date closed

    - These meetings will also serve as an opportunity for study staff to ask questions and share insights regarding their studies and serve as a venue to facilitate awareness of other research activities and share expertise with colleagues.
    - In between the weekly meetings, Anne Hopper and the Regulatory Specialist will follow-up with study staff who have questions, identify issues, or need guidance on studies.
- Investigators and study teams will be required to inform psychrsh@umn.edu (at a minimum) as planning for new studies begins. Once informed, the CTSI staff will assist with navigating the various research systems (OnCore, Clinical Trials Financial Services, Fairview Research Administration), answering questions, and providing guidance.
- Additionally, Anne and the Regulatory Specialist are available to assist investigators and staff with study questions, navigation of the research environment, etc.
- As studies are monitored, a copy of the monitoring report will be shared with the CTSI management group, so they are able to follow-up and assist with resolving findings. In addition, the Monitor is available to offer guidance to the study teams, as questions related to the monitoring visits arise.
- In early July, Psychiatry Research Staff will be asked to complete the new HIPAA course (***HIPAA 16 - HIPAA Training***, available through U Learn), if it isn't already complete. Additionally, staff will be asked to confirm that their ***CITI Basic course*** training is up to date (available through CITI; sign in through the "Log in through my institution" section on the right side). The requirement will be that these two trainings are complete no later than July 31, 2016.
- During the middle of July, CTSI's Workforce Development team will conduct a proctored Clinical Research Coordinator competency-based assessment, which will serve as the basis for providing in-person group and individual educational and training activities.
- After the proctored assessment, staff will be informed of the requirement to complete both the online Clinical Research Coordinator training program and CITI's Good Clinical Practice (GCP) course prior to August 15, 2016.
    - Topics included in the Clinical Research Coordinator training program training program include:
        - Non-Fairview Employed Research Staff (NERS) (as required)
        - Research 101 for Clinical Research Coordinators (offers certificate of completion)
        - Bloodborne Pathogens
        - Good Clinical Practice
        - Hazardous Material Shipping
        - Navigating Research at the University of Minnesota
        - Research Ethics (offers certificate of completion)
        - Role of CRC Certification (offers certificate of completion)
        - University of Minnesota and Fairview Research Policies (offers certificate of completion)
        - Participant Recruitment and Retention
- Beginning in August 2016, Jennifer Maas will conduct in-person group training sessions, where the topics will be based on the results of the Clinical Research Coordinator

assessment. These sessions will focus on the work of the research staff, but all investigators will be informed of the sessions and invited to attend.

- As new training sessions are developed and offered by HRPP (or others) on topics such as new policies or the capacity to consent, the CTSI team will ensure that investigators and study team members are aware of the sessions and will be strongly encouraged to attend.
- In late August, the ***Good Clinical Practices: The Informed Consent Process*** course will begin as a pilot for Psychiatry investigators and study staff.
- All research staff will be added to the CRC listserv managed by the CTSI, and will be strongly encouraged to attend the bi-weekly Clinical Research Professional Development Series.
- A proctored post-assessment will be administered upon completion of the training program to ensure all competencies have been met.

PSYCHIATRY MONITORING PLAN

(for studies that are not a part of the current CTSI Monitoring Program)

Step 1.

Meet with each investigator and coordinator to do “a pre-monitoring visit”.

At this visit, the monitor will review regulatory binder requirements, case report form completion, and IRB and GCP requirements with the investigator and study team.

Set up first monitoring visit for 3 weeks from date to review regulatory binder and any subject data if applicable.

Step 2.

3 weeks after start up visit, first monitoring visit will take place.

After completing monitoring visit and reviewing with coordinator and PI the items that require prompt attention. Prompt attention items are items deemed critical to the study conduct or subject safety (if any), see examples below. If the study has items that need prompt attention follow-up review visits will be scheduled at 3-week intervals until all items are completed. If the study does not have any items that require prompt attention, a review visit will be scheduled for 6 weeks after first visit.

If prompt attention items are not completed after 3 weeks, monitor will use the CTSI monitoring escalation plan.

Step 3.

Once study has been monitored two consecutive times and does not have any major findings (prompt attentions items) we will put it on a 6-month visit schedule.

Items requiring ***Prompt Attention*** (including but not limited to):

Consent issues:
Wrong version consent signed
Consent process not documented
Missing signatures or signature dates
No consent for subjects

HIPAA:
No HIPAA forms signed or missing forms

Data Issues:
Missing data on CRF's that are primary endpoints
SAE's not reported
Signature logs not complete for who can consent

Enrollment:
Ineligible subjects enrolled
Subject eligibility not documented
Improper recruitment of study subjects

Protocol compliance:
Missed assessments that affect subject safety or study objectives

Good Clinical Practices: The Informed Consent Process

Background and Purpose

Recommendations from two 2015 External Reviews of clinical research at the University of Minnesota defined some priorities for the training and education of investigators, research coordinators, and research staff. Priority training needs include:

- Good Clinical Practices
- Reporting of adverse events and protocol deviations
- Source Documentation
- Documentation of informed consent
- Inclusion/exclusion criteria assessment prior to consenting
- Safety monitoring.

Concurrent to the University of Minnesota reviews, in 2014 - 2015, the National Center for Advancing Translational sciences (NCATS) sponsored a national task force initiative, Enhancing Clinical Research Professionals' Training and Qualification (ECRPTQ). The purpose of that project is to 'improve the efficiency, safety, and quality of clinical research, as well as reduce redundant training requirements.' To date, the task force has delivered two products to NCATS for approval: 1) recommendations for a national mandate that all study personnel engaged in drug, device, biologic, and/or behavioral intervention studies should receive **GCP training**, and 2) minimal **competencies** necessary for research personnel to execute safe, high quality, and efficient clinical trials, the definition of which will serve as the basis for the development of a training approach to teach and assess those competencies.

The Education and Training component of the University's Advancing Human Research Protections Implementation Team is in the process of evaluating current training resources and identifying priority areas of needed enhancement. Within the context of that larger process, we will begin to upgrade training in the most critical areas of need by developing competency-based, hybrid-format programs for investigators and research teams. The University already offers a number of good knowledge-based training programs—including a semester-long Standards for Research with Human Participants course, ongoing IRB and CTSI presentations, The Clinical Research Coordinators Orientation curriculum, and the CITI basic training course—on which to base additional skill-building and application courses. It has been recommended that new training programs will be pilot-tested within the Department of Psychiatry.

Based upon the priorities outlined in the external reviews, this proposal outlines the first course to be developed and piloted within the Department of Psychiatry: *Good Clinical Practices: The Informed Consent Process*. The general scope of that course will include:

- Basic concepts and definitions, such as vulnerable populations, therapeutic misconception, and coercion
- Best recruiting practices
- Informed consent plans (PI) – ICH6
- Writing of forms (to appropriate grade level)
- Documentation of informed consent
- Documentation of inclusion/exclusion criteria assessment prior to consenting
- Protection of Privacy requirements
- Conducting an ongoing consent process throughout a research study for vulnerable participants and/or those with diminished and/or fluctuating decision-making capacity (including the legal use of surrogate decision-makers)

The Need: Quality Learning Programs and Environments

Educational theory has long held that knowledge-based learning is insufficient to ensure the development of skills and attitudes required to demonstrate basic competence and sustained performance. Yet, the learning objectives of the University's current *Informed Consent* modules in the Basic course (CITI) offer learning objectives (followed by multiple choice questions) that are inadequate to fully equip all research personnel with an understanding of what constitutes good clinical practices and adequate, appropriate protection of human participants in clinical trials.

Learning Objectives: By the end of the module you should be able to:

- ***Describe*** the requirements for complying with informed consent regulations.
- ***Describe*** the process for obtaining informed consent.
- ***Define*** vulnerable populations
- ***Describe*** the regulations for waiving informed consent.

(The five learning outcomes from the GCP course, *Informed Consent in Clinical Trials of Drugs, Biologics, and Devices* are a slight variation on this theme.)

When printed, the basic *Informed Consent* module consists of a little over four pages (including references and resources).

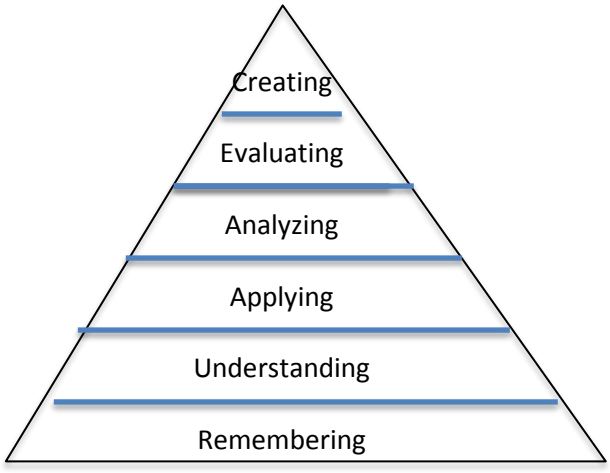
Although CITI courses and modules are a national standard used to train the many busy investigators and research staff in this country, relying solely on online modules characterized by multiple choice questions accompanied by only basic explanations is contributing to the challenges that the University is experiencing with the quality of our human subjects research. After taking the five minutes it took to complete this *Informed Consent* module and receiving a score of 100%, I do not feel that I ***know*** the regulations guiding informed consent (nor exactly where to find them as reference), could not ***set up or manage*** the process in a clinical study, and certainly did not have a chance to ***experience the underlying values critical to conducting safe clinical trials, nor to internalize the importance of*** this procedure within the context of the ethical conduct of research.

Quite simply, this 'get it done as quickly as possible' read-through of the CITI *Informed Consent* module did not constitute a meaningful learning opportunity.

Why? Basic learning theory and principles offer multiple explanations. Consider the CITI module learning outcomes and assessment described above against the learning frameworks summarized below. In every case, the CITI module addresses only the lowest levels of thinking and learning within each model.

Bloom's Revised Taxonomy of Cognitive Levels

Benjamin Bloom's definition of levels of thinking build in upward order of difficulty, from basic memorization to high orders of critical thinking skills. Since the 1950's, educators have used Bloom's taxonomy of learning objectives as a guideline for the purposeful design of learning based on the needs of the target learners.



Anderson, L.W., Krathwohl, D.R., & Bloom, B.S. (2001). *A taxonomy for learning, teaching, and assessing: A revision of Bloom's taxonomy of educational objectives.* Allyn & Bacon.

Kirkpatrick's Evaluation Framework

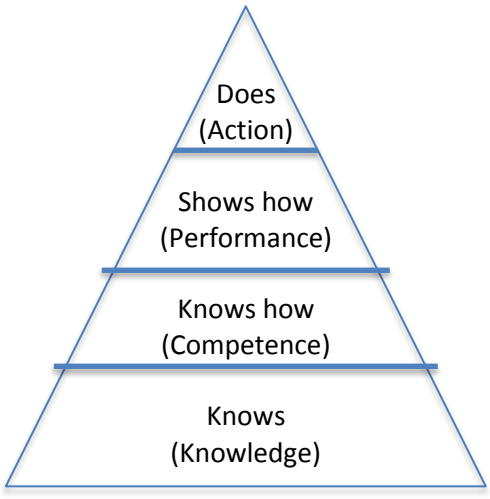
Also in the 1950's, Donald Kirkpatrick developed a training evaluation model to measure the effectiveness of training based on four levels: 1) reaction, 2) learning, 3) behavior, and 4) results. As he continued to revise the model in later years, using it as a standard for defining measurable learning outcomes, Kirkpatrick continued to postulate the highest form of learning outcome to be ***performance***. In 2015, Kirkpatrick's model was adapted into the following framework, which stipulates performance outcomes related to change in practice as well as impact on patients, families, and communities in the context of interprofessional clinical care. This model can also be applied to the design of training and education in clinical research.

Level 1a:	Learner's reaction
Level 2a:	Modification of attitudes/perception
Level 2b:	Acquisition of knowledge and/or skills
Level 3:	Behavioral change
Level 4a:	Change in organizational practice
Level 4b:	Benefits to patients or clients

Barr, H., Koppel, I., Reeves, S., Hammick, M., & Freeth, D.S. (2008). *Effective interprofessional education: argument, assumption and evidence (promoting partnership for health).* John Wiley & Sons.

Miller's Pyramid of Assessment

Developed for the purpose of assessing clinical skills, George Miller, MD, developed a now commonly used framework for designing and measuring competence and performance of medical cognition and behavior:



Miller, G.E. (1990). The assessment of clinical skills/competence/performance. *Academic Medicine* 65(9), S63-S67.

Learning and Performance Ecosystems

Current constructs from the world of learning and learning organization design suggest that successful learning occurs within settings in which learning is both formal and informal, structured and self-directed, and supported at the moment-of-need in order to promote effective performance.

This would suggest, for example, that investigators and research teams not only be provided programs to learn knowledge, skills, attitudes, achieve competence, and demonstrate performance, but also ongoing access to experts, best-practice resources, and peer-learning at the point of need in the process of implementing their clinical studies.

Rosenberg, M.J., Foreman, S. 2014. Learning and performance ecosystems: Strategy, technology, impact, and challenges. The eLearning Guild, www.eLearningGuild.com.

The University of Minnesota is not only a research institution, but also an educational institution. What is being suggested in this proposal is that it is time to re-examine the training programs currently being offered to investigators and the research workforce, and ensure that those programs provide more than just easy and rapid access to the most basic baseline of knowledge about research with human participants. Instead, we need to seriously address how to design, deliver, evaluate, and create a culture that supports exemplary learning programs that provide knowledge of how to conduct human research studies and offer practice in skillful clinical study management. Such learning programs require learner-centered activities and simulated decision-making about ethical issues that comprise the challenges of real-world research with human subjects.

Audiences

The proposed training program, ***Good Clinical Practices: The Informed Consent Process***, will be designed so that it can be flexibly used to train investigators as well as research coordinators and staff. The initial pilot of the program will be offered to Department of Psychiatry research coordinators and staff as well as faculty who wish to attend. To the degree possible, we intend to develop the course so that it can be adapted to the needs of researchers conducting various types of research, for example, social-behavioral research, for which a shortened version may be appropriate. The course also offers an opportunity for the Post Approval Review program to leverage the course to educate investigators who are non-compliant with consent regulations.

Preliminary Goals and Learning Outcomes

The overarching ***goal*** for course participants is to:

> *Confidently, ethically, and humanely carry out all tasks appropriate to their roles within the research team in the informed consent process for regular and special populations of participants according to the FDA 21CFR 50.25 and 45CFR46.111 requirements, ICH GCP principles and Good Clinical Practice guidelines, Minnesota Law, and University of Minnesota guidelines.*

Possible learning outcomes:

By completing the training, participants will be able to:

- Demonstrate a general understanding of and the capacity to appropriately use as reference 21 CFR 50.25 and 45CFR46.111 requirements, GCP Guideline 4.8: Informed Consent of Subjects, and U of M IRB guidelines (including 2016 guidelines and templates) to carry out their specific research tasks
- Demonstrate an ongoing awareness of and ability to use as guideposts key concepts such as therapeutic misconception and coercion, and the differentiation of goals between research and care
- As such, to utilize recruitment strategies that do not breech conflict of interest (such as physicians recruiting their own patients) or therapeutic misconception arenas.
- Evaluate the general quality and completeness of an informed consent plan, including all required documentation throughout the process as well as adherence to privacy requirements
- Implement strategies to develop consent forms—adapted from standardized templates—that are appropriate to specific research participants
- Demonstrate correct and appropriate conduct of the consent process throughout a research study, including documentation of inclusion/exclusion assessment prior to consenting, protection of vulnerable populations and/or studies with individuals with diminished and/or fluctuating decision-making capacity (including the legal use of surrogate decision-makers, and strategies for protection of privacy). (For example, in therapeutic research, ensure that participants can describe what will happen in research vs what will happen in clinical care for their condition.)
- Consider the topic, locus, and culture of each research study and its participants, and—while maintaining consistent ethical standards—adapt the informed consent process appropriately

- In the case of real-world challenges and 'grey areas' that investigators and research teams encounter in the informed consent process, to reflect upon and generate solutions that are positive for human participants while maintaining study goals.
- Demonstrate methods to evaluate and ensure that the consent process has been understood by and has been beneficial to research participants.

We might also consider integrating competencies from the **NCATS/ECRPSTQ domains and competencies**:

- Ethical & Participant Safety Considerations:
  - Apply relevant principles of human subject protections and privacy throughout all stages of a clinical trial
  - Define vulnerable populations and additional safeguards needed for protection of those populations
  - Explain how inclusion and exclusion criteria are included in a clinical trial protocol to assure human subject protection
- Study and Site Management:
  - Develop strategies to manage participant recruitment, study activities, and track progress
- Leadership, Professionalism, and Team Science
  - Identify, analyze, and address ethical and professional conflicts associated with the conduct of clinical trials, in particular, the informed consent process
  - Identify and apply professional guidelines and codes of ethics as they relate to the conduct of clinical trials, in particular, the informed consent process
  - Recognize the potential effects of cultural diversity and the need for cultural competence in the design and conduct of clinical trials

Description of the Course

The blended format for the Informed Consent Course for research staff may include online pre-work and two two-hour in-person workshops in which participants will work as large and small groups to complete a variety of activities. IRB personnel and research experts will be invited to participate in the facilitation of the face-to-face workshops. If possible, a community member who has participated in research and/or served as an LAR will be invited to lead a pertinent part of the program. Learners will be encouraged to bring mobile devices (e.g., laptops or tablets) to use throughout the workshop sessions in order to more easily familiarize themselves with informed consent resources.

Possible topics, activities, and formats for the course follow, and will be designed to support the achievement of the suggested learning outcomes. It is likely that a shorter version, possibly with less in-person practice, will be configured for investigators. Also, versions for specific types of research that may not require as much in-depth study and practice can be configured as needed.

Examples, scenarios, and quotations from community participant focus groups will be integrated throughout the online modules and the workshops. One or two participants will be invited to participate in a panel in the first workshop.

Session 1 Pre-Work 40 minutes seat time: 2 modules

Topics/Content	Activity Ideas	Formats/Media	Time
Informed Consent Guidelines • Code of Federal Regulations Title 21 (21 CFR 50.25) and 45CFR46.111 • GCP Regulation 4.8: Informed Consent of Subjects • University of Minnesota guidelines • Fairview guidelines • Relevant slides from Standards course (assuming permission by Steve Miles)	• Conduct a 'scavenger hunt' (finding specific information per questions and cases) referring to online resources that may include: o CITI GCP Basic *Informed Consent* module that covers 45CFR46.116(a) and 21CFRPark 50.25(a) (if we can get access for learners just for that module or a couple preceding it and not require completion of the quizzes) o Belmont Report and Declaration of Helsinki o Overview of GCP 4.8 using the University's GCP course at ctsieducation.umn.edu o Guidelines regarding U of M requirements and IRB preferences at: www.research.umn.edu/irb/guidance/consent.html and http://www.research.umn.edu/irb/guidance/guide4.html	• Learners will be directed to a course webpage from which they can download the pdf questions and case assignment questions • Learners can bring completed assign-ments on a mobile device or in print form	15 - 20 minutes
Informed Consent: Key Concepts	• Key definitions, concepts, and examples of therapeutic misconception, coercion, vulnerable populations, capacity to consent, assent and consent, etc. • References to the SOP Definition Library and HRPP Policies	• Use portions of existing modules such as "Integrating Research into Clinical Environments • Include first-hand reports and examples from research participants	15 – 20 minutes

Session 1

Topics/Content	Activity Ideas	Formats/Media	Time
Overview and Context-Setting of Informed Consent	• IRB expert provides overview of Informed Consent planning and IRB review and approval process regarding **content of consent plans**. Includes: o Differences between and preferences for use of GCP Reg. 4.8 and FDA 21 CFR 50.25 o Common areas of need found by the IRB with U of M protocol/informed consent submittals o Informed consent is an ongoing process; commitment to keep participants informed o Roles and responsibilities on the team	• Presentation with demonstration of where to find resources online	15 minutes
Introduction and Stage Setting	• Placing the Informed Consent process within the ethical framework of the Belmont Report and Respect for persons • Integrate ethical recruitment strategies from the outset • Therapeutic misconception/ensuring that participants can describe the target outcomes of the research as well as what will happen	• Large group • Review in small groups	15 minutes

	with clinical care pertaining to their condition • Quick exercise to apply key content – demonstrate one standard but some adaptation based on type of study		
Preparing the Informed Consent Form	• Referring to handouts/links from the GCP course and the IRB website, the IRB representative provides an overview of effective consent forms and refers to new University templates • Overview of language for the consent process • In small groups, learners evaluate strengths of example consent forms, and how they might be improved for specific audiences (e.g., word choices, graphics, etc.) • IRB representative leads large group debrief.	• Large group presentation • Small group work and large group debrief (University's GCP course contains good suggestions/handouts for this)	30 minutes
The Informed Consent Process: Good Practice Strategies	• Small panel of research manager or coordinator and, optimally, one or two **participants** who have participated in clinical trials present good practice strategies of the consent process (e.g., response to non-verbal cues, good questions to ask, participant explanation of study) • Video 'critique' in large group with responses from panel o Include specific discussion of protection of privacy requirements and strategies throughout the process o Discussion of participants or witness signatures • Q&A from the large group	• Realistic video presentation of one or two individuals being consented • Possibly checklist of good practice informed consent strategies • Panel discussion regarding the video • Include new materials such as Participant Contact Card, Bill of Rights, Core Commitments	45 minutes
Evaluating and ensuring an ethical and high quality consent process	• Small group discussion about how to obtain feedback from participants to ensure their ongoing understanding of the study and their role as well as their comfort in participating • Large group report out and summary	• Small groups discuss strategies for obtaining ongoing feedback from participants regarding their understanding of and comfort with the study	15 minutes
Commitment to change	• Individuals suggest one or two 'take-aways' that they plan to implement • Session summary and conclusion	• Large group • Summary handout of 'To Do's and Not To Do's' in the informed consent process	15 minutes

Session 2 Pre-Work

Topics/Content	Activity Ideas	Formats/Media	Time
Ethical Recruitment and Informed Consent of Special Populations and in Special Circumstances	• Online module summarizing regulations and guidelines for recruitment and consent in: o Research with vulnerable populations o Research with participants with diminished or fluctuating decision-making capacity o Emergency situations o International studies o ADA populations o ESL and non-literature populations • New policies (Courtney) • Assent • Translated Short Forms and federal requirements • Perhaps use the University's module, *Integrating Research into Clinical Environments*, and provide learners overview of research vs care (therapeutic misconception; benefits of research, etc.)	• Create a short module based on/adapting the 'Communicating with Patients' section of the Intro to Translational Research module that focuses on special populations	20 minutes

Session 2

Topics/Content	Activity Ideas	Formats/Media	Time
Informed Consent of Special Populations and in Special Circumstances	• Apply what's been learned in a presentation and discussion of cases that illustrate definitions of, challenges, and concerns for vulnerable populations, individuals with limited and/or fluctuating capacity for decision-making, or other specific scenarios such as different (i.e., nonwestern) understandings of consent, consent across geographies, language or disabilities challenges, emergency situations, etc. • Assessing capacity to consent • Discussion of strategies for ongoing consent process throughout a study	• Small group discussions of a series of cases • Large group report-outs from individual groups of their cases (peer-learning) • New materials: SOPs, worksheets, checklists for consent/assent/LAR	30 minutes
Informed Consent Documentation	• Interactive presentation of the regulations and good practices pertaining to documentation, such as: o Documentation of inclusion/exclusion criteria after consent is signed o Documentation that participants must receive o New information requiring update of a written informed consent form o Documentation of consent in source document such as the participant's medical record o Signatures and dating of informed consent with special populations, including	• Interactive PowerPoint or presentation of situations in which learners suggest requirements and sources for those requirements	20 minutes

	witnesses or LAR • How do you find and use the correct version? • Staying organized by integrating OnCore • Sharing of information post-study closure/ dissemination of results (and sharing incidental findings)		
Rolling Role Play	• Small groups are assigned to conduct one part of the consent process for a case that includes: o Recruitment check using and documenting inclusion/exclusion criteria o Completing the first part of the consent process o Consenting at a second visit and/or when new information is available o Checking for documentation o Introducing new information o Obtaining feedback o Interpersonal and communication skills	• Develop cases and participant descriptions. Facilitators play participants. Small groups are given 5 minutes to plan their section, and 1 member does the role play. Debriefs with the large group ensure key points are addressed • Consider Philphott Jones' SPIKES model (Courtney)	30 minutes
Managing Challenges	• Real scenarios are presented in individual slides of events that have challenged the ethical conduct of the consent process. A panel including a department head, IRB expert, investigator, and CRC would be valuable to facilitate the discussion. Roles and responsibilities of investigators, research team members; sources of conflict resolution at the University; negotiating with sponsors resources to refer to should be included.	• Panel and large group discussion • (Courtney): Identifying non-verbal cues; cultural awareness; handling a 'pushy' LAR; potential participant qualifies but concerns exist; PI wants someone enrolled but coordinator doesn't	30 minutes
Conclusion	• Summary • Sent as email survey, learner assessment will contain questions about key concepts, some in scenarios. Qualitative information will also be gathered regarding intention and actual application of what was learned. • Course evaluation questions will be included in that survey for ongoing quality improvement.	• Qualtrics online survey to be sent following course	5 minutes

Course Owners

Kelvin Lim and Susan Craddock will serve as the 'course owners' or primary stakeholders for this course. Each will provide review/feedback, oversight, and approval of the course throughout and at the end of the development process.

Subject Matter Experts and Consultants

The next step in developing this course and finalizing a plan will be for the instructional designer to convene experts in the Informed Consent process to review and revise this course design, including the planned learning outcomes, content, and suggested formats. The role of the subject matter experts is to determine and provide access to the appropriate content to be learned, reflect the learning styles and format preferences of learners, and review the course as it is developed by the instructional designer to ensure its quality. Subject matter experts/consultants should expect to spend approximately 10 – 12 hours total working on this project over a three—four month timeframe. Subject matter experts may each work on a separate part of the course, so that their time gathering and contributing content will be minimized and not duplicated. The subject matter experts might include the following:

Amanda Galster	Research Support Manager	Dept. of Pediatrics, Medical School
Brenda Prich	Research Support Manager	CTSI
Courtney Jarboe	Education & Outreach Specialist	HRPP/IRB
Jeff Wosniak	Associate Professor	Dept. of Psychiatry, Medical School
Mia Wong	Clinical Research Associate (Monitor)	CTSI Monitoring Team
Sheila Kelleher	Sr. Quality Analyst	HRPP/IRB
TBD	Community Member/Research Participant	

Subject matter experts have volunteered to provide content for the following course sections/activities:

Section/Activity	Content Expert(s)
Pre-Work Module 1: Informed Consent Guidelines	Courtney Jarboe
Pre-Work Module 2: Key Concepts	Susan Craddock Kelvin Lim Courtney Jarboe
Session 1: Overview and Context Setting	Amanda Galster
Session 1: Introduction and Stage Setting	Amanda Galster
Session 1: Preparing the Informed Consent Form	Courtney Jarboe (Bethany Hansen)
Session 1: The Informed Consent Process: Good Practice Strategies	Mia Wong Sheila Kelleher (Bethany Hansen)
Session 1: Evaluating and Ensuring an Ethical Consent Process	Sheila Kelleher (Bethany Hansen)
Session 1: Commitment to Change	Janet Shanedling

Section/Activity	Content Expert(s)
Pre-Work Module 3: Ethical Recruitment… Special Populations	Jeff Wozniak Amanda Galster Mia Wong (Michelle Biros)
Session 2: Informed Consent of Special Populations and in Special Circumstances • Assessing capacity	Brenda Prich Amanda Galster Courtney Jarboe
Session 2: Informed Consent Documentation	Brenda Prich Amanda Galster
Session 2: Rolling Role Play	Sheila Kelliher
Session 2: Managing Challenges	Mia Wong Courtney Jarboe Sheila Kelleher (role plays from Kathryn Sklenar?)
Session 2: Conclusion	Janet Shanedling

Deliverables

Resources currently available at the University will serve as the basis for enhanced course development. If possible, access for all learner participants to the University's CITI module, *Informed Consent,* would be optimal. The University's Good Clinical Practices course—accessible through ctsieducation.umn.edu—may be used for online pre-work, specifically the section: *Investigator Roles and Responsibilities, GCP Guideline 4.8: Informed Consent of Subjects*. IRB sites with guidelines and preferences will be used as well not only for content, but as practice accessing resources for ongoing use. Deliverables for the course will include:

1. ***Final design document*** (course 'blueprint') that will be based upon review of this proposal and collaborative revision with content experts.
2. ***Online pre-work/modules***
3. ***Web page*** with all links and materials for the course, both for participants and for presenters.
   - Assignments and links for Session 1 and Session 2 pre-work
   - 'Job aids' and handouts (for example, templates and tips for informed consent forms)
   - Cases and scenarios
   - Agendas
   - GCP, FDA, U of M resources
   - Links to pertinent module sites
   - Interactive space for Q&A
4. ***Facilitator Guide***
5. ***Learning Assessment and Course Evaluation survey***

   * Documented integration of the competency-based learning assessment items developed for the CTSI Clinical Research Coordinator Orientation in collaboration with Mayo.

Development Process

IRB experts and University and Fairview research personnel (including a Dept. of Psychiatry researcher and possible a coordinator) will be asked to serve as content experts working with the instructional designer(s) to design and develop this course. The inclusion of a community member who has served as or supported a research study participant would also be value for ensuring accuracy, focus on priorities, and credibility of content.

Development Activity	Deliverable	Who	When
1. Convene subject matter experts	Provide feedback and revisions to the course design	Instructional designer with content experts	June 13, 2016 Complete
2. Finalize course design	Final course design	Instructional designer	June 27
Stakeholder Review and Approval			July 8
3. Gather content	General ideas, sources, and content	Content experts	By activity/module
4. Group Interviews with Previous Research participants			July 29 – August 7 (Being scheduled)
5. Develop pre-work cases and assignments	**Session 1 Pre-work Module 1**: • Scavenger hunt questions and cases • Resources and links to use • Develop course web-page and link to Moodle to track completion and **program scavenger hunt** **Session 1 Pre-work Module 2:** • Design and program 10 – 15 minute module, including activity tracking) **Session 2 Pre-work Module:** • Interactive online module about special populations and circumstances • Self-assessment	Instructional designer Content experts Instructional technologist Instructional technologist Instructional designer Instructional technologist Content experts	Storyboard: July 15 Review: July 22 Finalize: July 29 Program: 8/12 Storyboard: July 29 Review: August 5 Finalize: August 12 Program: 8/31 Storyboard: Review: Finalize: Program: 9/15
6. Develop Facilitator Guides and Presentation Materials for Session 1 and 2	Facilitator Guides to contain: • Agendas • Outlines/scripts for each section • Rolling role play (Session #2) • Scenarios for discussion of real challenges in studies and guidelines for conducting that discussion • Inventory of all participant materials PowerPoints and presentation materials	Instructional designer Content experts	Sesssion 1 • Draft 1: 7/29 • Review: • Finalize: 8/19 Session 2 • Draft 1: 8/31 • Review: • Finalize: 9/16

Development Activity	Deliverable	Who	
7. Create Video of Consenting Process	Short video with possibly 2 - 3 consenting situations (2-3 minutes each) for critique and discussion in Session 1	Instructional designer Content expert(s) Volunteer 'actors' Instructional technologist	Storyboard: July 29 Review: August 5 Video Shoot: Aug. 8 – 12 Edit: August 12 – 25 Final: August 26
8. Develop In-person Participant Materials	• Checklist of good informed consent strategies • Small group cases for Session #2 for working with special populations • Rolling role play assignment	Instructional designer Content experts	
9. Develop Learner Assessment and Course Evaluation	• Qualtrics Survey	Instructional designer	
10. Final review of materials for pilot	• Provide feedback to instructional designer	Content experts	
11. Finalize all pilot materials and Prepare Facilitators		Instructional designer	Session 1: 8/26 Session 2: 9/23
Stakeholder Review and Approval			
12. Run pilot			Session 1: 8/29 – 31? 9/12-13? Session 2: 9/26 – 30?
13. Final revision following pilot	Based on participant and facilitator feedback, make revisions to final course	Instructional designer	
14. Configure course for Investigators	Revise course for shorter version for investigators (e.g., less in-person practice)	Instructional designer Content experts	
Stakeholder review of investigator course			

Clinical Research Study Checklist Fairview Behavioral Health Services (*Version 2016.04.26)*

The purpose of this Checklist is to provide a process so that leadership and clinical staff can provide input into how clinical research is developed and performed on Fairview Behavioral Health Services and provide a mechanism for monitoring the status and progress of research projects. The Behavioral Health Services Research Oversight Committee will meet every 6 months to review the implementation of this checklist/process plan.

Directions:

- It is the responsibility of the primary investigator to initiate and complete this checklist
- The Executive Dyad will review and sign the checklist as endorsed or returned with feedback pre-IRB
- In the event the checklist is returned with feedback, the checklist may be reinstituted once issues are addressed and the Dyad has endorsed by signature.

Principal Investigator	
Project Title	

1. Protocol Review and Gatekeeping
    a. Pre•IRB
        i. Investigator presents research plan to monthly clinical hospitalist meeting with key leadership present (unit medical directors, dyad leadership •• Knight and Banik) to discuss and get input on clinical research process. Decide if input is needed from the public or other stakeholders (e.g. patient family advisory board, NAMI, risk management). **Date Completed**_____
        ii. Implementation input from involved clinical unit. **Date Completed** _____
            1. Explanation of research purpose, plan and significance by investigator
            2. Primarily focused on the recruitment process, consenting/assenting process, procedures and roles of the staff.
            3. Define staff education needs.
            4. Assess/inquire with staff if there would be any additional clinical burden/delay in routine pt care that may occur with research implementation.
            5. Define communication needs. Document the input provided and each contributor.

        iii. Investigator finalizes research implementation plan based on input from unit staff. **Date Completed** _____
        iv. Dyad leadership (Executive Medical Director and Behavioral Health Administrator)reviews and endorses or returns with feedback pre•IRB implementation plan

            Endorsed: Signatures/Date

            Returned with Feedback: Signatures/Date

    b. Post•IRB
        i. Investigator returns to the involved clinical unit meeting to update on IRB status, review any changes suggested by IRB if any, update research implementation plan as needed. **Date Completed** _____
        ii. Dyad leadership reviews and endorses post•IRB implementation plan. **Date Completed**_____
        iii. Dissemination to all unit staff:
            1. Investigator visits the Council and explains study. **Date Completed** _____
            2. Provide a 1-page study synopsis to support staff/physicians to reference.**Date Completed**_____
            3. Summary is sent by email to all using read•receipt mechanism. **Date Completed**_____

2. Research Monitoring
    a. Research begins. **Date Begun** _____
    b. Quarterly research updates by investigator to Unit Council and System Dyad Leadership. *(At this time, the clinical staff can also provide feedback and suggestions on how the study is going from a clinical staff perspective. Recommend updates to the protocol as indicated based on this discussion.)*
    Dates Completed: _____ _____ _____ _____
    c. Between routine quarterly updates, if a concern about a study should arise, unit staff will approach the program director, who will raise the issue with medical director, dyad leadership, and/or investigators.
    Dates Completed as applicable: _____ _____ _____ _____
    d. Feedback • On completion of the research project a presentation will be made to unit staff to inform of the results of the research. **Date Completed:** _____

UNIVERSITY OF MINNESOTA

Twin Cities Campus

Office of the Dean
Medical School

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Office: 612-626-4949
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Memo

To: Brooks Jackson

From: Mark Paller

Date: 6/30/2016

Re: status of research by Dr. Stephen Olson

In the last two weeks there have been numerous questions regarding the status of Dr. Stephen Olson, a faculty member in the Department of Psychiatry, with regards to his eligibility to participate in clinical research. I take this opportunity to provide you with a status report.

Presently, Dr. Olson is not participating in clinical research, a choice he made because of the harsh attention that has been focused on research he performed a decade ago. However, should he wish to re-engage in clinical research he must meet the following criteria that were outlined in the *Implementing the Recommendations of the External Review of the University of Minnesota Human Research Protection Program Work Plan.*

> **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.

Dr. Olson is aware of these requirements and agrees to this plan should he wish to restart his research. He has been an eager and willing participant in all departmental discussions with regards to improving human research protections, specifically with regards to insuring better interactions with clinical staff before a clinical trial is begun and while it is being conducted, how to determine ability to provide consent, and how to avoid conflicts of interest when one is an investigator and the physician for a patient who might participate in one's trial. Dr. Olson did attend the national symposium on human research participant ethics that was held on 2 December 2015. The entire department, including Dr. Olson, is awaiting finalization of other aspects of the Implementation Plan, including additional training, new policies, and CTSI oversight of psychiatric clinical research.

UNIVERSITY OF MINNESOTA

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April 25, 2016

Mark S. Paller, MD, MS
Senior Associate Dean
Interim Head, Department of Psychiatry

Dear Dr. Paller:

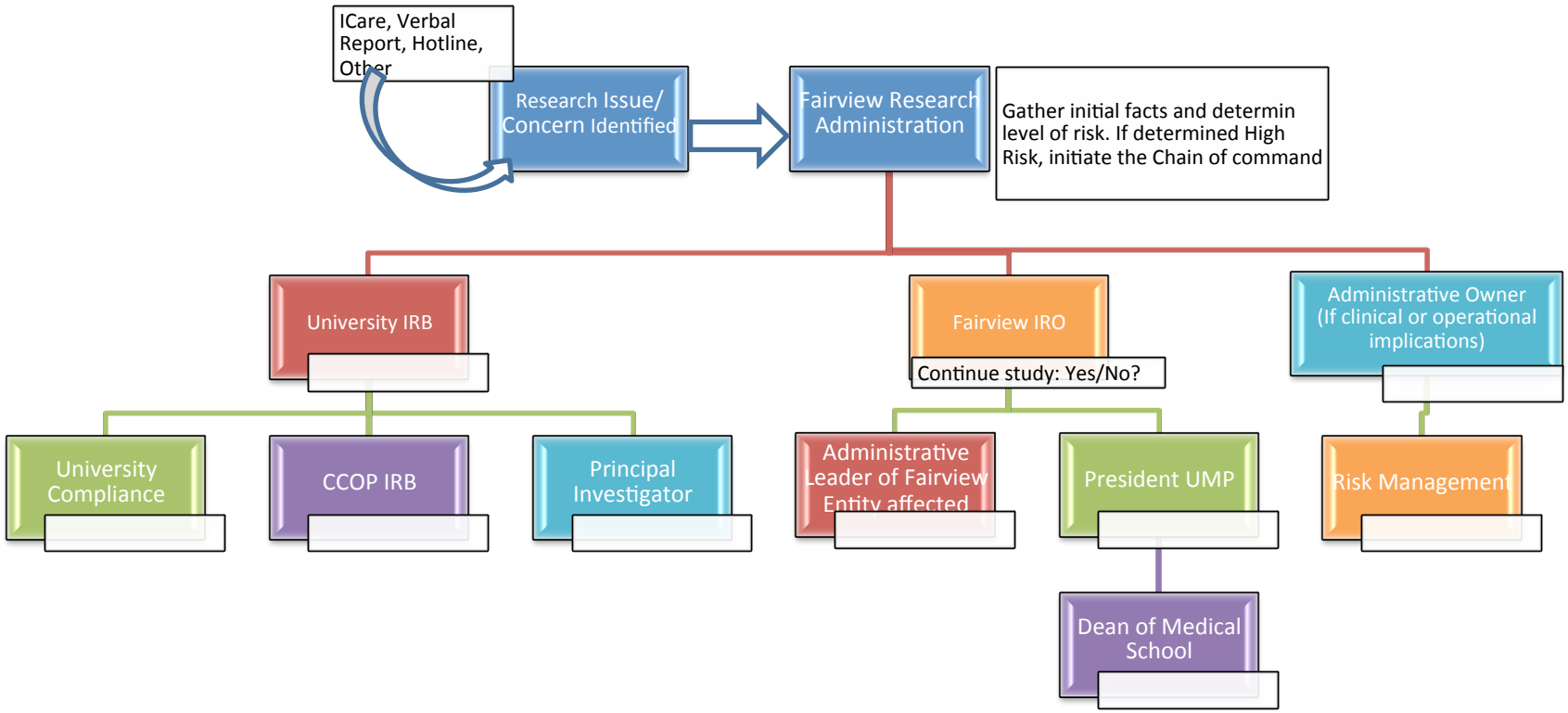
During the faculty meeting of April 20, 2016, we discussed and approved the following Department of Psychiatry Dual Role Consenting Policy.

“To mitigate issues of therapeutic misconception when a study investigator is also the treating clinician of a potential study participant, the investigator/clinician should not be involved in the consenting process. Questions about the study should be answered by another study team member not involved in the potential participant's clinical care. Potential participants should be given the option to see another clinician, not involved with the study to discuss treatment options before deciding to participate in the study.”

Sincerely,

Kelvin O. Lim, M.D.
Drs. T.J. and Ella M. Arneson Land Grant Chair in Human Behavior
Professor and Vice Chair for Research

Fairview Research Administration (FRA) Chain of Command



Clinical Research Study Checklist Fairview Behavioral Health Services (*Version 2016.03.25)*

The purpose of this Checklist is to provide a process so that leadership and clinical staff can provide input into how clinical research is developed and performed on Fairview Behavioral Health Services and provide a mechanism for monitoring the status and progress of research projects. The Behavioral Health Services Research Oversight Committee will meet every 6 months to review the implementation of this checklist/process plan.

Directions:

- It is the responsibility of the primary investigator to initiate and complete this checklist
- The Executive Dyad will review and sign the checklist as endorsed or returned with feedback pre-IRB
- In the event the checklist is returned with feedback, the checklist may be reinstituted once issues are addressed and the Dyad has endorsed by signature.

Principal Investigator	
Project Title	

1. Protocol Review and Gatekeeping
    a. Pre-IRB
        i. Investigator presents research plan to monthly clinical hospitalist meeting with key leadership present (unit medical directors, dyad leadership -- Knight and Banik) to discuss and get input on clinical research process. Decide if input is needed from the public or other stakeholders (e.g. patient family advisory board, NAMI, risk management). **Date Completed_____**
        ii. Implementation input from involved clinical unit. **Date Completed _____**
            1. Explanation of research purpose, plan and significance by investigator
            2. Primarily focused on the recruitment process, consenting/assenting process, procedures and roles of the staff.
            3. Define staff education needs
            4. Define communication needs. Document the input provided and each contributor
        iii. Investigator finalizes research implementation plan based on input from unit staff. **Date Completed _____**
        iv. Dyad leadership (Executive Medical Director and Behavioral Health Administrator)reviews and endorses or returns with feedback pre-IRB implementation plan

            Endorsed: Signatures/Date

            Returned with Feedback: Signatures/Date

    b. Post-IRB
        i. Investigator returns to the involved clinical unit meeting to update on IRB status, review any changes suggested by IRB if any, update research implementation plan as needed. **Date Completed _____**
        ii. Dyad leadership reviews and endorses post-IRB implementation plan. **Date Completed_____**
        iii. Dissemination to all unit staff:
            1. Investigator visits the Council and explains study. **Date Completed _____**
            2. Summary is sent by email to all using read-receipt mechanism. **Date Completed_____**

2. Research Monitoring
    a. Research begins. **Date Begun_____**
    b. Quarterly research updates by investigator to Unit Council and System Dyad Leadership. *(At this time, the clinical staff can also provide feedback and suggestions on how the study is going from a clinical staff perspective. Recommend updates to the protocol as indicated based on this discussion.)*
    Dates Completed: _____ _____ _____ _____
    c. Between routine quarterly updates, if a concern about a study should arise, unit staff will approach the program director, who will raise the issue with medical director, dyad leadership, and/or investigators.
    Dates Completed as applicable: _____ _____ _____ _____
    d. Feedback - On completion of the research project a presentation will be made to unit staff to inform of the results of the research. **Date Completed: _____**

BOARD OF REGENTS
DOCKET ITEM SUMMARY

Audit & Compliance **September 8, 2016**

AGENDA ITEM: Review of RFP Process for External Audit Contract

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

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

PRESENTERS: Gail Klatt, Associate Vice President, Internal Audit
Michael Volna, Interim Vice President & CFO
Suzanne Paulson, Interim Controller

PURPOSE & KEY POINTS

The purpose of this item is to discuss the Request for Proposal (RFP) process for hiring external auditors. The Controller's Office will issue an RFP for external audit services, as the current contract with Deloitte & Touche is in its seventh and final year. The review of the RFP process includes an outline of the scope of work, evaluation criteria, evaluation committee, Board participation, and timeline.

BACKGROUND INFORMATION

The Audit & Compliance Committee is responsible for hiring external auditors in conformity with Board of Regents Policy: *Audit Committee Charter* and Board of Regents Policy: *Board Operations and Agenda Guidelines*.

UNIVERSITY OF MINNESOTA
BOARD OF REGENTS
AUDIT COMMITTEE

REQUEST FOR PROPOSAL FOR EXTERNAL AUDIT SERVICES
SEPTEMBER 8, 2016

Summary of Process:

The Controller's office of the University will issue a Request for Proposal (RFP) for external audit services.

The Board of Regents Audit and Compliance Committee Charter require that the committee recommend for Board approval the engagement and related fees of independent auditors that perform external audits.

The current contract for external audit services is in the seventh and final year of the contract.

The scope of services covered by the RFP will include the following:

- Annual audit of the Consolidated Financial Statements of the University of Minnesota;
- Annual audit of the Regents of the University of Minnesota Insurance Company (RUMINCO LTD);
- Annual audit as outlined in the provisions of the Office of Management and Budget Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.
- Annual audit to satisfy the requirements of the Minnesota Office of Higher Education's Financial Aid Programs;
- Testing to meet the "Minimum Agreed-upon-Procedures" described in the NCAA Financial Audit Guidelines for Men's and Women's Division I Athletics on the Twin Cities and Duluth campuses.

The RFP also will cover other potential services that may be requested of the selected firm, including but not limited to tax services, and audits and agreed-upon-procedures of University departments or programs, such as the Student Organizations, as necessary.

The RFP is proposed for a period of up to seven years, covering fiscal years 2017 through 2023. This period consists of a four year contract with three one year optional extensions.

The RFP will set forth 13 selection criteria that will be the basis of evaluation and scoring of the responses. These criteria are:

- Qualifications of the firm, partner and audit staff;
- Relative continuity and turnover of the staff;
- Higher education experience of the firm and the firm's staff
- Experience with OMB 2 CFR 200 audits of federal financial assistance;
- Experience with regulatory cost accounting principles, including 2 CFR 200 and federal Cost Accounting Standards;
- Experience with NCAA athletics examinations
- Knowledge and experience auditing in a Peoplesoft/Oracle enterprise environment;
- Knowledge and experience with the COSO internal control framework;
- Training opportunities available to U of M personnel through the firm;
- Suitability of the audit workplan;
- Reporting and presentation
- Cost;
- The firm's commitment to the University's small business and community economic development goals.

An evaluation committee has been created with representation from the University departments that have the most knowledge of the audit process and interact most directly with the external auditors. Representation includes the Controller's Office, Accounting Services, Internal Audits, Sponsored Financial Reporting, the Office of Student Finance, Intercollegiate Athletics, and others from the CFO organization as appropriate.

Management will work with the Audit and Compliance Committee and Chair to formalize the process for committee involvement and ultimate approval of the final firm. This proposed process is modeled after the previous RFP process.

The RFP will be issued mid September 2016. Responses are requested by the middle of October with evaluations and interviews to be conducted in November and early December. The final firm will meet with Board and University representatives in early January. Management intends to present its recommendations to the Audit and Compliance Committee at the February meeting for final approval and awarding of the contract.