BOARD OF REGENTS

UNIVERSITY OF MINNESOTA

Audit & Compliance

September 2015

September 10, 2015

8:00 a.m. - 9:30 a.m.

West Committee Room, McNamara Alumni Center

AUD - SEP 2015

BOARD OF REGENTS
DOCKET ITEM SUMMARY

Audit & Compliance   **September 10, 2015**

AGENDA ITEM: Discussion of Change in Committee Name

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

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

PRESENTERS: Regent Laura Brod

PURPOSE & KEY POINTS

Board leadership recently changed the name of the Audit Committee to the Audit and Compliance Committee. Chair Brod will discuss the genesis of, and rationale for, this change and what enhanced outcomes are expected from it. The governance and oversight implications associated with this change could impact the committee's work plan for the upcoming year.

BACKGROUND INFORMATION

The Audit Committee formally recognized its oversight of the compliance function during the last update of its charter in February 2014.

BOARD OF REGENTS
DOCKET ITEM SUMMARY

Audit & Compliance   **September 10, 2015**

AGENDA ITEM: 2015-16 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

PURPOSE & KEY POINTS

The purpose of this item is to review and discuss the 2015-16 committee work plan. The work plan ensures 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 a series of discussions to inform the committee about the compliance program and institutional ethics. Information will also be provided throughout the year to enable the committee to carry out the oversight responsibilities that have been delegated to it for the implementation of the Human Participant Research Protection Program improvements.

BACKGROUND INFORMATION

Each standing committee of the Board of Regents establishes an annual work plan. 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.

Audit & Compliance Committee
2015-2016 Work Plan

Date	Topics
2015	
September 10-11	• **External Assessment of UMN Data Security Program and Maturity (Education and Governance)** The purpose of this item is to inform the Committee of the results of an external assessment of the University's Data Security Program and to obtain the Committee's reaction to the VP of IT/CIO's evaluation of the maturity level the University should strive to achieve. • **Update on Human Participant Research Protection Implementation Plan (Oversight)** This item will discuss the actions being taken to implement the work plan to improve the Human Research Protection Program. Specifically, the work team structure, timeline, and a proposed dash board will be reviewed with the Committee. The current status/resolution of participant recruiting during 72 hour holds will be discussed. • **Discussion of Change in Committee Name (Governance)** This item will involve discussion by committee members as to the intent of the change in the committee's name to include Compliance and what this intends to achieve in terms of governance and oversight. The outcomes desired and how best to achieve them will also be discussed so this can be appropriately reflected in the committee's work plan. • **Internal Audit Update (Fiduciary)** The purpose of this item is to update the Audit Committee on Internal Audit activities, results, and observations. The status of outstanding audit recommendations is also communicated. The update comes to the committee three times per year. The report is required under Board policy. • **2015-2016 Committee Work Plan Discussion (Governance)** The purpose of this item is to set the agenda for the Audit Committee for the next fiscal year. Full Board Item: • **Data Security: Policies, Practices, and Roles at the University**
October 8-9	• **Review Annual Financial Statements (Fiduciary)** Even though the committee will not meet in October, it will need to review the annual financial statements prior to their finalization in mid-October. As in previous years, this will be handled by the Chair via a conference call.
December 10-11	• **External Auditor Report (Fiduciary)** The purpose of this item is to communicate to the Audit Committee the results of the FY 15 external financial statement and federal award audits. This report is required under Board policy. • **Update on Human Participant Research Protection Implementation Plan (Oversight)** This item will provide an update on the current status of the implementation efforts related to human participants in research to enable the Audit Committee to carry out the oversight delegated to it by the Board of Regents.

	• **Compliance Program Review Recommendations (Governance)** The administration is currently reviewing the institutional compliance program. This item will include the sharing of the resulting recommendations and solicitation of the committee's feedback and advice. • **Institutional Compliance Officer Semi-Annual Report (Governance)** The purpose of this item is to update the Audit Committee on the status of the institutional compliance program, to inform them of compliance related initiatives, and to alert them to any material compliance vulnerabilities that currently exist. • **Information Item: Semi- Annual Controller's Report (Fiduciary)** This item is intended to inform the Audit Committee of initiatives or actions being taken to improve the financial reporting and/or financial internal controls within the University. This report is required by Board policy.
2016	
February 11-12	• **External Auditor's Review of Completed Audit Work and Letter to Management (Fiduciary)** 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. • **Update on Human Participant Research Protection Implementation Plan (Oversight)** This item will provide an update on the current status of the implementation efforts related to human participants in research to enable the Audit Committee to carry out the oversight delegated to it by the Board of Regents. • **Primer on HIPAA Compliance at the University (Education)** This item will educate the Committee on the Health Insurance Portability and Accountability Act (HIPAA) and its associated regulatory and operational requirements around the privacy and security of protected personal health information. • **Proposed Components of a Formalized Institutional Ethics Program (Governance)** This item is tentative and is dependent on the recommendations resulting from the administration's review of its current compliance program structure. If establishing an institutional ethics program is recommended, this item would discuss and/or propose specific components and structure of such a program. • **Internal Audit Update (Fiduciary)** The purpose of this item is to update the Audit Committee on Internal Audit activities, results, and observations. The status of outstanding audit recommendations is also communicated. The update comes to the committee three times per year. The report is required under Board policy.
May 12-13	• **Changes to the Audit Committee Charter (Governance)** The Audit Committee Charter will need to be updated to reflect the change in its name and capture any other changes that are deemed necessary from the discussion on the outcomes desired and the compliance program discussions.

	• **External Auditor Review and Review External Auditor Relationships and Services Provided (Fiduciary)** This item will communicate the scope of work and fees paid for all engagements of external auditors for the last fiscal year. It also will include a review of the University's official external auditor's performance. The need to re-bid the external audit contract will also be discussed. • **External Audit Plan (Fiduciary)** 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. • **Update on Human Participant Research Protection Implementation Plan (Oversight)** This item will provide an update on the current status of the implementation efforts related to human participants in research to enable the Audit Committee to carry out the oversight delegated to it by the Board of Regents. • **Institutional Compliance Officer Semi- Annual Report (Governance)** The purpose of this item is to update the Audit Committee on the status of the institutional compliance program, to inform them of compliance related initiatives, and to alert them to any material compliance vulnerabilities that currently exist.
June 9-10	• **Internal Audit Plan (Fiduciary/Governance)** The internal audit work plan for FY 2017 will be presented to the Audit Committee for discussion and concurrence. • **Internal Audit Update (Fiduciary)** The purpose of this item is to update the Audit Committee on Internal Audit activities, results, and observations. The status of outstanding audit recommendations is also communicated. The update comes to the committee three times per year. The report is required under Board policy. • **Update on Human Participant Research Protection Implementation Plan (Oversight)** This item will provide an update on the current status of the implementation efforts related to human participants in research to enable the Audit Committee to carry out the oversight delegated to it by the Board of Regents. • **Information Item: Semi-Annual Controller's Report (Fiduciary)** This item is intended to inform the Audit Committee of initiatives or actions being taken to improve the financial reporting and/or financial internal controls within the University. This report is required by Board policy.

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

BOARD OF REGENTS
DOCKET ITEM SUMMARY

Audit & Compliance   **September 10, 2015**

AGENDA ITEM: Update on Implementation of the Human Research Protection Program Work 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 discuss progress made on the Board resolution passed in June 2015 related to the Human Research Protection Program work plan implementation. The Board specifically recognized the following objectives of that plan:

1. Strengthening membership and processes of the Institutional Review Board;
2. Additional education and training for investigators;
3. Stronger protections for participants with limited or fluctuating capacity to consent;
4. Enhanced engagement with research participants and families;
5. Formation of a Community Oversight Board; and
6. More stringent management of conflicts of interest.

President Kaler has charged team leads for each of the implementation areas. These teams have started their work, first by identifying their work scope and by assembling the teams they need to implement their section. Each member has been assigned staff and been given background materials. In addition, the Research Compliance Advisory Committee (a committee of accomplished University researchers) has agreed to serve as a steering committee for this work.

Several recommendations of the external review and implementation team have already been addressed and reported to the Regents and the Legislature. Those include:

- Establishment of the Fairview University Research Oversight Committee (FUROC).
- Retaining an external advisor from the external advisory panel to assess progress on the original recommendations.
- Outsourcing review of Psychiatry clinical trials.
- Hiring Compass 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.

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 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 27, 2015 meeting, the Board of Regents approved immediate and longer-term action plans to implement the recommendations.

The Team was chaired by 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 subjects 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.

The 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 on 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.

On June 11, 2015, 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

UNIVERSITY OF MINNESOTA

Government and Community Relations

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TO: Reed Polakowski, Minnesota Legislative Reference Library

FROM: Keeya Steel, University of Minnesota Office of Government Relations

DATE: July 1, 2015

RE: University of Minnesota mandated report: Human Subjects Research Standards – July 2015

Enclosed are two copies of the mandated report Human Subjects Research Standards – July 2015, pursuant to 2015 Minnesota Law Chapter 69 Article 3 Section 26.

The report includes:
- June 11, 2015 Board of Regents Resolution
- June 11, 2015 Board of Regents Docket Item
- Implementation Final Work Plan

This report can also be found online: http://govrelations.umn.edu/mandated-reports.html.

If you have any questions regarding this report or to obtain additional copies, please contact the Office of Government and Community Relations at 612-626-9234.

cc: Senator Terri Bonoff, Senate Higher Education and Workforce Development Chair
Representative Bud Nornes, House Higher Education Policy and Finance Chair
Senator Jeremy Miller, Senate Higher Education and Workforce Development Ranking Minority Member
Representative Gene Pelowski, House Higher Education Policy and Finance Ranking Minority Member

Driven to Discover℠

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

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

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

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

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

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

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

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

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

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

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

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

BOARD OF REGENTS
DOCKET ITEM SUMMARY

Audit   **June 11, 2015**

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

☐ Review	☒ Review + Action	☐ Action	☐ Discussion

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

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

Purpose & Key Points

The purpose of this item is to:

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

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

Background Information

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

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

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

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

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

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

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

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

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

Implementation Team Charge

The Team was specifically charged with the following:

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

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

Implementation Team Process

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

Implementation Team Report

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

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

The key components of the report are:

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

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

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

President's Recommendation

The President recommends adoption of the resolution.

Preface

Advancing Human Participant Research
Public Comment Summary

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

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

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

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

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

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

June 11, 2015

Implementation Team Members:

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

Table of Contents

1. Executive Summary

Introduction

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

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

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

Key Parts of the Work Plan

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

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

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

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

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

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

3

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

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

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

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

4

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

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

5

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

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

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

6

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

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

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

7

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

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

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

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

8

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

2.   Introduction

2.1.   Reason for the Implementation team

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

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

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

10

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

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

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

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

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

2.2. Team Charge

The Implementation team was specifically charged with the following:

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

2.3. Team Process

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

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

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

2.4. **Structure of the Report**

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

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

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

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

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

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

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

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

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

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

- Provide education in ethics to all of those who oversee and conduct research on human beings.

- Protect and promote the rights and interests of research participants who are vulnerable to various kinds of coerced consent or who lack (or may come to lack) the capacity to consent to (or continue to consent to or decline) continued participation in research.

- Comply with the letter and be committed to the spirit of the laws and regulations that pertain to the treatment of patients and of persons who are enrolled in research.

- Be transparent and accountable in all research activities. This includes a culture where anyone who observes a breach of the ethics or rules for research may report his or her observations without fear of retaliation and with confidence that his or her concerns will be investigated.

- Manage individual and institutional conflicts of interest that potentially undermine the well-being of research participants regardless of whether they arise from financial, career, or personal interests.

- Sustain a culture of engagement among all colleges in the U of M that recognizes the special status of university-based research. This status is grounded in the integrity of academic research, as well as in respect for cultural diversity and for the social, economic, and cultural implications of biomedical research.

- Effectively engage in a dialogue with the broader community that has a stake in benefitting from research and an interest in protecting their loved ones who may participate as research participants.

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

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

Specific Actions

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

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

16

- Statements and websites will be reviewed and discussed with a newly created Community Oversight Board described later in this report as well as the Research Compliance Advisory Committee (RCAC). The RCAC is a high level faculty advisory committee who provides guidance and consultation to the Vice President for Research on issues related to research risk and compliance.

- Future strategic plans for segments of the U of M that relate to research participant research will include statements on the U of M's values as they relate to research participant protection.

- Planning for basic and advanced education of researchers conducting studies that use research participants will include the voice of research participants, research ethicists, and educators. Section 12 "Educating and Training of Investigators" has further details on including these voices.

- Educational opportunities on human research participant protections will include moderated discussions at department faculty meetings that will involve peer-to-peer education.

- The U of M will host a Campus Conversation or other forum on the topic of human research participant protection.

- The U of M will regularly benchmark itself against its peers to ensure that our human research participant protection programs meet or exceed the norm.

4. IRB Membership

Covers External Review report recommendations: 3.2.1, 3.2.2, 3.2.3

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

17

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

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

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

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

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

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

- **Increase number of IRB members**

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

19

- **Compensate IRB board members**

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

- **Establish requirements for attendance**

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

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

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

20

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

5. IRB Protocol Review Process

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

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

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

21

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

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

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

6.   Scientific Review of Studies

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

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

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

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

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

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

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

A. Eliminate Department Review

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

B. Revise HRPP Managed Review Procedures

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

1. The review criteria will appropriately combine what is now listed in IRB Policy 904 for review method 3c and review method 4.

2. Criteria will be developed for determining which studies require review by a biostatistician prior to the scientific assessment.

3. Peer reviewers:

    a. A minimum of two appropriately qualified experts will be required. The HRPP can require more than two reviewers if in their judgement scientific review would be aided by additional expertise. Reviewers can be from inside or outside the U of M.

    b. If the HRPP determines that a specialized reviewer is required from outside the U of M, the HRPP is authorized, on a limited basis, to provide an appropriate honorarium to that reviewer.

    c. Potential reviewers may be suggested by the investigator or may be suggested by the HRPP independently of the investigator. The HRPP, however, determines who will review and invites the reviewers.

    d. The names of the peer reviewers are not released to the investigator.

    e. Reviewer suggestions must come with a short statement of the expertise of the reviewer so that it is clear they are qualified to conduct a scientific review of the study in question.

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

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

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

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

4. Create a review form to be used by the peer reviewers. This form will replace the "ScientificReviewTemplate.doc" form and will require peer reviewers to address each point of the set of new criteria. The form should provide explicit instructions to the peer reviewer on how to conduct the peer review, much in the way that NIH provides instructions to reviewers of NIH grant applications.

5. HRPP staff will screen peer reviewer submissions for incomplete reviews, and work with the reviewer to complete an adequate review.

6. HRPP staff will not make any conclusions based on the peer reviews, but will organize and submit the required number of peer reviews to the IRB panel that is reviewing the study.

25

7. The investigator will receive the scientific reviews, with reviewer names deleted.

8. The HRPP managed review process could be done through the CTSI Clinical Translational Research Portal. However it is implemented, the process should have a single flow so that investigators are clear about the process.

9. Ideally, the goal is to provide a 10 day turnaround time on reviews.

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

C. Revise IRB Panel Review Procedure

1. Add to the IRB meeting checklist an item to discuss the type of scientific review that occurred for the study being considered and whether the scientific reviewers had any concerns.

2. Document the IRB's review of the scientific assessment documents in the IRB minutes.

D. Revise IRB Policy 904

Revise IRB Policy 904 to reflect the above changes.

7. Fairview University Research Oversight Committee

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

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

8.   **Monitoring of Studies**

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

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

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

27

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

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

- **Increase and expand PAR monitoring**

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

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

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

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

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

- **Perform live consent monitoring**

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

9. For Cause Investigations

Covers External Review report recommendations: 3.2.8, 3.2.9, 3.2.10

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

29

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

To address these issues, we propose the following:

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

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

Covers External Review report recommendations:
Capacity to Consent 3.4.1, 3.4.2, 3.4.3, 3.4.4

Vulnerability to Coercion 3.4.5, 3.4.6

Longitudinal Assessment of Capacity 3.4.7, 3.4.8

Legally Authorized Representatives 3.4.9, 3.4.10

Use of Surrogate Consent 3.4.11, 3.4.12

30

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

Capacity to Consent

Definitions:

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

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

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

General Considerations:

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

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

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

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

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

IRB Review Procedures:

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

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

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

32

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

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

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

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

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

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

33

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

Planning Before the Study for Impaired Consent Capacity

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

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

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

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

34

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

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

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

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

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

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

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

Assessing Capacity to Consent and Obtaining Consent

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

During the Study

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

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

36

Legally Authorized Representatives

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

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

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

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

37

Consent Advocate

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

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

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

Research with Research Participants who are Vulnerable to Coercion or Exploitation

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

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

Definitions:

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

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

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

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

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

40

General Considerations

The IRB expects that principal investigators will:

- Demonstrate awareness of the nature of the vulnerability of research participants in the trial under consideration.

- Create procedures to avoid the coercion or exploitation of vulnerable persons by: ensuring that each potential subject understands that participation is voluntary, that to the extent feasible comparable health and social services will be available regardless of consent to participate in a clinical trial, that ensuring other people, including supervisors, in closed communities like schools, military units, prisons, or chronic care facilities will not know who in their institution has and who has not consented to participate in research.

- To avoid the risk of therapeutic misconception, protocols, and consent documents for studies in which treating caregivers are also investigators should contain a paragraph to note that the potential participant's caregiver has dual responsibilities to both care for the patient and to conduct the research. The potential participant may request to see another caregiver to discuss treatment options before deciding to participate in the study.

The IRB will:

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

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

41

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

11. Department of Psychiatry

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

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

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

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

42

Education

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

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

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

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

43

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

Climate Assessment

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

Creating a Culture of Inclusion

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

44

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

Fairview Health Care System Oversight

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

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

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

45

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

Required Resources

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

12. Engaging Research Participants

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

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

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

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

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

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

47

- Incorporate monitoring of distribution of materials related to research participant reporting and implementation of plans to express research appreciation in IRB annual and final reports, along with any deviations.

- Create and broadly publicize policy and procedures for handling concerns about research from research participants, family members, legally-authorized representatives, research personnel, and clinical staff.

- Create and broadly publicize mechanisms for potential, current, and past research participants, family members, and LAR to provide confidential feedback and/or report concerns about the research process (e.g., toll-free telephone number, website).

- Create a mechanism for promptly addressing all reported research concerns and notify the reporter when the matter has been fully addressed.

- Develop and require investigators to distribute a handout (such as a small card) at study enrollment to research participants, family members, and LAR regarding where and how to provide confidential feedback or share concerns about the research procedures, including the mechanism for handling reported concerns. This is in addition to information provided on the informed consent form.

- Establish a process for reporting results to individual research participants when practical and when the participant has indicated they would like to receive study results. This process may vary from study to study because of differences in study design. For example online survey studies may be anonymous and feedback would be impossible or studies requiring samples to identify molecular mechanisms of disease may not yield results that can be easily translated to the non-scientific community.

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

48

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

13. Education and Training of Investigators

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

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

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

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

- Create a new position of a Human Research Procedures, Policies and Ethics Education Coordinator within the CTSI with links to the Center for Biomedical Ethics. The education coordinator will be responsible for establishing guidelines for basic and advanced research compliance and research participant protection training that is reviewed and approved by an oversight process in the HRPP. The education coordinator will ensure that both required and optional training modules are available and kept current.

- Provide clear expectations and education for documenting the education of investigators and their teams with respect to RCR, HIPAA, GCP, and CITI training.

- Conduct an evaluation of the educational resources of the HRPP, schools, departments, and divisions in the AHC, CTSI, and the Center for Biomedical Ethics specifically dedicated to the education and training of the research community to ensure that appropriate resources are in place to offer basic and advanced training opportunities in research participant protections.

- Provide appropriate training opportunities for all personnel working with vulnerable populations and mandate it be completed before the study can begin. It is important to note that CTSI can be an effective partner by supplementing the NCATS endorsed training in best clinical practices (GCP) with appropriate content on these issues that reaches the entire translational and clinical research workforce.

50

- Design a coordinated plan for delivery of research participant protection updates that could involve newsletters, websites or presentations prepared for department, division, center or other academic unit investigator meetings.

- Address mandated requirements for advanced training including content prepared or presented by the Center for Biomedical Ethics that will specifically address research in vulnerable populations.

- Supplement current requirements for minimal training to initiate research involving research participants with both required and recommended advanced refresher training that should be promoted by departments, divisions, centers and other academic units by recommending that these topics be included in regular faculty, investigator and research staff meetings.

- Provide easier access to training tailored to different research topics: social behavioral studies, observational or epidemiologic studies, therapeutic intervention studies, studies on vulnerable research participants, or those with diminished capacity to consent. Topics on HRPP policies and procedures should be included.

- Engage the community on relevant research related committees, task forces, and educational programs to help researchers, research staff, research administrators, and U of M leadership form relationships with community stakeholders and thus more directly solicit their input on community priorities and areas of community concern. This can be facilitated by the CTSI Community Engagement Core which regularly and successfully engages in such activities.

14. Accountability Metrics

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

51

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

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

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

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

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

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

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

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

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

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

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

53

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

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

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

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

15. Managing Conflicts of Interest

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

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

http://www.policy.UMN .edu/Policies/Operations/Compliance/CONFLICTINTEREST_PROC02.html

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

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

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

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

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

16. Community Oversight Board

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

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

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

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

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

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

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

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

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

- Advising the HRPP on best practice methods for disseminating research findings and other reports to the community.

- Suggesting strategies to address ethical and operational aspects of study conduct with vulnerable populations, including those with impaired decision-making.

- Informing the HRPP about information, misinformation, or rumors circulating in the community and concerns from the community and research participants/surrogate decision-makers.

- Advising how to address negative research experiences with the community.

- Helping build trust with the community by conveying information about research to the community.

- Completing research ethics and other required training and providing feedback on that training and suggestions for its improvement.

- Assisting in the dissemination of COB results and activities to appropriate audiences.

17. **External Advisor**

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

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

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

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

18. Post-Report Activities

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

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

61

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

19. **Analysis of Resources Required for Implementation**

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

62

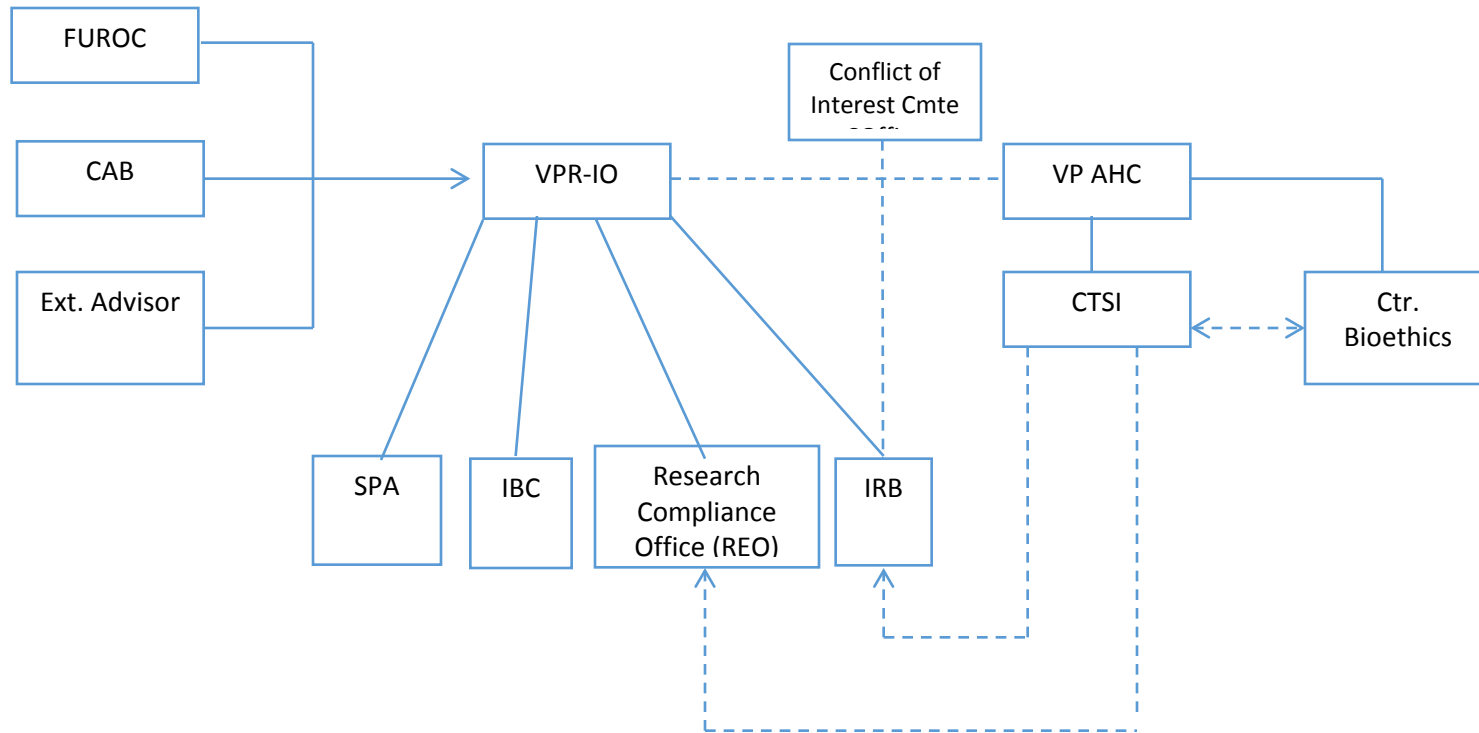|	
9. External Advisor on implementation	RESEARCH COMPLIANCE OFFICE
- $50,000 one time	
10. External consultant for Dept. of Psychiatry implementation culture change	AHC
- $50,000 one time	
11. Co-review by PAR and an external IRB of protocols that involve decisionally impaired research participants.-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

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

63

20. **Conclusion**

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

21. Appendices

21.1. Advancing Human Subjects Research Organizational Chart

21.2. Advancing Human Subjects Research Protocol Process Flowchart

Protocols → Psychiatry Study

Psychiatry Study → CTSI (Yes, optional for others)

Psychiatry Study → Scientific review by Federal Agency or Cancer Center (No)

CTSI → Scientific review by Federal Agency or Cancer Center

Scientific review by Federal Agency or Cancer Center → Scientific Review at IRB (No)

Scientific review by Federal Agency or Cancer Center → Vulnerable or Impaired population? (Yes)

Scientific Review at IRB → Vulnerable or Impaired population?

Vulnerable or Impaired population? → Medical IRB panels (No)

Vulnerable or Impaired population? → Medical IRB panel with vulnerable population emphasis (Yes)

Pre-Approval Process — Protocols, CTSI

Scientific Review — Scientific review by Federal Agency or Cancer Center, Scientific Review at IRB

IRB — Vulnerable or Impaired population?, Medical IRB panels, Medical IRB panel with vulnerable population emphasis

21.3. List of External Review Recommendations

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

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

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

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

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

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

71

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

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

UNIVERSITY OF MINNESOTA

July 27, 2015

TO: Regent Johnson, Chair
             Regent Brod, Chair, Audit Committee

FROM: Brian Herman, Vice President for Research

SUBJECT: August report to the Legislature

Included for your review and approval is the second report to the Legislature on implementation of the work plan to improve research with human participants at the University of Minnesota. As was the case last month, these are due to the legislative office by the 1st of each month. The report includes a narrative summary of what has been accomplished since the last report along with a full progress dashboard.

SUMMARY

The implementation work plan rollout has begun with specific duties being assigned to responsible parties. President Kaler charged me as the University Institutional Official (IO) and Vice President for Research with overall responsibility and accountability for implementation. I have identified all the team leads for each section of the Implementation Team's work plan and those individuals have also been charged by President Kaler. The leads have each been assigned staff support and are receiving more specific instructions about their task. Finally, I have asked the OVPR Research Compliance Advisory Committee to serve as the steering committee for duration of the work plan's rollout. The RCAC is an established group of esteemed faculty researchers who have been actively engaged with the recommendations from the external review and as such have agreed to advise and oversee the rollout of the changes.

In addition to creating a structure, several of the work plan recommendations were implemented since the last progress report. The External Review Panel and the Implementation Team both recommended that University's IRB staff attend IRB meetings at peer institutions to assess best practices. The IRB senior staff is planning visits to peer institutions of similar size and complexity. The first visit will occur on July 28th and July 29th to Penn State IRB. Penn State uses both a nationally recognized policy toolkit and an associated electronic IRB system currently under consideration by the University. Two additional visits are planned.

In response to external review panel concerns about adequate time for IRB review and discussion, the IRB has implemented meeting agenda "caps" to ensure a more appropriate balance of reviews and to allow focus on the complex applications. The IRB has also doubled the total number of IRB continuing review meetings and increased the number of medical meetings. HRPP Director Debra Dykhuis is the lead on these work teams.

Vice President Herman is the lead for the development of the Fairview University Research Oversight Committee (FUROC). This new committee was recommended by the Implementation Team to serve as a body to enhance communication between the University and Fairview, to improve the culture of collaboration, and to create a space to hear and review concerns. This work team includes Vice President Jackson and Fairview COO Carolyn Wilson. The team met and is in the process of identifying members for FUROC. Vice President Jackson and COO Carolyn Wilson will be charged by Vice President Herman as the chairs for this committee.

President Kaler's charge to the Implementation Team included engaging an external advisor with deep knowledge in human participant protection programs to work with the University on implementation. Vice President Herman has engaged Davis Strauss, M.D., a member of the External Review panel and Director of Psychiatric Research at the New York Psychiatric Institute, Vice Chairman for Research Administration, Department of Psychiatry, Columbia University College of Physicians and Surgeons.

Finally, following the report of the Office of the Legislative Auditor, VP Herman suspended enrollment and IRB review of all Department of Psychiatry interventional drug studies until re-reviewed by an independent IRB. Enrollment into 15 studies was suspended and 3 additional studies not yet approved by the IRB were forwarded to Quorum IRB for review. Of those: 2 were closed by UMN PIs, 2 are pending submission to Quorum, 7 were approved and suspension was lifted, 2 were approved but require further action per UMN requirements, 1 was approved pending modifications, and 1 was submitted and withdrawn by the UMN PI.

Approval for new applications for interventional drug trials in the Department of Psychiatry will continue to be outsourced to Quorum IRB. That practice will continue until all recommendations in the work plan have been implemented.

The attached dashboard shows the full scope of work, assigned leadership and status of the implementation. This will be updated monthly and included with this report. For complete details of all the implementation work, past and present, please see
http://research.umn.edu/advancehrp/index.html

enclosure

Work plan Section	Status	Lead	Scope
IRB Membership	〇	Billings, Biros	Recruit membership
			Form new committees
			Set compensation structure and policy
FUROC	〇	Herman	Establish committee
For Cause Investigations	〇	Webb	Establish Research Compliance Office
		Waldemar	Transition For Cause Investigations
Community Oversight Board	☐	Herman	Establish board structure
			Finalize membership
			Invite members
External Advisor	√	Herman	Hire external advisor: external review panel member
Scientific Review of Studies	☐	Billings, Biros	Eliminate department reviews
			Define a new HRPP process
Cultivating a Culture of Ethics	〇	Aronson, Zentner, Wolf	Create a document explaining the University's commitment to research participant protection
			Clear statements on HRPP, IRB, OVPR and AHC websites
			Host a campus conversation or other forum on human research participant protection
			Regular benchmark our program against our peers
IRB Protocol Review Process	〇	Dykhuis	eIRB
			New forms and procedures
			New FTEs
			Benchmarking visits
Monitoring of Studies	〇	Dykhuis	New FTEs
			Reengineer PAR function
Human Research Participants Who Have Impaired or Fluctuating Capacity to Consent	☐	Miles	Implement tool to assess capacity
	☐		Train and communicate change to researchers
	〇	Dykuis	LAR policy changes
	〇		72-hour hold policy
Department of Psychiatry	〇	Paller	CTSI management of trials
			Engage consultant for climate assessment, plan
Engaging Research Participants	☐	Eder	Create a research participant satisfaction survey and a plan to collect and analyze data
			Revise IRB forms to include a section expressing appreciation and a plan for sharing research results
			Create and publicize mechanisms for participants and families to provide confidential feedback and report concerns, develop a small handout

			Create and publicize procedures for handling concerns and for notifying reporter when they have been handled
			Create position of Community Liaison officer
			Create link to Community Advisory Board
Education and Training of Investigators	O	TBD	Integrate and coordinate training
			Curriculum development
			Training delivery
Accountability Metrics	☐	Waldemar	Track and report accountability metrics
Conflict of Interest	☐	Durfee	Implement updated policy

√= Completed

O= In Progress

☐ Not Started

Advance HRP Website: http://research.umn.edu/advancehrp/index.html

UNIVERSITY OF MINNESOTA

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Minneapolis, MN 55455-0421
612-625-3394
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MEMORANDUM

TO: Regent Johnson, Chair
Regent Brod, Chair, Audit Committee

FROM: Brian Herman, Vice President for Research

DATE: August 25, 2015

RE: Report to Legislature

Included for your review and approval is the third report to the Legislature on implementation of the work plan to improve research with human participants at the University of Minnesota. The report, due to the Legislature on September 1, includes a narrative summary of what has been accomplished since the last report along with the full progress dashboard.

SUMMARY

This month we updated two IRB policies (501 – *Vulnerable Populations* and 506 – *Adults Lacking the Capacity and/or Adults with Diminished Capacity to Consent*). These policies and IRB form Appendix were revised to prohibit recruitment of persons temporarily confined under an involuntary medical hold (72 hour emergency hold, 12 hour "intent to leave" period, or 72 hour "intent to leave" period for persons with chemical dependency) into a psychiatric drug, device, or biologic trial. IRB Form Appendix 1 *(Populations with Additional Considerations)* has been amended to restrict any member of the study team from participating in a decision to rescind or discontinue a medical hold before its expiration for a research study. These changes address the external review recommendation to develop standards that protect against real or perceived coercion in psychiatric treatment settings in which individuals may fear involuntary court proceedings. While not specifically referenced in the implementation team report, it was brought to the attention of the team at the end of the process and has been the subject of significant discussion inside and outside the University.

Secondly, we have engaged an external clinical and translational research management and consulting firm (Compass Point Research) to conduct a review of 100 random protocols to further ensure we have addressed issues of human participant protection. These protocols will be reviewed for compliance with institutional requirements, governing regulations, and good clinical practice. This also was not specifically referenced in the work plan but was requested by the President and Board of Regents.

Several recommendations of the external review panel referenced IRB minutes and meeting management. This was also a concern of AAHRPP during their recent accreditation visit. In addition to the improvements reported last month, HRPP staff has made changes to enhance the documentation of items of disagreement among members at meetings and has implemented a revised template to collect required regulatory determinations of the IRB and facilitate deliberation.

Last month we reported the first meeting of the committee working to develop the Fairview University Research Oversight Committee. That committee has been charged and membership formed. Planning is underway for a first meeting this fall.

Finally, to continue to assure transparency and allow for participation and input from those interested, we have updated the website to reflect language changes adopted in the implementation work plan and to provide contact information, opportunities to sign up for progress reporting, and updates on the implementation work.

The attached dashboard shows the full scope of work and this month's updated status of each item. As you can see, all areas are underway and some completed. For complete details, please visit research.umn.edu/advancehrp or contact me with any questions.

Work plan Section	Status	Lead	Scope
IRB Membership	O	Billings, Biros	Recruit membership
			Form new committees; restructure biomedical; target membership to accurately reflect protocol submission
			Set compensation structure and policy for medical and nonmedical IRBs
FUROC	√	Herman	U establish committee jointly with Fairview
For Cause Investigations	O	Webb	Establish Research Compliance Office (RCO)
		Waldemar	Transition For Cause Investigations to RCO; establish more robust procedures specific to complainant and SAE reporting
Community Oversight Board	O	Herman	Establish board structure and guidelines
			Finalize membership; appoint chair
			Invite members
External Advisor	√	Herman	Hire external advisor (external review panel member); 2015 AAHRPP Accreditation
Scientific Review of Studies	O	Billings, Biros	Eliminate department reviews
			Define a new IRB process and policy in consultation with other required reviews e.g. CTSI
Cultivating a Culture of Ethics	O	Aronson, Zentner, Wolf	Create language explaining the University's commitment to research participant protection
			Clear statements on HRPP, IRB, OVPR and AHC websites
			Host a campus conversation or other forum on human research participant protection
			Regular benchmark our program against our peers
IRB Protocol Review Process	O	Dykhuis	Implement new eIRB technology
			Implement IRB forms and procedures
			Add new FTEs
			Complete benchmarking visits
Monitoring of Studies	O	Dykhuis	New FTEs
			Reengineer PAR function
Human Research Participants Who Have Impaired or Fluctuating Capacity to Consent	O	Miles	Implement tool to assess capacity
	☐		Train and communicate change to researchers
	☐	Dykuis	Implement LAR policy changes
	√		Implement 72-hour hold policy
Department of Psychiatry	O	Paller	Transition to CTSI management of trials
			Engage consultant for climate assessment, plan
Engaging Research Participants	O	Eder	Create a research participant satisfaction survey and a plan to collect and analyze data

			Revise IRB forms to include a section expressing appreciation and a plan for sharing research results
			Create and publicize mechanisms for participants and families to provide confidential feedback and report concerns, develop a small handout
			Create and publicize procedures for handling concerns and for notifying reporter when they have been handled
			Create position of Community Liaison officer
			Create link to Community Oversight Board
Education and Training of Investigators	O	Ingbar, Schacker	Integrate and coordinate HRPP training
			Curriculum development
			Training delivery
Accountability Metrics	O	Waldemar	Track and report accountability metrics
Conflict of Interest	O	Durfee	Implement updated policy

√= Completed
O= In Progress
▤ Not Started

For more details see about the work scope and alignment with the external review panel recommendations, see Advance HRP
Website: http://research.umn.edu/advancehrp/index.html

BOARD OF REGENTS
DOCKET ITEM SUMMARY

Audit & Compliance   **September 10, 2015**

AGENDA ITEM: External Assessment of UMN Data Security Program and Maturity

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

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

PRESENTERS: Bernard Gulachek, Interim Vice President and Chief Information Officer
Brian Dahlin, Chief Information Security Officer
Clinton E. Davies, Principal, BerryDunn LLC

PURPOSE & KEY POINTS

This is the final in a series of three discussions with the committee regarding information security at the University. The purpose of the series is to educate committee members about the University's approach to information security and to support the Board's fiduciary oversight of security policies and programs. The series was designed to build a common understanding of issues and practices so committee members can develop a point of view concerning risk tolerance, as well as consider the cultural cost/benefit tradeoffs inherent in investing in additional efforts to mature the University's information security framework.

This final item in the series seeks input and discussion around the strategic goals of the information security framework and the trade-offs inherent in further growing program-level maturity. It will review the results of an external assessment of the University's risk management approach. BerryDunn, an independent audit and consulting firm, identified the strengths and weaknesses of the current security program, as well as its level of maturity in relation to other higher education institutions.

The first discussion in the series highlighted the types of adversaries and threats in the current environment, the types of incidents encountered, and several high-profile incidents at peer institutions and in the public sector. The second discussion provided a comprehensive overview of the University's information security framework and how it is positioned to mitigate likely types of risks.

BACKGROUND INFORMATION

In May 2013, the committee discussed the University's data security framework, which is one component of the overall information security program. At the time, the University was transitioning from a two-level data security classification (public vs. private) to a three-tier system that acknowledges different types of private data have different levels of associated risk and benefit from tailored controls.

External Assessment of UMN Data Security Program and Maturity

Bernard Gulachek, Interim VP & Chief Information Officer
Brian Dahlin, Chief Information Security Officer
Clinton Davies, BerryDunn LLC

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Information Security in Higher Education

A Continued Focus

CIC CIO Meetings Agenda Item:

- Private/public sector breaches continue to show vulnerabilities

- The media continues to demonstrate a high level of interest

Board of Regents Meetings Agenda Item:

- Finance Committee: Focused questions on security risks of The Upgrade

- Audit Committee:

  - September 2014: "Information Security Risk Primer"

  - December 2014: "University of Minnesota Data Security Strategy"

  - Today: "External Assessment of UMN Data Security Program and Maturity"

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The Charge for Information Security

1. **STRATEGIZE**
    Create an Information Security strategy compatible with the University of Minnesota culture.

2. **DEVELOP**
    Establish and maintain an Information Security Program that incorporates:
    – Security Risk Management
    – Incident Management
    – Exception Management

3. **MAINTAIN**
    Programs assist in meeting Information Security regulatory requirements.
    – Includes responsibility for HIPAA Security Officer
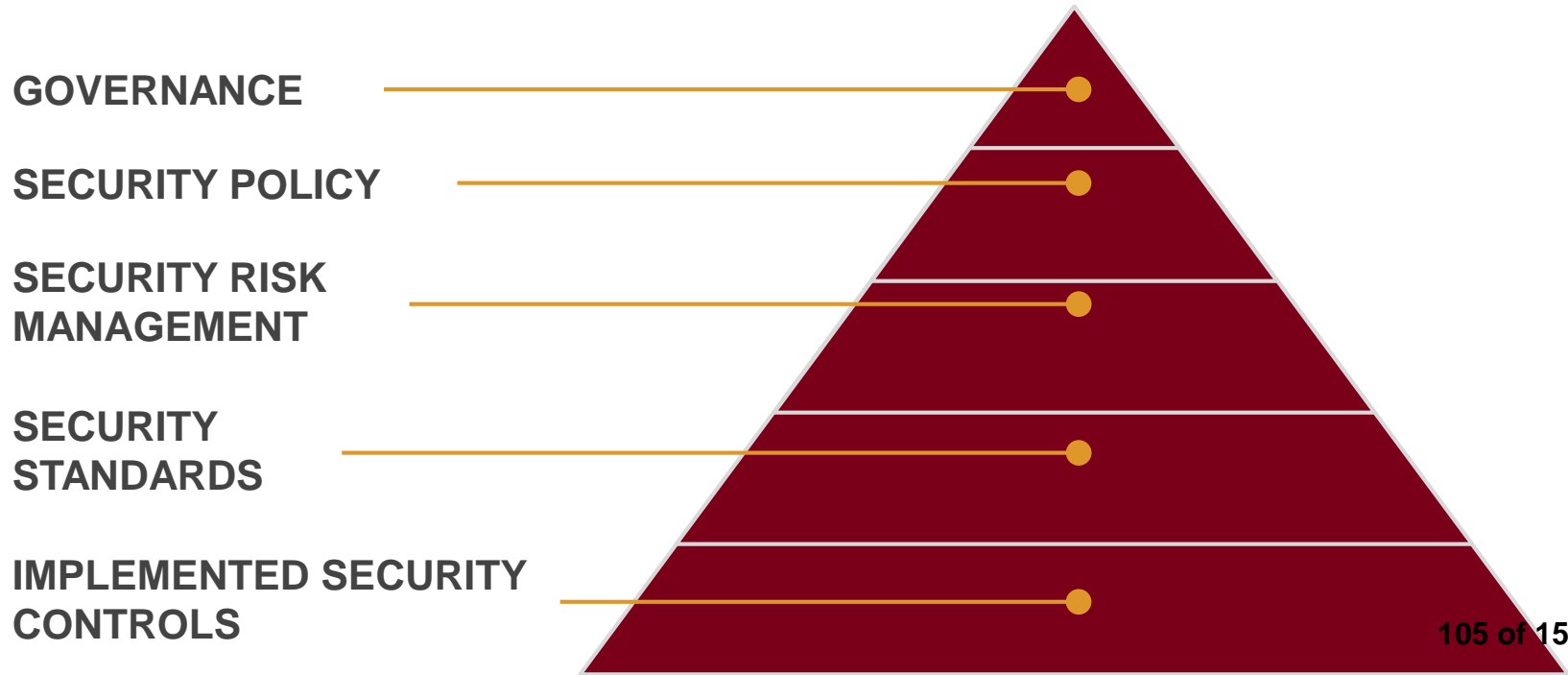
The University's Information Security Framework – 2015

- GOVERNANCE
- SECURITY POLICY
- SECURITY RISK MANAGEMENT
- SECURITY STANDARDS
- IMPLEMENTED SECURITY CONTROLS
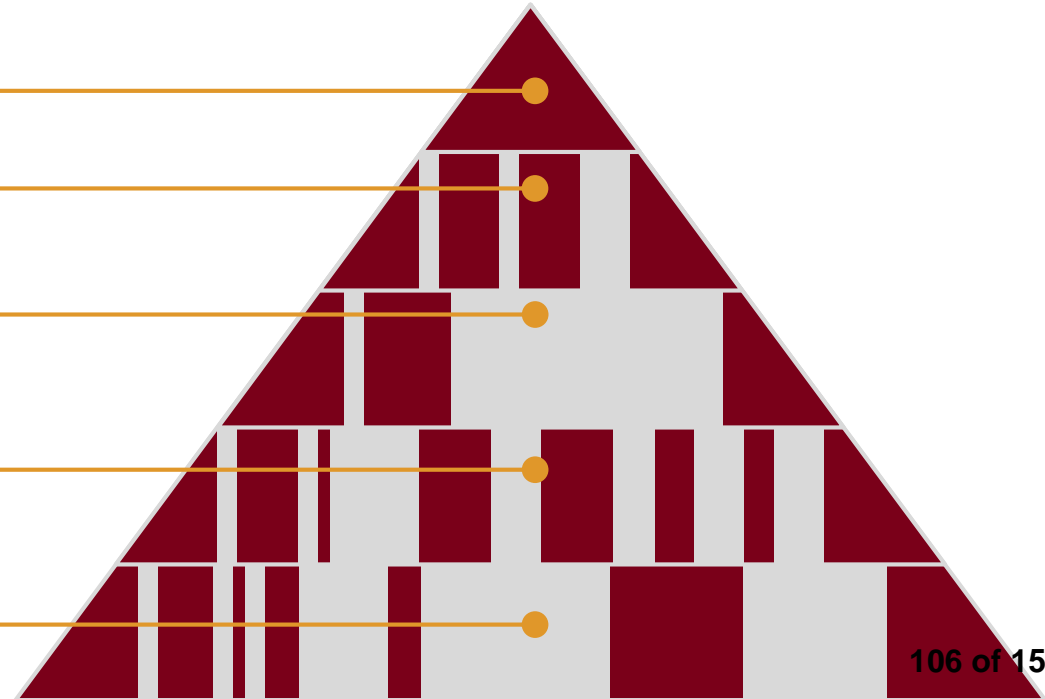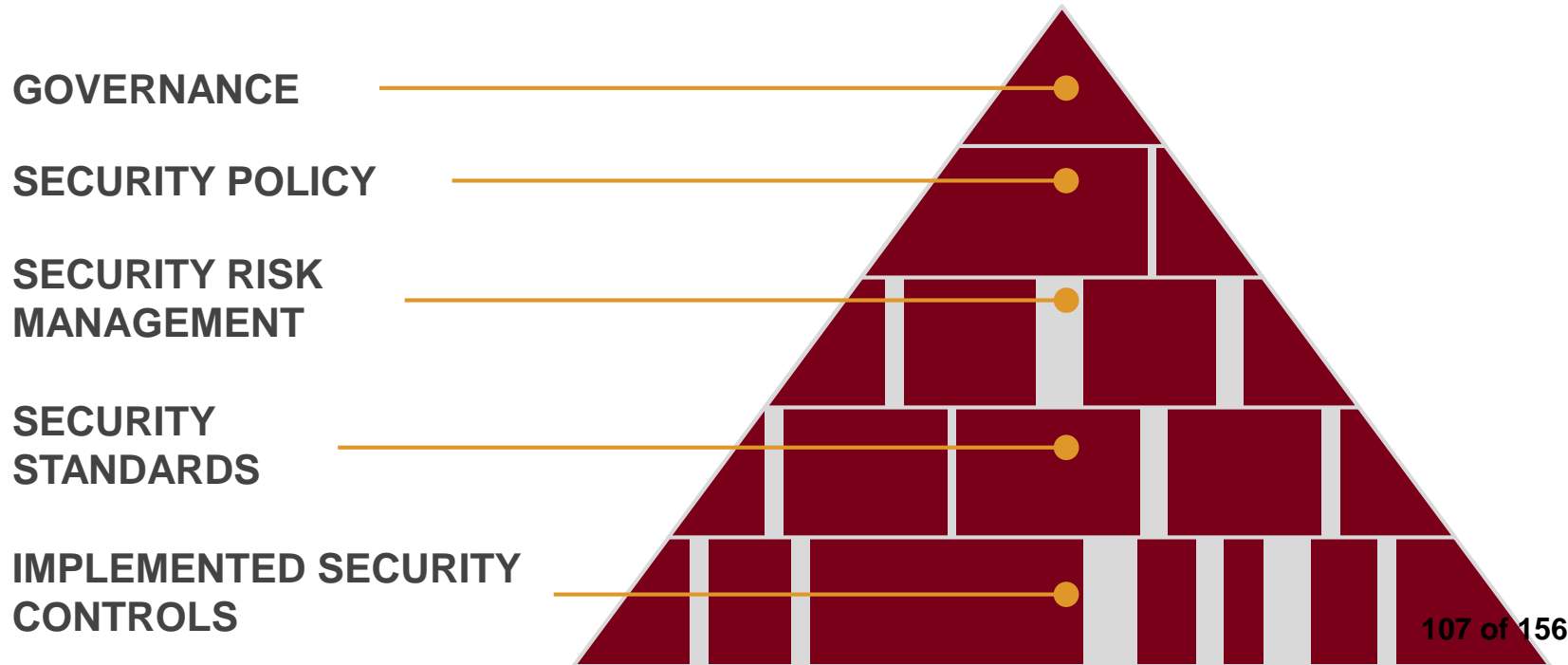
Assessing Progress Against Our Charge

We are engaged in independent, objective and quantitative assessment of strategy and maturity.

- Used Information Security Maturity Assessment Tool specific to higher education (HEISC)

- Analysis based on practices in higher education, interviews with information security officers, reports published by EDUCAUSE & SANS Institute.

- Provides overall HEISC current/projected maturity score and ratings in 12 ISO areas.
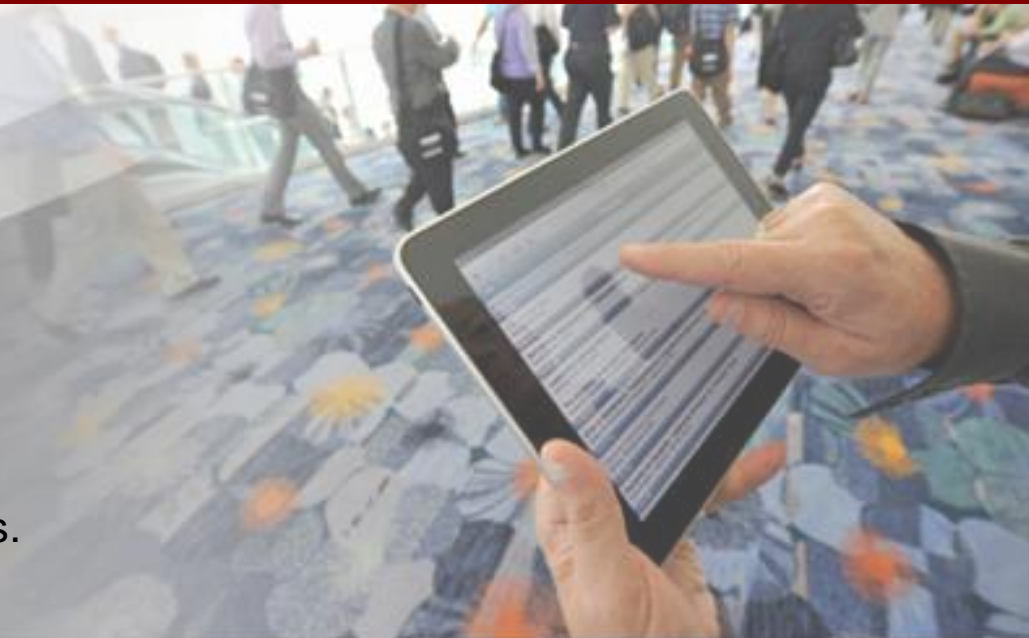
Assessing Progress Against Our Charge

We are engaged in independent, objective and quantitative assessment of strategy and maturity.

- Independent audit and consulting firm working in multiple sectors, including technology and higher education.

- Member, HLB International global network of accounting firms, business advisors.

- Extensive experience in information security in private/public firms.

ISO: International Organization for Standardization

- A systematic approach to information security.

- Provides a family of information security standards.

- Used across many different industries.

What Is HEISC, Why Is It Important?

HEISC: Higher Education Information Security Council

- Advancing information security strategies in higher education.

- Strengthening collaboration within higher education.

- Building the information security profession.

- Publishing an assessment tool that is quantitative, repeatable and provides a basis for comparison with peers.

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About HEISC Sections:

Format:

- 101 questions, aligning with specific sections of the ISO 27002 security standard.
- Covers 12 areas

Questions focus on:

- Communications & Operations Management
- Access Control
- Information Systems Acquisition, Development, and Maintenance

Use a maturity model scale of 0-5

Section	Section Name	Section Descriptions
ISO 4	Risk Management	Assessing Security Risks
ISO 5	Security Policy	Review of Information Security Policies
ISO 6	Organization of Information Security	Management and Coordination
ISO 7	Asset Management	Inventory and Classifications
ISO 8	Human Resource Security	Awareness, Training, and System Access
ISO 9	Physical and Environmental Security	Entry Controls, Secure Disposal, Equipment Maintenance
ISO 10	Communications and Operations Management	Change Management, Segregation of Duties, Documented Operations Procedures, Backup Controls, System Use Monitoring
ISO 11	Access Control	Password Management, User Access Rights, User Authentication
ISO 12	Information Systems Acquisition, Development, and Maintenance	Security Requirements, Data Validation, Information Leakage
ISO 13	Information Security Incident Management	Reporting and Evidence Collection
ISO 14	Business Continuity Management	Documented Plan
ISO 15	Compliance	Data Protection, Policy Compliance

IT@UMN   HEISC Maturity Assignment Level Definitions

0
Not Performed

No security controls or plans in place. Controls are nonexistent.

1
Performed Informally

Agreement in the organization that identified actions should be (and are) performed. The practices are not formally adopted, tracked or reported on.

2
Planned

Base requirements for control area are planned, implemented, and repeatable.

3
Well Defined

Processes are more mature: they are documented, approved, and implemented organization-wide.

4
Quantitatively Controlled

The primary distinction from Level 3 is that the process is measured and verified (e.g., auditable).

5
Continuously Improving

Defined, standard processes are regularly reviewed and updated. Improvements reflect an understanding of, and response to, a vulnerability's impact.

University of Minnesota

Higher Ed. Estimate

Cost (Cultural + Financial)

HEISC Maturity Scores

Overall Maturity Score
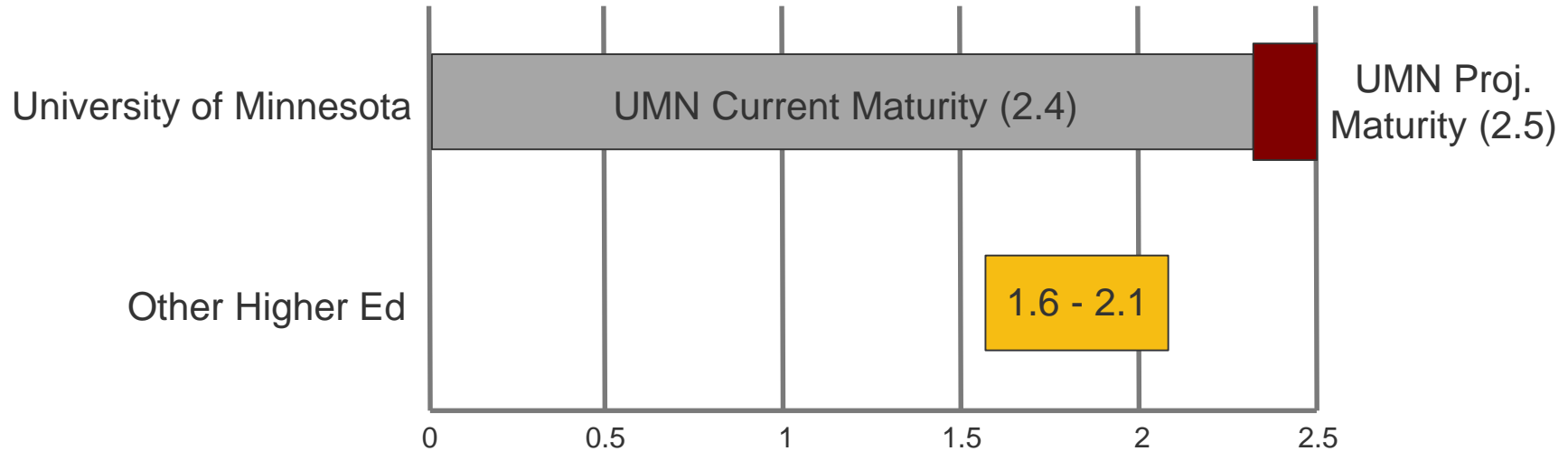
Comparison Area	HEISC Maturity Score
Maturity Score for UMN	2.4
Projected Maturity Score for UMN	2.5
Higher Ed Maturity Score Range	1.6 – 2.1
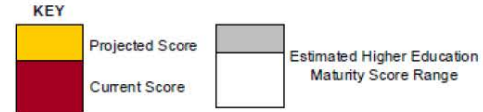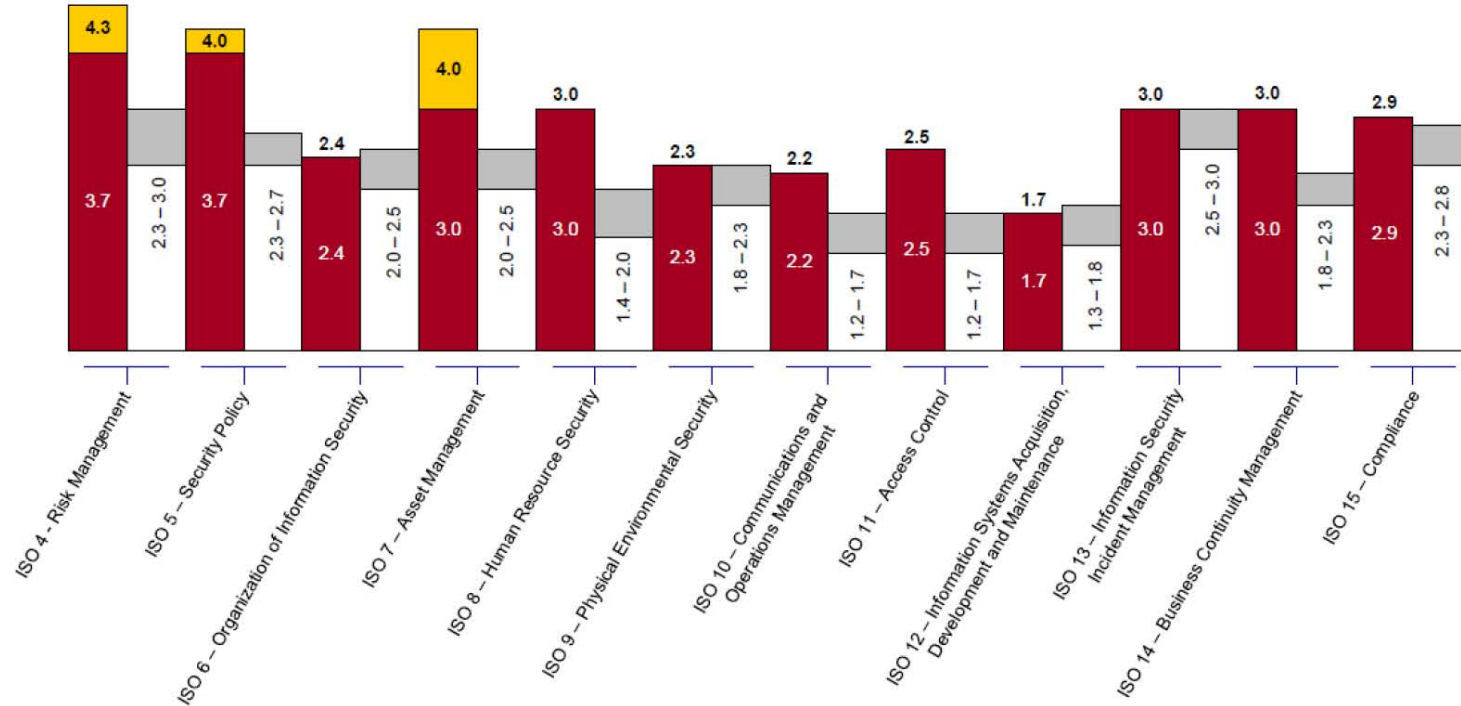
Strengths	Opportunities
• Responsibility given to the CISO empowers the Information Security department.	• *Log Management:* Provide notification process for system performance.
• Published "UWide" Policy Library and Information Security Standards	• Continued organization-wide adoption of the Information Security program.
• Formal processes to identify risks and address them through implemented plans.	• *Access Controls:* Enhancement of the Network Access Control Standard for detecting/blocking unauthorized or improperly configured devices.
• Formalized, well-documented approach to incident security.	• *Secure Coding:* New standard with procedures for data validation, error handling, and other controls.
• UIS is increasing community awareness about information security	

BerryDunn

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BerryDunn Recommends That UMN:

1. Understand the HEISC matrix, opportunities to strengthen maturity.

2. Increase consistent deployment of policies and standards through a focus on increasing organization-wide "buy-in" and awareness.

3. Grow participation, compliance and achieve stronger maturity through continued collaboration with units. (Strides with Internal Audit, Compliance, Finance, Academic Health and other key stakeholders.)

4. Use the HEISC tool to reassess at regular intervals to identify where maturity has increased and where gaps may still exist.

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The University of Minnesota…	At the same time…
• Our maturity compares very favorably to benchmarks in higher education.	• The University is a complex and diverse entity, and the threat is a matter of probability.
• Strong in U-Wide policy, classifying data, IS spend.	• More mature programs still have incidents.
• Foundation built on planned, implemented and repeatable control process.	• Our risk based approach is appropriate.
	• Maturity will increase as our consistent approach extends.

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Recognizing Our Strengths

KEY	
Projected Score (yellow)	Estimated Higher Education Maturity Score Range (gray)
Current Score (red)	

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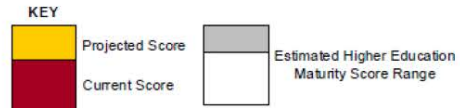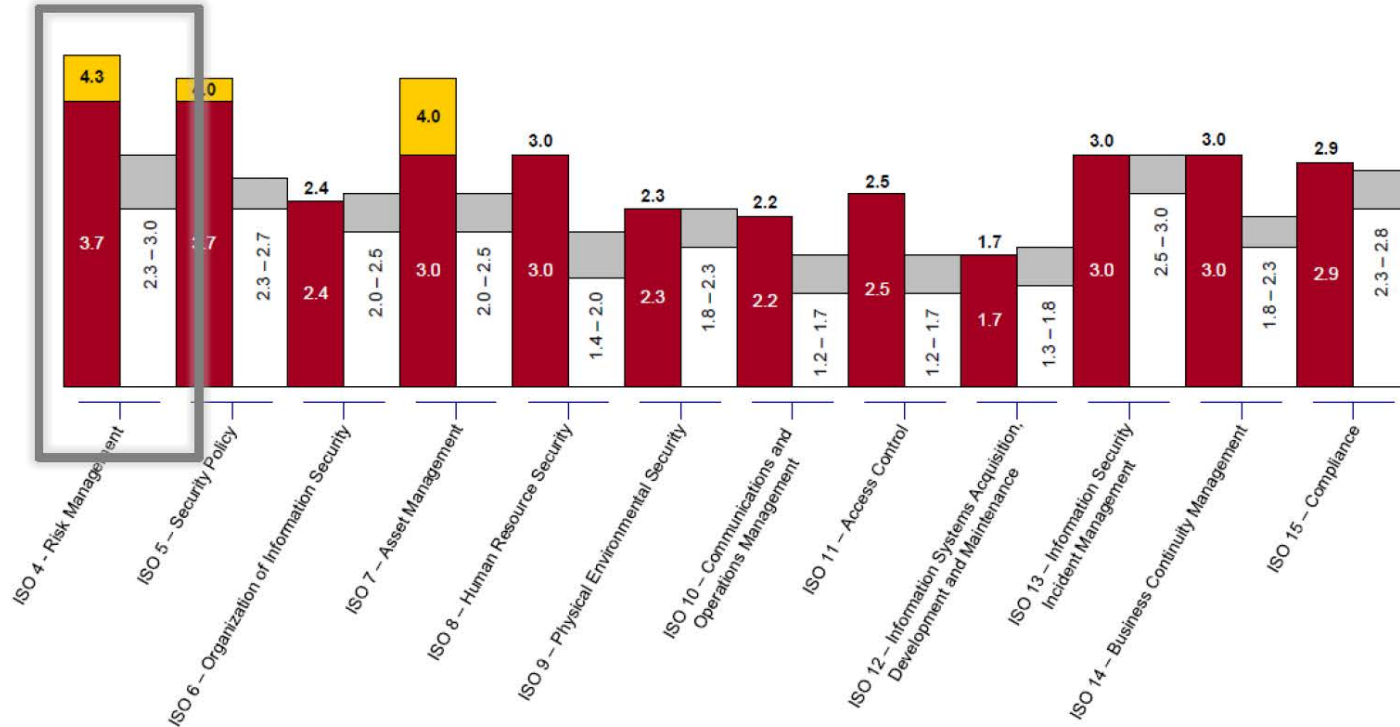
Risk Management: Current Score 3.7 / Projected Score 4.3

4.3

3.7

2.3-3.0
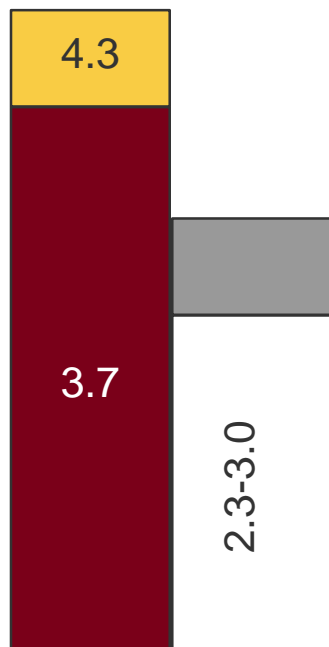
Reflects substantial results from institutional focus and investment.

Includes notable progress on:

- Formal information security risk management policy development.
- Risk assessments implemented across the organization.
- Prioritizing assessment on critical systems and higher risk areas.

Strong institutional and unit leadership is paying dividends.

Most institutions still developing campus-wide approaches.

Example: ISO 10 – Communications & Operations Management

| Ref #	Questions	Not Performed = 0; Performed Informally = 1; Planned = 2; Well Defined = 3; Quantitatively Controlled = 4; Continuously Improving = 5; Not Applicable = Blank	Item Score	Category Score	Basis for Current Score	Steps to Strengthen Maturity	Projected Score After CISO Initiatives
	HEISC Questions and Score Template				**BerryDunn Comments**		
	Communications and Operations Management (ISO 10)	Total Score for ISO 10 -->		2.15			
30	Does your institution maintain security configuration standards for information systems and applications?		Well Defined	3		The Securing Private Data, Computers, and Other Electronic Devices policy and related procedures provide general guidance on security configuration standards.	The University could publish and implement more detailed procedures for hardening the security configuration on all platforms (VMware, Windows, Linux) and critical applications used within the organization and then implement controls to determine general adherence to the procedures across the organization at a level that can be measured and verified.	3
31	Are changes to information systems tested, authorized, and reported?		Well Defined	3	The Change Control Standard provides the process based on the security level of the system undergoing a change. In addition, the University has weekly CAB meetings to review and approve changes.	The University could implement controls to determine adherence to the standard across the organization at a level that can be measured and verified.	3
32	Are duties sufficiently segregated to ensure unintentional or unauthorized modification of information is detected?		Planned	2	Duties are segregated in some areas, including the production environments where developers do not have access.	The University could publish and implement a standard on the segregation of duties to outline general separation recommendations (e.g. Network Engineers should not be System Administrators; log review duties should not coexist with access to alter or delete logs, etc.)	2
33	Are production systems separated from other stages of the development life cycle?		Well Defined	3	The Change Control Standard specifies that separate development, test and production environments must be maintained for high security risk areas.	The University is currently creating a standardized Programming Development Framework and could implement controls to determine that adherence to the Change Control Standard and the new Framework were in place across the University at a level that can be measured and verified.	3

ISO 10: Comm. & Ops Mgt.
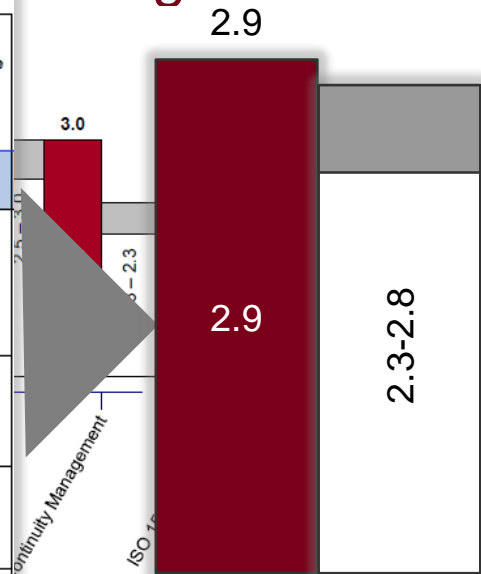
KEY

Projected Score

Current Score

Estimated Higher Education Maturity Score Range

Maturity Costs: Monetary & Cultural

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ISO Area	Current (Projected Final) UMN Score	Example Cost to Increase Score	Financial Cost	Cultural Cost
ISO 12 IS Acquisition, Development, Maintenance	1.7	1. Formal process for security review of vendor software 2. Education for secure coding practices 3. Central code development & approval process	1. <$100k 2. $100k-$500k 3. <$100k	1. Low 2. Low 3. High
ISO 10 Communications & Operations Management	2.2	1. Implement data loss prevention 2. Monitoring compliance of external information systems service provider	1. >$500k 2. $100k-$500k	1. High 2. Low
ISO 6 Organization of Information Security	2.4	1. Security team in the formal approval process for purchases of hardware, software, and services 2. Independent security reviews at planned intervals	1. <$100k 2. $100k-$500k	1. High 2. Medium
ISO 11 Access Control	2.5	1. Policy to limit network ports by default, open as necessary 2. Measures to prevent and detect rogue access for all wireless LANs	1. <$100k 2. $100k-$500k	1. High 2. High

Confidence in Strategy and Focus

- Managing natural tension within our open culture.

- Security Advisory Committee will review and guide efforts.

- Using internationally accepted security framework (ISO 27001/27002) and accessing industry best practices to be prepared.

- In contact with other Big Ten institutions, FBI, others to share information on security threats and protocols.
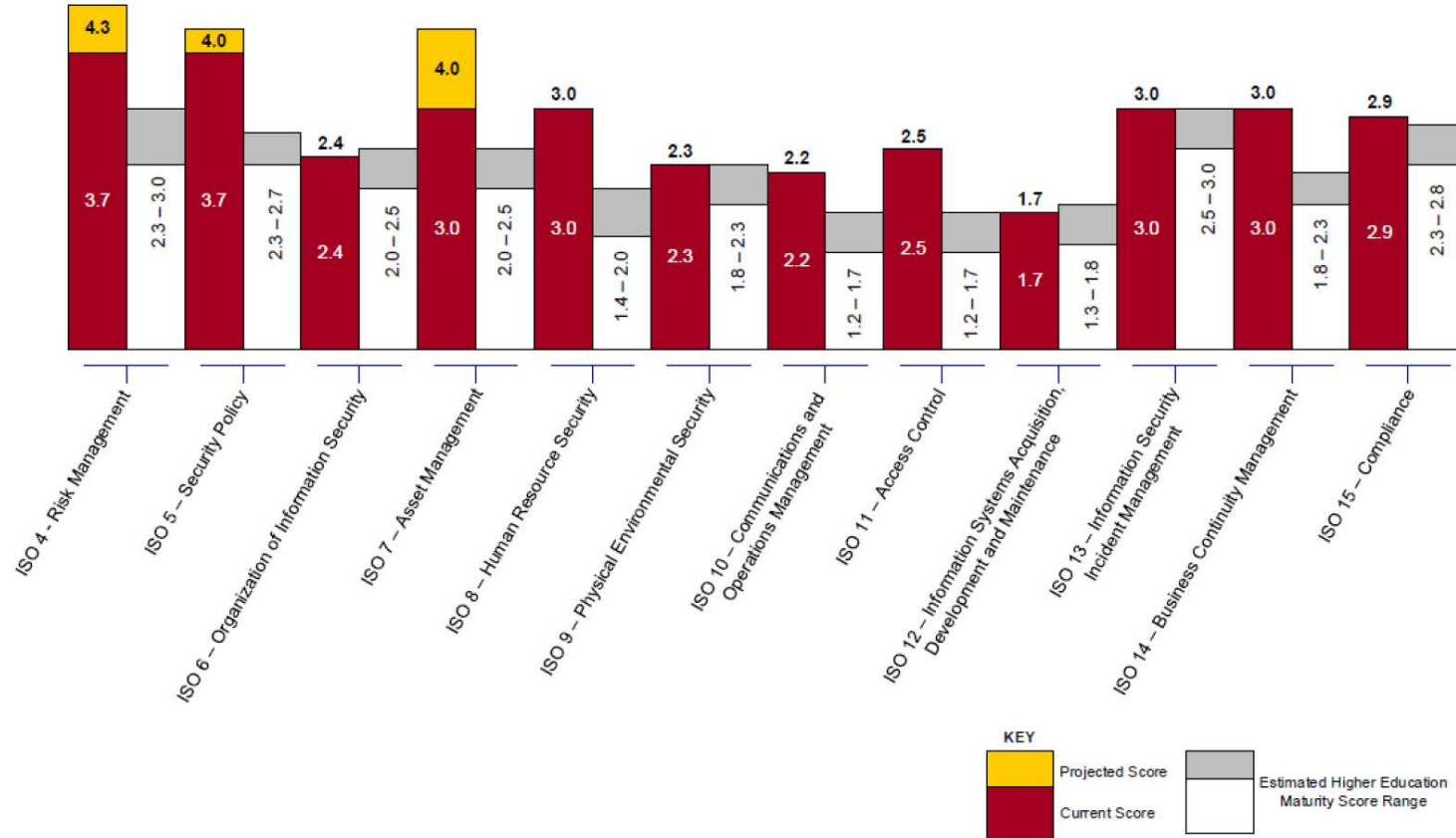
University of Minnesota

Driven to Discover℠

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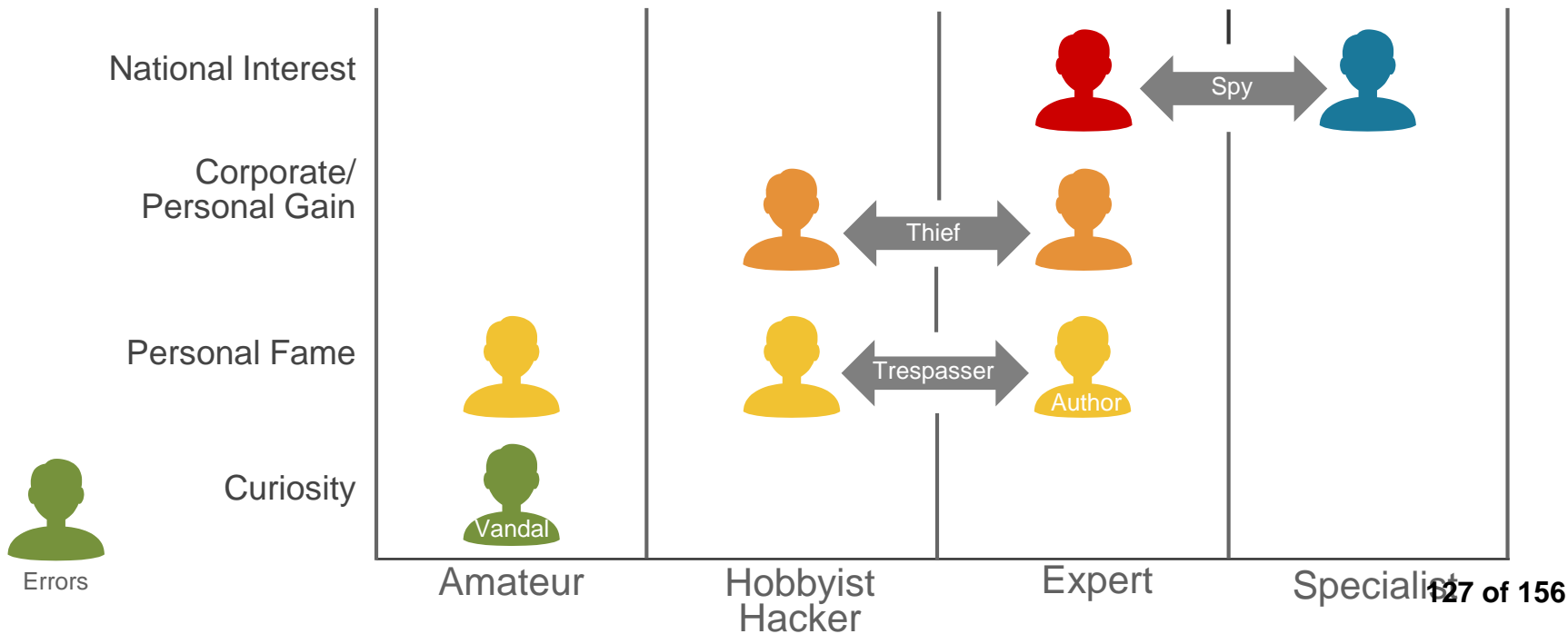
The Language of Information Security

Security Incident

An information security incident indicates that the security of an information system, service, or network could have resulted in a breach of private data.

Breach

The unauthorized acquisition, access, use or disclosure of data maintained by the University.

"Breach" does not include:

1. Authorized and good faith acquisition, access, or use of private data by an employee, contractor, or agent of the University,
2. Incidents involving data that have been rendered unusable, unreadable, or undecipherable through valid encryption, or
3. Incidents involving de-identified data.

A healthy program tracks many incidents and has minimal breaches.
The University averages 3,069 information security incidents per month.

Errors

Volume = 2,332 (76%)

Prevention

Detection & Remediation

Amateurs

Volume = 614 (20%)

Prevention

Detection & Remediation

Hobbyist Hackers

Volume = 123 (4%)

Prevention

Detection & Remediation

Experts

?

?

?

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Review: Information Security Risk Primer
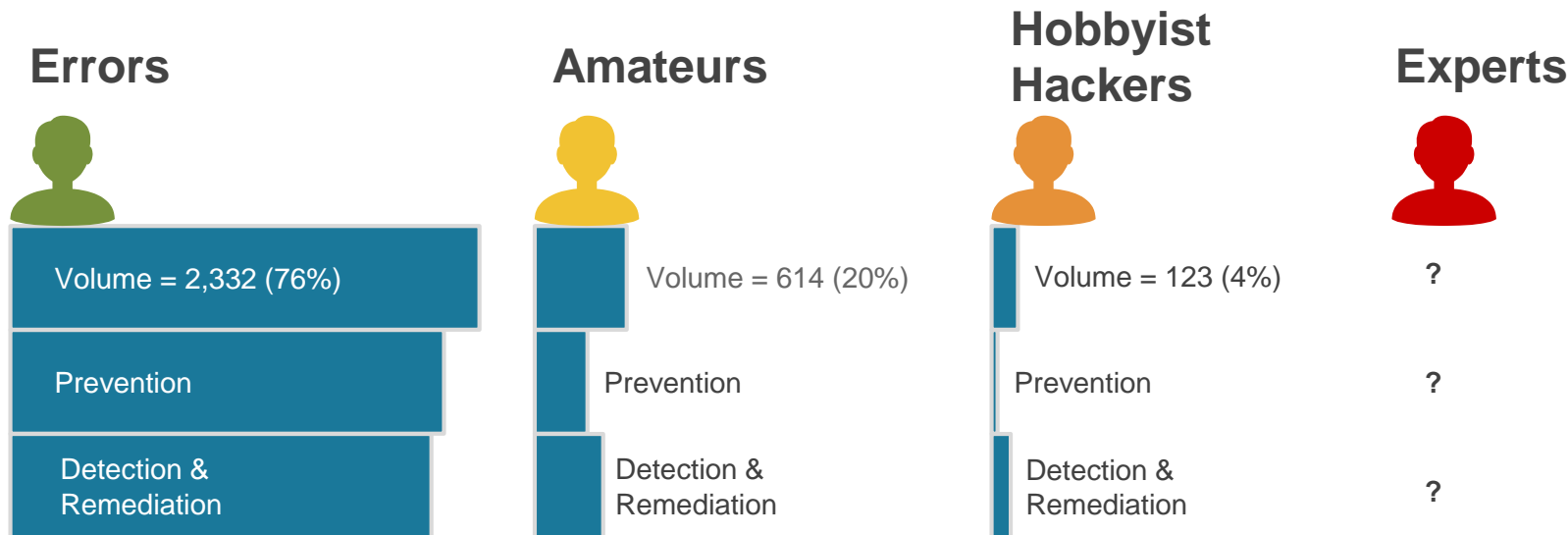
We closely track our peer institutions.
They have experienced 2.3 million records lost since 2012, and counting.

INSTITUTION	WHEN	RECORDS LOST
University of Nebraska	Jun 2012	654,000
University of North Carolina	May 2012	350,000
Arizona State University	Jan 2012	300,000
N Florida State College	Oct 2012	279,000
Indiana University	Feb 2014	146,000
University of Maryland	Feb 2014	287,580
North Dakota University System	Mar 2014	291,465
Penn State University	May 2015	18,000

* In FY15, UMN had 22 breaches resulting in the exposure of 4,647 records

The Significant Challenge of Information Security

- Our controls provide good due diligence.

- We have additional technical controls in place.

- But security incidents **will** occur…

    The high-impact security breach **will** occur, and…

        Security incidents from Experts **will** remain undetected...

No matter the controls we implement.

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Review: University Data Security Strategy

Information Security Standards

Before:
Securing Private Data Policy

After:
Information Security Policy

Basic

- Training
- Authentication
- Configuration
- Firewall
- Anti-Virus
- Security Patches

Enhanced

- Access Control
- Virus Protection
- Security Patches
- Local Data Owner
- Encryption
- Data Storage
- Physical Security
- Backups
- Technical Vulnerability Management
- Secure Data Deletion & Secure Disposal
- Change Control
- Log Management
- Risk Assessment

Security Levels: High, Medium, Low

- Access Control - Application
- Access Control - Mobile
- Access Control - Network
- Access Control - OS
- Access Control - User Responsibilities
- Account Provisioning
- Backups
- Change Control
- Data Center Operations, Storage
- Encryption – End-User Device
- Firewall - Device, Network
- Information Security Awareness, Education and Training

- Management of End-User Device
- Media Sanitization
- Physical Security
- Risk Assessment
- Security Patches
- Strong Authentication
- Technical Vulnerability Management - IT Professionals
- Technical Vulnerability Management - U Community
- User Administrative Privilege
- Virus/Malware Protection

BOARD OF REGENTS
DOCKET ITEM SUMMARY

Audit & Compliance   **September 10, 2015**

AGENDA ITEM: Internal Audit Update

| | Review | | Review + Action | | Action | X | Discussion |

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

PRESENTER: Gail Klatt, Associate Vice President, Internal Audit

PURPOSE & KEY POINTS

To update the Audit and Compliance Committee on Internal Audit activities, results, and observations to help the committee fulfill its fiduciary responsibilities under its reserved authority for oversight of the internal audit function, as outlined in the committee charter.

- Since the last follow-up at the June 2015 meeting, 16% of the outstanding recommendations rated as "essential" were implemented by University departments. This is significantly fewer than the expected rate of 40%. Approximately 50% of the recommendations remaining were associated with audits that were receiving their first follow-up. However, approximately 60% of the total remaining recommendations are now past management's original target implementation date. Four units fully implemented all their remaining "essential" recommendations.
- An updated control evaluation chart is included for each audit to show progress made on the "essential" items.
- One audit report containing one recommendation rated as "essential" was issued in the last three months.

BACKGROUND INFORMATION

This report is prepared three times per year and is presented to the Audit and Compliance 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 10, 2015

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

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

Audit Observations/Information

Status of Critical Measures

As part of our on-going efforts to provide the Audit 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 2016 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	Progress Towards Annual Audit Plan Completion	Time Spent on Investigative Activities
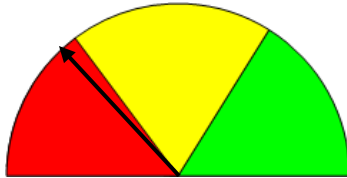
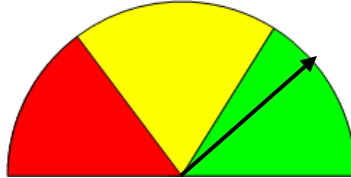|		
Implementation rates were 16% for the period, significantly less than our expected rate of 40%. 60% of the recommendations remaining are past their targeted implementation dates.	Time spent to date on the FY 2016 audit plan is about what was expected and budgeted for the year to date.	Time spent on investigative activities and special projects is more than expected and budgeted for the year to date.
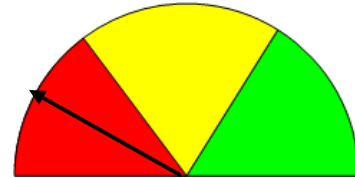
Other Items

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

- We completed non-scheduled audit work at the request of the Office of the Legislative Auditor. The current audit focus was the University's use of funds received from the Environment & Natural Resource Trust Fund. A draft report has been issued to management, and no major issues were identified.

- We purchased licenses for data analytic software, and all auditors recently attended a three day training session on its use. We will use this software to expand and increase the efficiency of our data retrieval and analysis capabilities, and it will enable us to develop queries and test entire populations of data.

Quality Assurance Review Recommendation

- The following recommendation was included in our most recent external Quality Assurance report (February 2015):

"Consider further reducing the extensive time spent on following up on audit issues. We discussed various options for doing this without overly increasing risk to the University. The Office will further discuss and, if appropriate, bring a proposal to the audit committee for consideration."

The review team felt that there was an opportunity to reduce the time associated with our follow up activities if we relied more on management representations as to the implementation of individual recommendations rather than actually verifying that implementation has occurred and is sustainable.

We reviewed the time we spend on follow up relative to our peers and have found that we actually spend less time than the majority of our counterparts. Our follow up process, including the verification of implementation, is quite efficient and we complete this work consistently within the 2% of our resources that we allocate to this effort.

We strongly believe in following a "trust, but verify" audit approach. We believe it is important to affirm that the actions taken to implement audit recommendations both 1) mitigate the risk vulnerability identified to a reasonable level, and 2) are demonstrated to be sustainable. We have a very long historical context that this validation is very valuable in that we frequently find additional work by management is needed to fully mitigate the underlying risk.
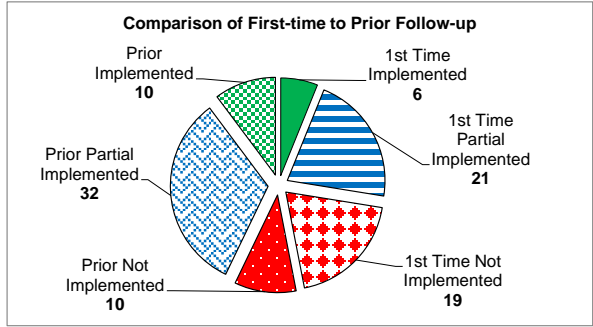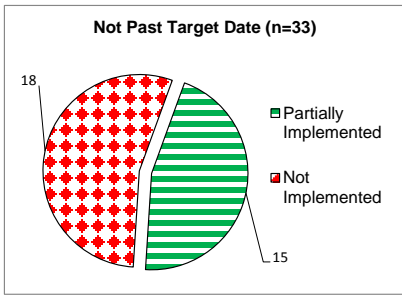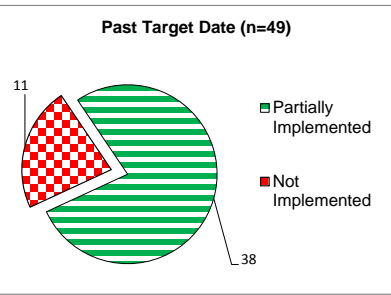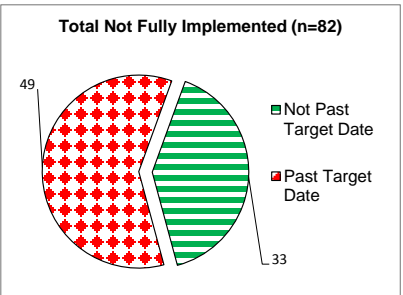
We, therefore, with the Audit and Compliance Committee's concurrence, do not plan to change our current practices.

Status of "Essential" Recommendations as of August 28, 2015

Report Date	Audit (P) Indicates a University process audit	Original Report Control Rating	# of Essential Recommendations in the Report	# of Essential Recommendations Remaining From Prior Quarter	Current Quarter Results					Overall Progress Towards Implementation*
					Implemented	Partially Implemented		Not Implemented		
						Not Past Target Date	Past Target Date	Not Past Target Date	Past Target Date	
Audits > 2 years old (see the following report for details on unresolved issues)										
Oct-11	UMD School of Fine Arts	Adequate	10	2			1		1	Satisfactory(1)
May-13	Travel & Employee Reimbursements (P)	Good	1	1			1			Satisfactory
Audits < 2 years old; have received prior follow-up										
Dec-13	**UMD Information Tech. Systems & Services**	**Good**	**6**	**3**	**3**					**Completed**
Feb-14	University-wide Purchasing Process (P)	Good	2	2			1		1	Satisfactory
Apr-14	UM - Crookston Campus	Good	6	1			1			Satisfactory
Jun-14	Identity Management	Needs Improvement	11	6	2	1	3			Satisfactory
Jun-14	Parking & Transportation Services	Adequate	10	10			10			Unsatisfactory (2)
Jul-14	UMD University for Seniors	Good	2	1			1			Satisfactory
Oct-14	University Recreation and Wellness	Needs Improvement	6	1			1			Satisfactory
Nov-14	Baseline Tennis Center	Good	2	2			2			Satisfactory
Dec-14	**A Review of Top Researchers (P)**	**Good**	**1**	**1**	**1**					**Completed**
Dec-14	**Carlson School of Management**	**Good**	**3**	**3**	**3**					**Completed**
Jan-15	Athletics Aspire Contract	Adequate	1	1			1			Satisfactory
Jan-15	Server Room Security	Needs Improvement	17	17		2	7	6	2	Satisfactory
Jan-15	**Medical School Department Head Expense**	**Adequate**	**1**	**1**	**1**					**Completed**
Audits receiving first-time follow-up										
Apr-15	Dept. of Ophthalmology & Visual Neurosciences	Adequate	9	9	1		5		3	Satisfactory
May-15	Technology Vendor Due Diligence	Needs Improvement	4	4		2		2		Satisfactory
May-15	OIT Server Administration	Good	5	5		2		3		Satisfactory
May-15	SimPORTAL & CREST	Adequate	3	3	2	1				Satisfactory
May-15	Medical School Duluth	Needs Improvement	25	25	3	7	4	7	4	Satisfactory
	Total:		**125**	**98**	**16**	**15**	**38**	**18**	**11**	

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

(1): UMD School of Fine Arts/Glensheen continues to make significant progress as over 5,500 objects have now been entered into the online object database. However, the entire inventory may encompass over 10,000 items.

(2): Parking and Transportation Services continues to put considerable effort into resolving outstanding items, but given system limitations and resource constraints minimal progress on the eight Essential IT recommendations is being made.

Total Not Fully Implemented (n=82)

Past Target Date (n=49)

Not Past Target Date (n=33)

Comparison of First-time to Prior Follow-up

"Essential" Recommendation Implementation Trends

Month / Year of Follow-up Report

|	Sept. 2015	June 2015	Feb. 2015	Sept. 2014	June 2014	Feb. 2014	Sept. 2013	June 2013	Feb. 2013	Average
# of Essential Recommendations Receiving Follow-up	98	60	44	53	34	36	64	56	67	46
# of Recommendations Considered Fully Implemented	16	8	16	12	10	13	30	13	26	14
Implementation Percentage	16%	13%	36%	23%	29%	36%	47%	23%	39%	31%

64 of the 82 (78%) outstanding recommendations are IT related: 12 are the direct responsibility of OIT, the other 52 items are related to non-central IT units' operations, University Services' central security, and HIPAA related concerns.

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

Audit/ Report Date	Status- Partially Implemented (P) or Not Implemented (N)	Senior Management Contact	Summary of the Issue/Risk Involved	Current Comments From Management
UMD School of Fine Arts Oct-11	P	William Payne Bilin Tsai	Glensheen should update and expand its inventory records with the ultimate goal of having a complete record of the entire collection. Periodically, the presence and location of inventory items should be verified on at least a sample basis.	According to the director of Glensheen, additional objects are being discovered as the inventory process has progressed into more rooms in the mansion. The vendor's contract has been extended by $35,000 to facilitate completion of the project. In addition, a collections manager has been hired who will also be involved with the project. The director believes the inventory project could be completed by May 2016.
	N	William Payne Bilin Tsai	Glensheen management should work with Accounting Services to develop procedures for reporting the value of its collection.	Efforts to appraise the collection will commence after the inventory has been completed. These efforts are expected to take approximately six months.
# of Items 2				
Travel & Employee Reimbursements May-13	P	LaCretia Bell Michael Volna	Disbursement Services should continue their efforts to carefully review all cash advance requests to ensure that alternative methods of payment are not more viable before issuing the cash advance. This might include purchases made via vendor invoice or PCard. The corporate travel card is also an alternative for those travelers who do not have other means of paying for travel. In addition, the Controller's Office, in conjunction with OIB, should explore other options for better accommodating the need for compensating University human subjects.	The Controller's Office made procedural changes in response to the audit recommendation to help ensure cash advance requests are handled in the most appropriate manner. In addition, we are currently reviewing responses from a Request For Proposal for new technology that, if implemented, is intended to improve processes for paying University human participants on research projects, rather than using cash advances. A decision on whether to proceed will be made in the next few months, at which time we will consider the audit recommendation fully implemented.
# of Items 1				
Total: 3				

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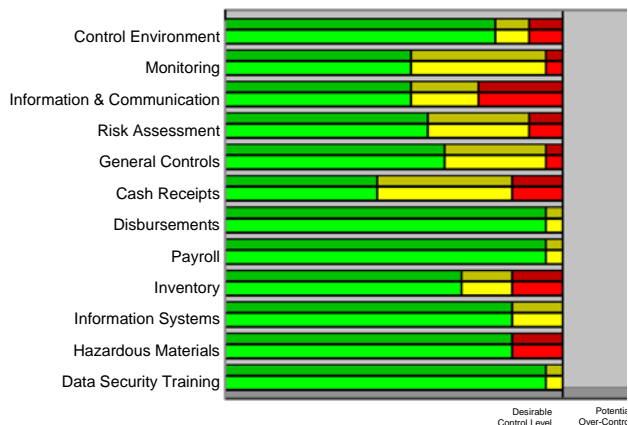
Original Report Evaluation	Previous Quarter Evaluation	Current Quarter Evaluation

U of MN Duluth - School of Fine Arts (October 2011)
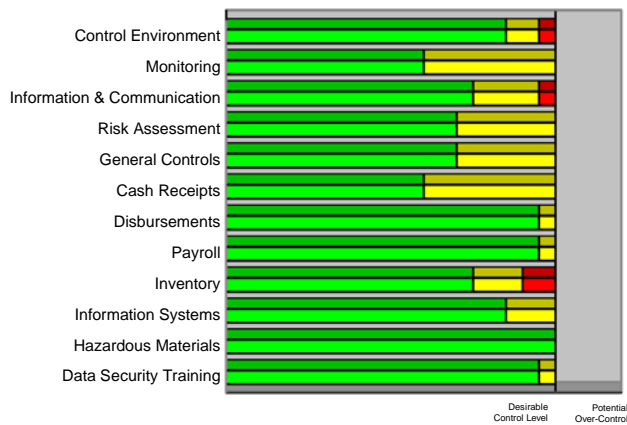
Travel & Employee Expense Reimbursement Process (May 2013)
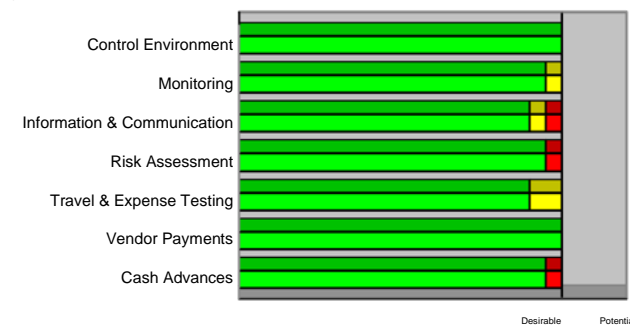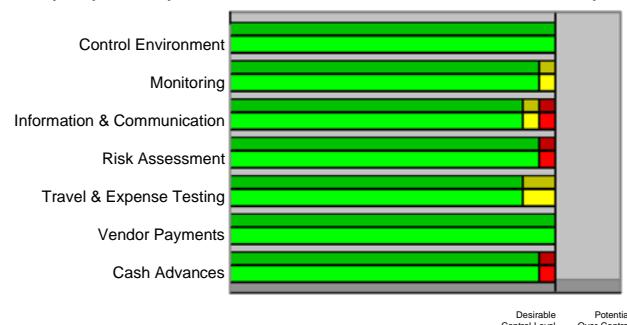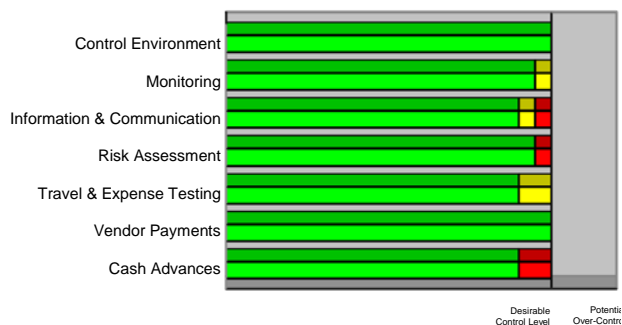
Adequate Control   Significant Control Level   Critical Control Level   Potential Over-Control

Original Report Evaluation

Previous Quarter Evaluation

Current Quarter Evaluation

University-wide Purchasing Process (February 2014)

Control Environment
Monitoring
Information & Communication
Risk Assessment
Administration
Contracts for Prof. Serv.
Price Comparisons
Change Orders
Central Bidding
Purchasing w/o a PO
Targeted Business Groups

Desirable Control Level   Potential Over-Control
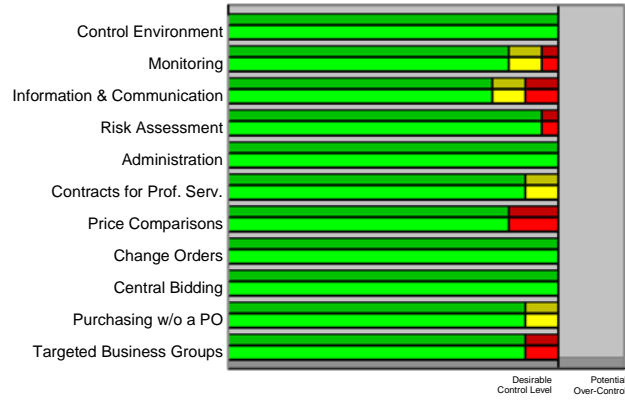
UM - Crookston Campus (April 2014)
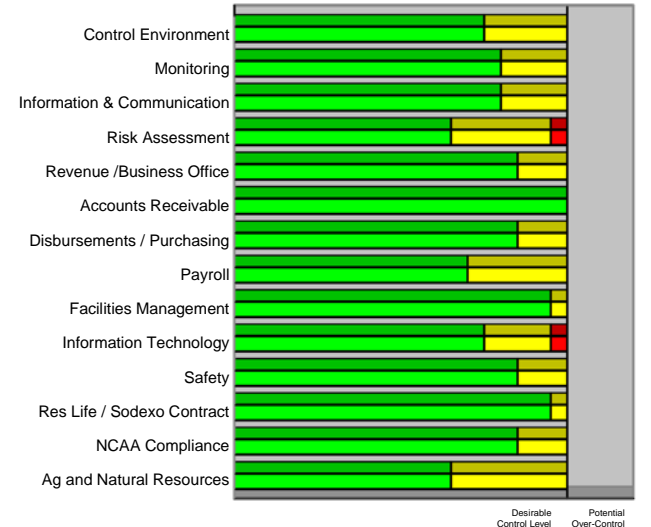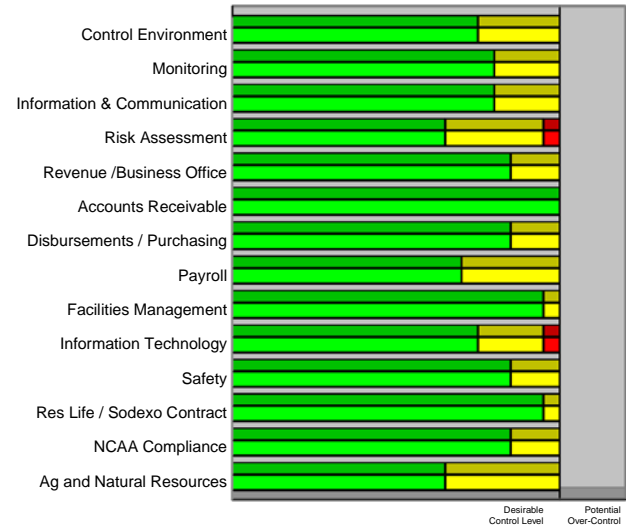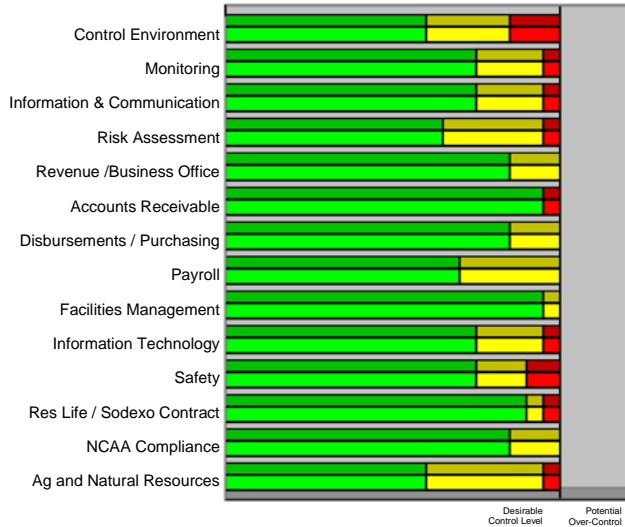
Control Environment
Monitoring
Information & Communication
Risk Assessment
Revenue /Business Office
Accounts Receivable
Disbursements / Purchasing
Payroll
Facilities Management
Information Technology
Safety
Res Life / Sodexo Contract
NCAA Compliance
Ag and Natural Resources

Desirable Control Level   Potential Over-Control

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

Original Report Evaluation

Previous Quarter Evaluation

Current Quarter Evaluation

Identity Management (June 2014)

Control Environment
Monitoring
Information & Communication
Risk Assessment
Strategy and Requirements
Credential Security
User Access & Administration
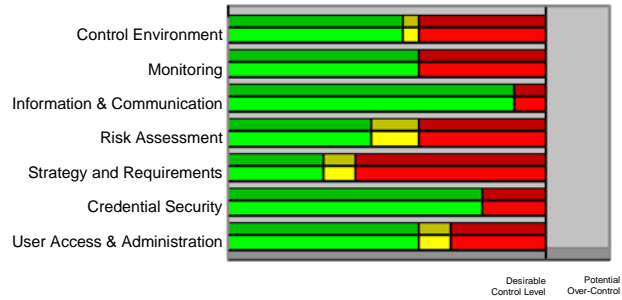
Desirable Control Level   Potential Over-Control

Parking and Transportation Services (June 2014)
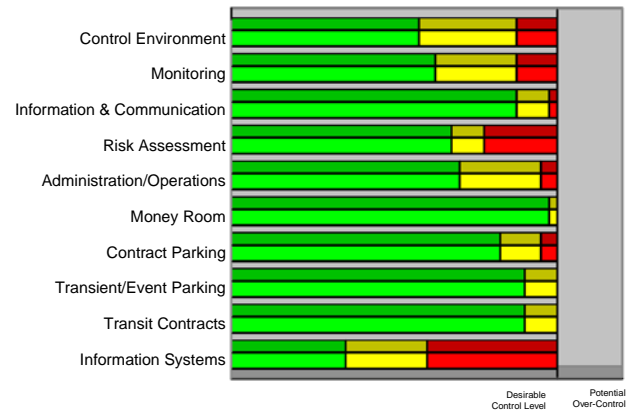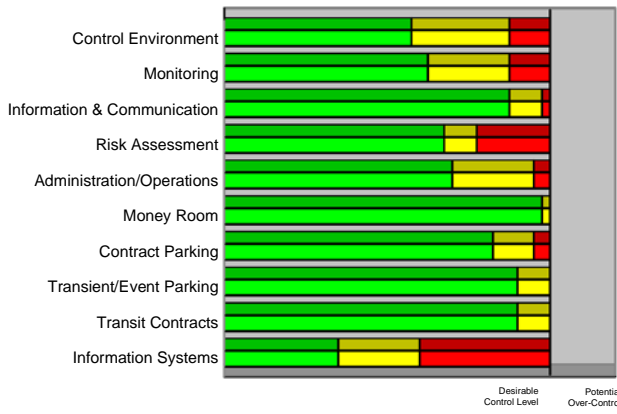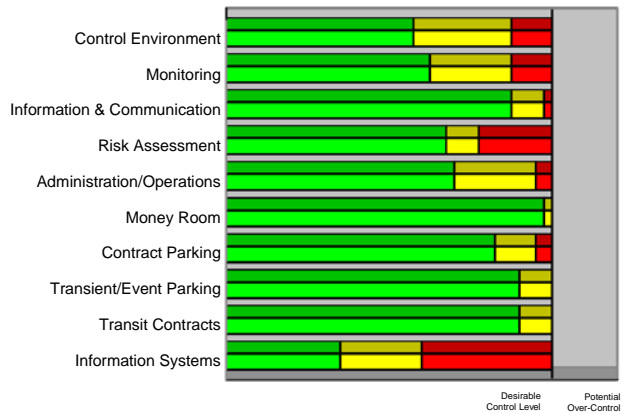
Control Environment
Monitoring
Information & Communication
Risk Assessment
Administration/Operations
Money Room
Contract Parking
Transient/Event Parking
Transit Contracts
Information Systems

Desirable Control Level   Potential Over-Control

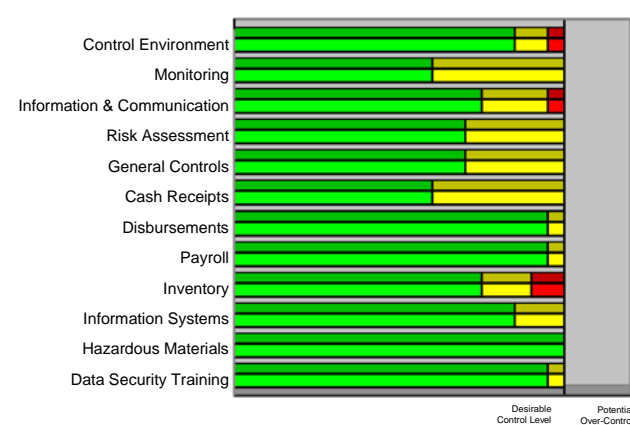■ Adequate Control   ■ Significant Control Level   ■ Critical Control Level   ■ Potential Over-Control

Original Report Evaluation | Previous Quarter Evaluation | Current Quarter Evaluation

UMD University for Seniors (July 2014)

Original Report Evaluation
- Control Environment
- Monitoring
- Information & Communication
- Risk Assessment
- General Controls
- Endowments
- Cash Receipts
- Purchasing & Disbursements
- Registration
- Information Technology

Previous Quarter Evaluation
- Control Environment
- Monitoring
- Information & Communication
- Risk Assessment
- General Controls
- Endowments
- Cash Receipts
- Purchasing & Disbursements
- Registration
- Information Technology

Current Quarter Evaluation
- Control Environment
- Monitoring
- Information & Communication
- Risk Assessment
- General Controls
- Endowments
- Cash Receipts
- Purchasing & Disbursements
- Registration
- Information Technology

University Recreation & Wellness (October 2014)

Original Report Evaluation
- Control Environment
- Monitoring
- Information & Communication
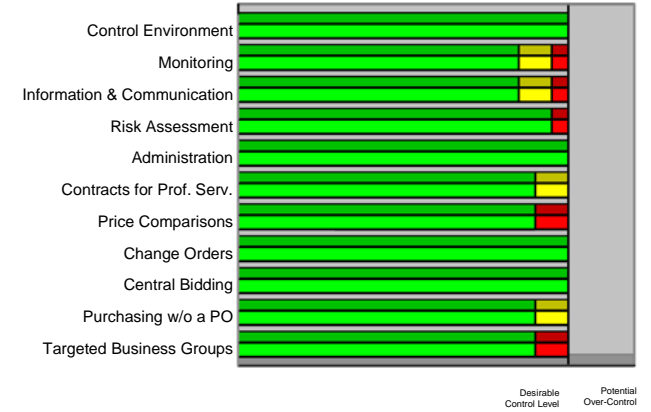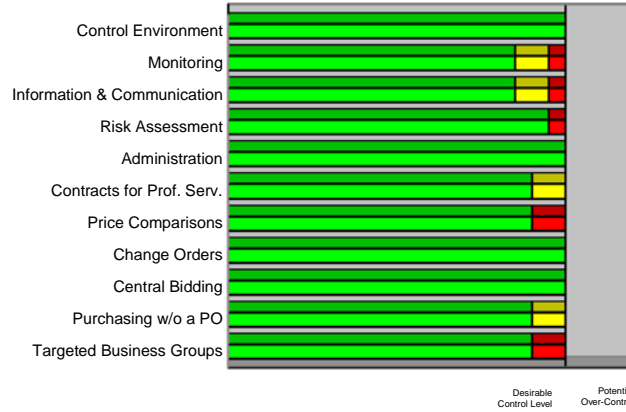- Risk Assessment
- Administration/Finance
- Cash Receipts/Revenue
- COA
- Disbursements
- Information Systems
- Payroll/Personnel
- Sport Clubs
- Youth Programs

Previous Quarter Evaluation
- Control Environment
- Monitoring
- Information & Communication
- Risk Assessment
- Administration/Finance
- Cash Receipts/Revenue
- COA
- Disbursements
- Information Systems
- Payroll/Personnel
- Sport Clubs
- Youth Programs

Current Quarter Evaluation
- Control Environment
- Monitoring
- Information & Communication
- Risk Assessment
- Administration/Finance
- Cash Receipts/Revenue
- COA
- Disbursements
- Information Systems
- Payroll/Personnel
- Sport Clubs
- Youth Programs

■ Adequate Control   ▨ Significant Control Issue(s)   ▥ Critical Control Issue(s)

Original Report Evaluation	Previous Quarter Evaluation	Current Quarter Evaluation

Baseline Tennis Center (November 2014)

Original Report Evaluation	Previous Quarter Evaluation	Current Quarter Evaluation
Control Environment	Control Environment	Control Environment
Monitoring	Monitoring	Monitoring
Information & Communication	Information & Communication	Information & Communication
Risk Assessment	Risk Assessment	Risk Assessment
Administration	Administration	Administration
Cash Receipts & Revenue	Cash Receipts & Revenue	Cash Receipts & Revenue
Disbursements	Disbursements	Disbursements
Payroll	Payroll	Payroll
Court Reservations	Court Reservations	Court Reservations

Athletics Aspire Contract (January 2015)

Original Report Evaluation	Previous Quarter Evaluation	Current Quarter Evaluation
Control Environment	Control Environment	Control Environment
Monitoring	Monitoring	Monitoring
Information & Communication	Information & Communication	Information & Communication
Risk Assessment	Risk Assessment	Risk Assessment
Contract Management	Contract Management	Contract Management
Financial Transactions	Financial Transactions	Financial Transactions

■ Adequate Control ▢ Significant Control Issue(s) ▮ Critical Control Issue(s)

Original Report Evaluation	Previous Quarter Evaluation	Current Quarter Evaluation

Server Room Security (January 2015)

Original Report Evaluation
- Control Environment
- Monitoring
- Information & Communication
- Risk Assessment
- Access Management
- Central Control Systems
- Physical Security
- Environmental Controls

Previous Quarter Evaluation
- Control Environment
- Monitoring
- Information & Communication
- Risk Assessment
- Access Management
- Central Control Systems
- Physical Security
- Environmental Controls

Current Quarter Evaluation
- Control Environment
- Monitoring
- Information & Communication
- Risk Assessment
- Access Management
- Central Control Systems
- Physical Security
- Environmental Controls

Ophthalmology and Visual Neurosciences (April 2015)

Original Report Evaluation
- Control Environment
- Monitoring
- Information & Communication
- Risk Assessment
- Information Systems
- Deposits & Receivables
- Payroll
- Sponsored Projects
- Administration
- Disbursements/Purchasing

NO PREVIOUS
CONTROL EVALUATION
CHART

Current Quarter Evaluation
- Control Environment
- Monitoring
- Information & Communication
- Risk Assessment
- Information Systems
- Deposits & Receivables
- Payroll
- Sponsored Projects
- Administration
- Disbursements/Purchasing

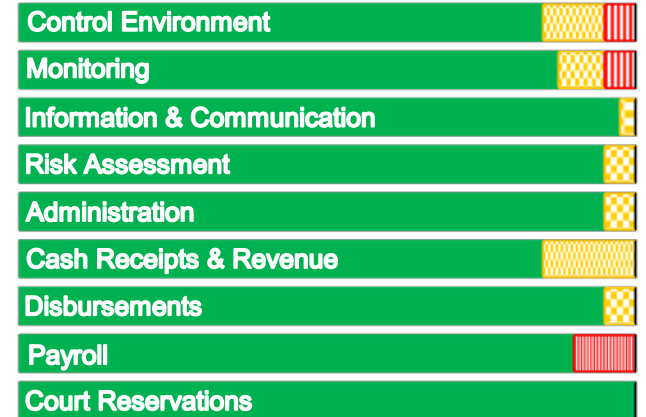■ Adequate Control   □ Significant Control Issue(s)   ▯ Critical Control Issue(s)

Original Report Evaluation | Previous Quarter Evaluation | Current Quarter Evaluation

Technology Vendor Due Dilligence (May 2015)

Original Report Evaluation	Current Quarter Evaluation
Control Environment	Control Environment
Monitoring	Monitoring
Information & Communication	Information & Communication
Risk Assessment	Risk Assessment
Directives & Rqmts.	Directives & Rqmts.
Functionality/Security Assmt.	Functionality/Security Assmt.
Selection & Contracting	Selection & Contracting
Implementation	Implementation

NO PREVIOUS
CONTROL EVALUATION
CHART

OIT Server Administration (May 2015)

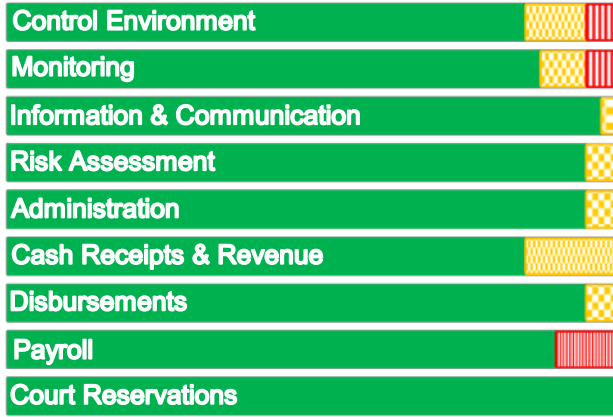| Original Report Evaluation	Current Quarter Evaluation
Control Environment	Control Environment
Monitoring	Monitoring
Information & Communication	Information & Communication
Risk Assessment	Risk Assessment
Logical Access	Logical Access
Change Management	Change Management
Service Management & Governance	Service Management & Governance
Configuration, Capacity & Performance	Configuration, Capacity & Performance

NO PREVIOUS
CONTROL EVALUATION
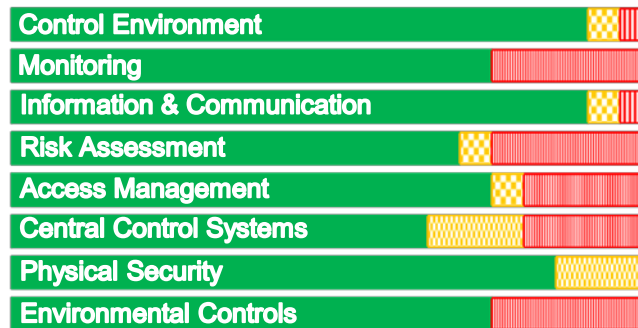CHART

■ Adequate Control   ☐ Significant Control Issue(s)   ▮ Critical Control Issue(s)

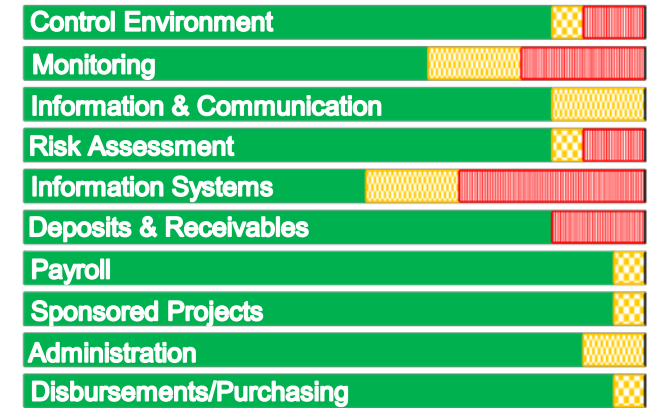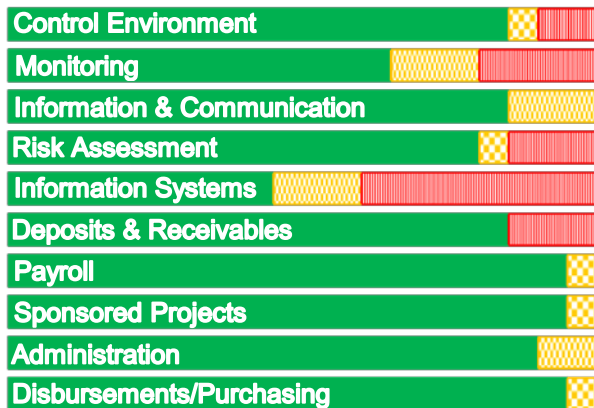| Original Report Evaluation	Previous Quarter Evaluation	Current Quarter Evaluation

SimPORTAL & CREST (May 2015)

Original Report Evaluation
- Control Environment
- Monitoring
- Information & Communication
- Risk Assessment
- Sponsored Projects
- Payroll
- Disbursements/Purchasing

Previous Quarter Evaluation

NO PREVIOUS
CONTROL EVALUATION
CHART

Current Quarter Evaluation
- Control Environment
- Monitoring
- Information & Communication
- Risk Assessment
- Sponsored Projects
- Payroll
- Disbursements/Purchasing

Medical School Duluth (May 2015)

Original Report Evaluation
- Control Environ.
- Monitoring
- Info. & Comm.
- Risk Assmt.
- General Controls
- Payroll
- Cash Receipts/A/Rs
- Disbursements
- Sponsored Projects
- Controlled Substances
- IT
- Private Practice

Previous Quarter Evaluation

NO PREVIOUS
CONTROL EVALUATION
CHART

Current Quarter Evaluation
- Control Environ.
- Monitoring
- Info. & Comm.
- Risk Assmt.
- General Controls
- Payroll
- Cash Receipts/A/Rs
- Disbursements
- Sponsored Projects
- Controlled Substances
- IT
- Private Practice
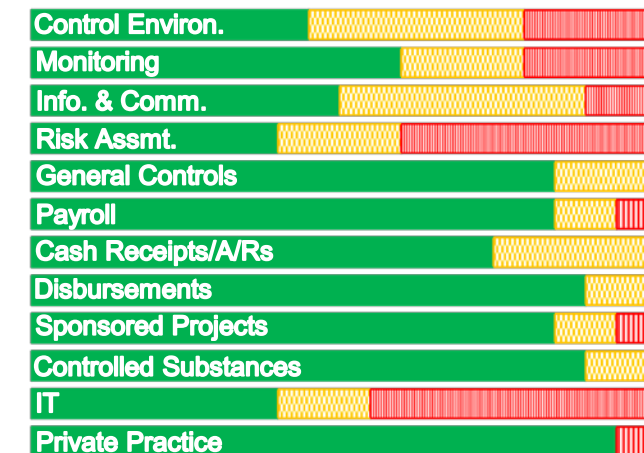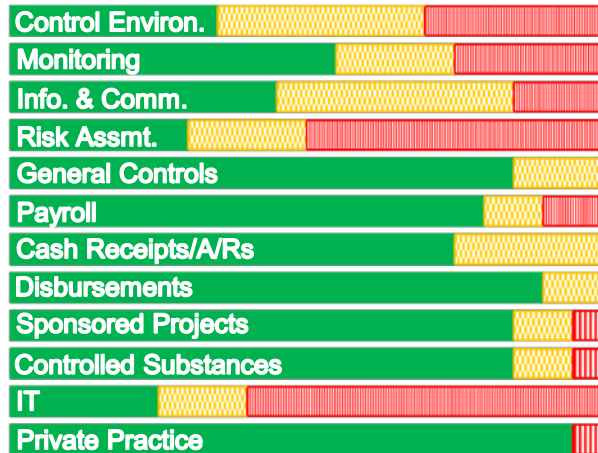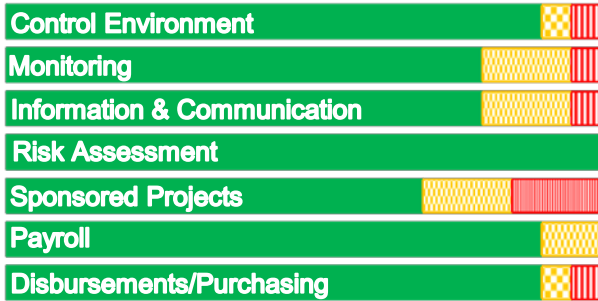
■ Adequate Control   ◻ Significant Control Issue(s)   ▮ Critical Control Issue(s)

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

Original Report Evaluation	Previous Quarter Evaluation	Current Quarter Evaluation

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

Chart categories (all three panels):
- Control Environment
- Monitoring
- Information & Communication
- Risk Assessment
- Oversight & Financial Activity
- Physical Security
- Server & Storage Management
- System Development
- Disaster Recovery Preparation
- Workstation Management

Desirable Control Level   Potential Over-Control

Legend:
- Adequate Control (green)
- Significant Control Level (yellow)
- Critical Control Level (red)
- Potential Over-Control (blue)

A Review of Top University Researchers (December 2014)

Chart categories (all three panels):
- Control Environment
- Monitoring
- Information & Communication
- Risk Assessment
- Regulatory Compliance
- Expense Allowability
- Effort Certification
- Subcontract Monitoring
- Technical & Progress Rpts.
- Conflict of Interest Mgmt.

Legend:
- Adequate Control (green)
- Significant Control Issue(s) (yellow)
- Critical Control Issue(s) (red)
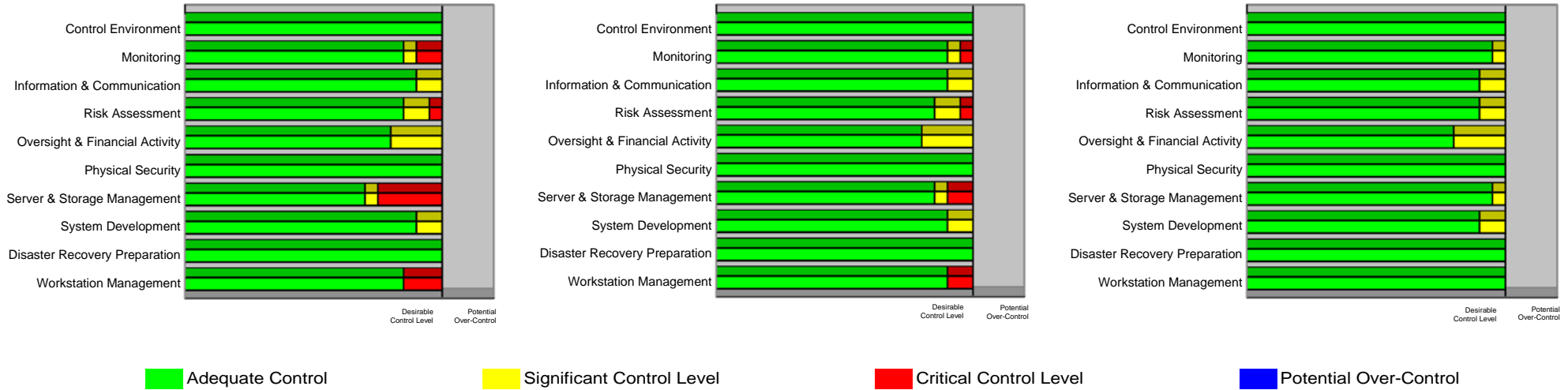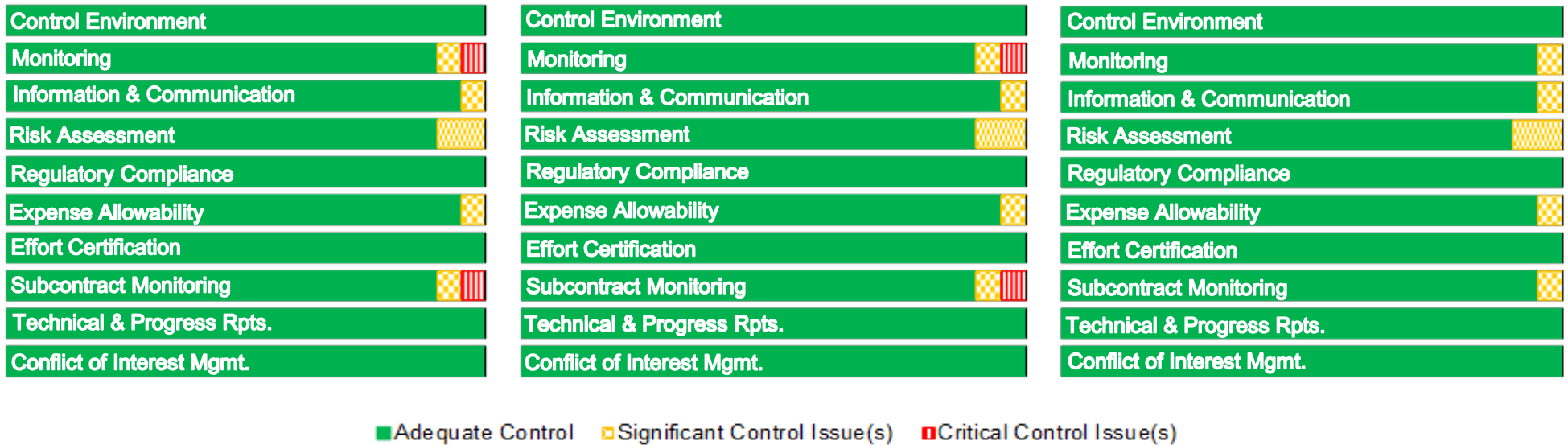
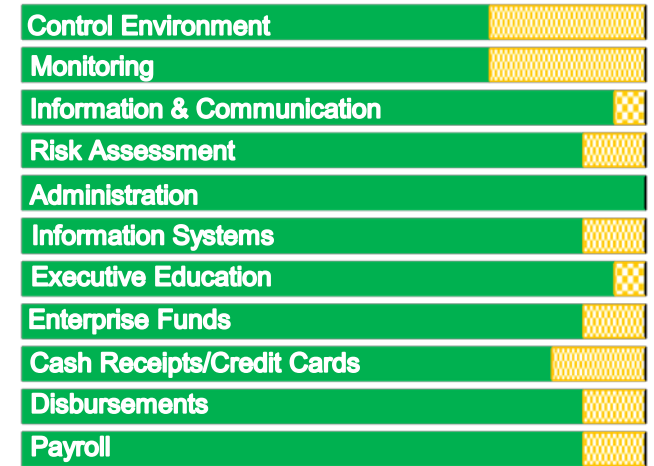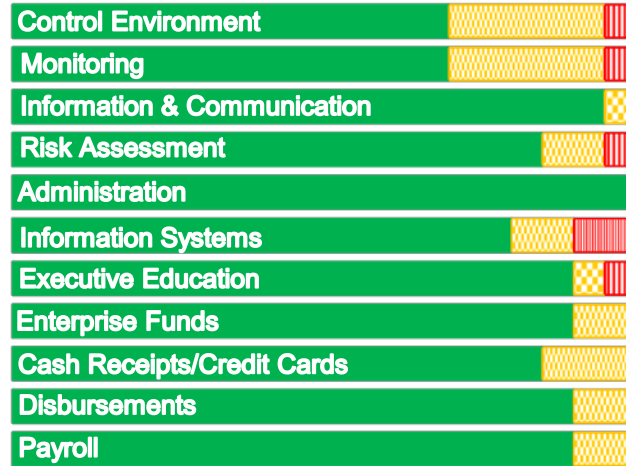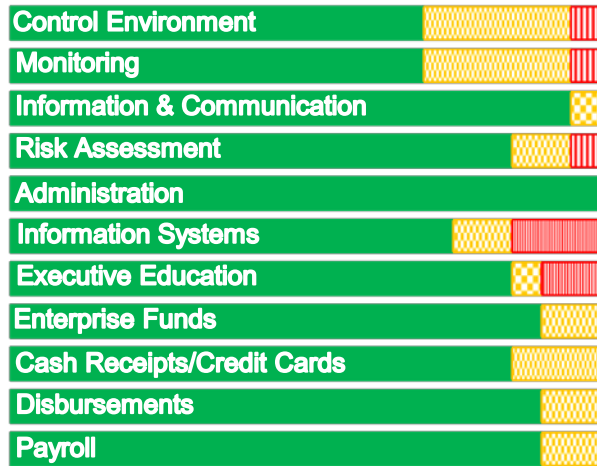| Original Report Evaluation	Previous Quarter Evaluation	Current Quarter Evaluation

Carlson School of Management (December 2014)

Original Report Evaluation	Previous Quarter Evaluation	Current Quarter Evaluation
Control Environment	Control Environment	Control Environment
Monitoring	Monitoring	Monitoring
Information & Communication	Information & Communication	Information & Communication
Risk Assessment	Risk Assessment	Risk Assessment
Administration	Administration	Administration
Information Systems	Information Systems	Information Systems
Executive Education	Executive Education	Executive Education
Enterprise Funds	Enterprise Funds	Enterprise Funds
Cash Receipts/Credit Cards	Cash Receipts/Credit Cards	Cash Receipts/Credit Cards
Disbursements	Disbursements	Disbursements
Payroll	Payroll	Payroll

■ Adequate Control   □ Significant Control Issue(s)   ▯ Critical Control Issue(s)

Audit Activity Report

Scheduled Audits
- Completed an audit of the College of Science and Engineering Dean's Office and related centers. Details are shown on the following chart.
- Issued draft reports for audits of the Clinical Translational Sciences Institute (CTSI), UMD Athletics, and the College of Food, Agricultural and Natural Resource Sciences Dean's Office and related centers.
- Began/continued audits of: 21st Century Development Funds, the College of Pharmacy, the Department of Medicine, Intercollegiate Athletics, UMD College of Education and Human Service Professions (CEHSP), NCAA sport compliance (men's and women's basketball), Boynton Health Service, and the College of Design.
- Continued to perform work on data integrity related to the PeopleSoft upgrade.

Non-Scheduled Audits
- Issued a draft report on an audit of selected University projects funded by state appropriations from the Environment and Natural Resources Trust Fund. This work was requested by the Office of the Legislative Auditor.
- Began a requested audit of UMD tuition waiver processes.

Investigations
- Performed investigative work on five issues in accordance with the University Policy on Reporting and Addressing Concerns of Misconduct.
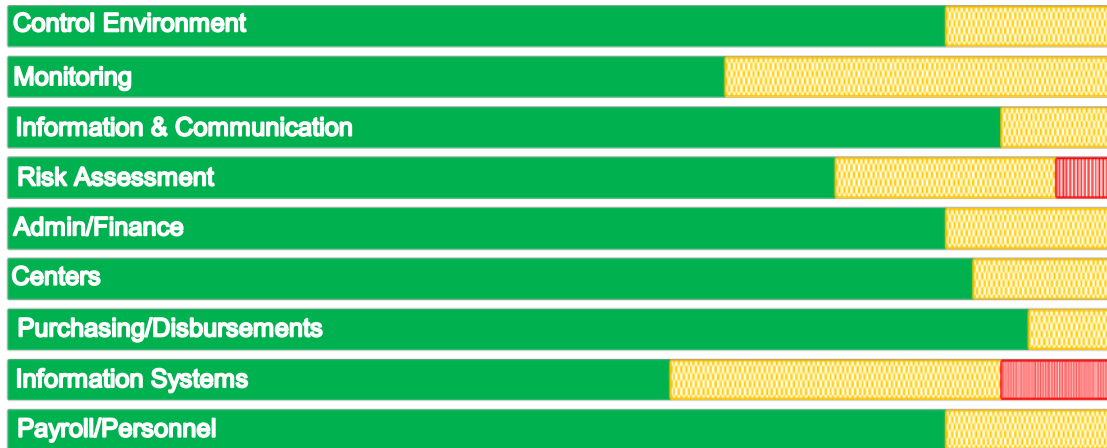
Special Projects
- Provided consulting services related to University payroll exception testing.
- Performed annual institution-wide testing of UMF-funded gift and endowment accounts and reported the results to the University of Minnesota Foundation.
- Provided technology consulting in several areas including the University's IT security framework, HIPAA security, and the University's IT strategic plan.
- At the request of University Services, we coordinated with their units to hire an external consultant to assess current UM policies and procedures used for large energy-based construction projects such as the Combined Heating and Power Plant Project. The consulting firm (Black and Veatch) conducted an on-site review on 8/26-27/15, and their report will be presented to University Services (VP Wheelock).
- At the request of Bookstores management, we reviewed and tested year-end inventory counts at Twin Cities Bookstores locations.
- At the request of the College of Liberal Arts, we reviewed processes related to the awarding of graduate student fellowships funded by gift and endowment accounts.

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 Community of Practice & Advance Leadership Program
  - Use Case Categorization Scheme Committee

Audit Reports Issued Since June 2015

College of Science and Engineering - Dean's Office

Control Environment		
Monitoring		
Information & Communication		
Risk Assessment		
Admin/Finance		
Centers		
Purchasing/Disbursements		
Information Systems		
Payroll/Personnel		

Report #	1601	Issue Date	Aug-15
# of Essential Recs.	1	Total # of Recs.	17
Overall Assessment	Good	Adequacy of MAP	Satisfactory

The CSE Dean's Office and the following centers were included in this audit: Babbage Institute, Characterization Facility, Nanofabrication Center, Technological Leadership Institute, UNITE, IPRIME, Digital Technology Center, Medical Device Center and Collegiate Shops. From the results of the audit work performed, we believe the CSE Dean's Office has developed a control environment and a system of internal controls that addresses most major business and compliance risks. However, some technology management practices need improvement. CSE manages several independent network segments, but does not comply with all University policy requirements for non-centrally managed network segments, including not receiving formal approval from OIT Data Network Services to run these network segments.

■ Adequate Control   ▫ Significant Control Issue(s)   ▮ Critical Control Issue(s)

BOARD OF REGENTS
DOCKET ITEM SUMMARY

Audit & Compliance   **September 10, 2015**

AGENDA ITEM: Consent Report

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

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

PRESENTERS: Regent Laura Brod

PURPOSE & KEY POINTS

The purpose of this item is to seek ratification of an emergency approval to retain independent, external legal counsel and establish an oversight committee.

BACKGROUND INFORMATION

UNIVERSITY OF MINNESOTA

September 3, 2015

Dear Members of the Board:

We write to inform you of an emergency approval that occurred since the last Board of Regents meeting on July 8, 2015. Board of Regents Policy: *Board Operations and Agenda Guidelines* provides for such approvals in Section II, Subd. 10, which reads:

> Upon the recommendation of the president, the Board chair, vice chair, and the respective committee chair may act on behalf of the Board when delay for Board approval poses a significant health, safety, or financial risk to the University. Any such emergency approvals will be brought to the next meeting of the Board, consistent with Board policy.

With our approval, on August 13, 2015 President Kaler asked the General Counsel to retain independent, external legal counsel on behalf of the Board to:

- Review and investigate all allegations of sexual harassment against Teague or other senior leaders in the athletics department received following Teague's resignation.
- Review and investigate as appropriate, any new EthicsPoints complaints regarding sexual harassment in the athletics department.
- Review whether the University knew or should have known of allegations of sexual harassment by Norwood Teague, but failed to address it.
- Review the University's vetting of Teague during his hiring process.
- Assess the University's climate in Intercollegiate Athletics with regard to reporting and addressing of sexual harassment, in partnership with the University's Office for Equal Opportunity and Affirmative Action.

The General Counsel retained Karen G. Shanfield and Joseph T. Dixon from the law firm of Fredrikson & Byron P.A. to complete this work.

We also took action on August 20, 2015 to establish a committee to oversee this review. The charge of the oversight committee is to:
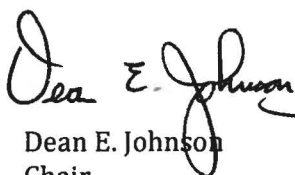
- Provide insight and direction to the external counsel.
- Ensure work is moving forward to fulfill the charge.
- Ensure the counsel has the access to the necessary people and resources.
- Ensure the counsel can conduct its work freely and act independently.

The committee consists of Regent Laura Brod (chair), Regent Abdul Omari, College of Education and Human Development Dean Jean Quam, and General Counsel William Donohue. At the request of the Faculty Consultative Committee, on September 3, 2015 we added Professor Christopher Uggen to the oversight committee. Professor Uggen is a tenured faculty member in the Department of Sociology, College of Liberal Arts, and is an accomplished scholar in the area of sexual harassment.
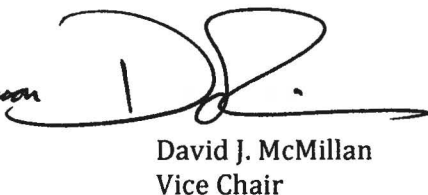
Driven to Discover℠

Traditionally, emergency approvals authorized under Board of Regents Policy: *Board Operations and Agenda Guidelines* are brought to the relevant committee as an information item at the next Board meeting. However, given the importance of this action and the significant public attention it has received, we have asked that it be added to the Audit & Compliance Committee's consent report for ratification.

Thank you for your attention to this request.

Sincerely,

Dean E. Johnson
Chair

David J. McMillan
Vice Chair

Laura M. Brod
Audit & Compliance Committee Chair

c.   President Eric Kaler

BOARD OF REGENTS
DOCKET ITEM SUMMARY

Audit & Compliance   **September 10, 2015**

AGENDA ITEM: Information Items

| | Review | | Review + Action | | Action | X | Discussion |

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

PRESENTERS: Gail Klatt, Associate Vice President, Internal Audit

PURPOSE & KEY POINTS

Tom Roos, the Deloitte & Touche lead client partner assigned to the University of Minnesota, has left the firm to accept a senior executive position with UnitedHealthGroup. Katherine (Katie) Knudtson, another partner at Deloitte & Touche who is currently part of the University of Minnesota engagement team, has been appointed as the lead partner for all University of Minnesota engagements. Knudtson has served on the University engagement for a number of years in several capacities, most recently as partner for the federal and state compliance audits. She has already transitioned into her new role and is actively involved in the planning process. While turnover at the partner level is relatively rare, Knudtson's experience with the University should result in a smooth transition. The University does not expect any impact to the previously reported audit plan, timeline, or deadlines.

A copy of Knudtson's professional biography is included for the committee's information, and she will be present at the September meeting in the event that the committee has questions for her.

Deloitte.

Client Service and Personal Profile

KATIE M. KNUDTSON
AUDIT PARTNER
MINNEAPOLIS
612-397-4184
kknudtson@deloitte.com

Career Highlights

Time Period	Location	Principal Responsibilities
2011 to Present	Minneapolis	Audit Engagement Partner UnitedHealth Group Incorporated (SEC Registrant and Subsidiaries)
2011 to Present	Rapid City, SD	Lead Client Service Partner National American University, Holdings (SEC Registrant)
2011 to Present	Minneapolis	Audit Engagement Partner University of Minnesota
2012 to Present	Minneapolis	Lead Client Service Partner Minnesota Vikings Football, LLC
2013 to Present	Minneapolis	Audit Engagement Partner Federal Reserve Bank of Minneapolis
2011 to Present	Minneapolis	Engagement Quality Reviewer for several clients

Relevant Experience

- Katie has been with Deloitte for more than fourteen years and has spent her career focused on auditing financial statements and internal controls of public and private companies in a variety of industries, including higher education, health care and insurance. She has been a partner in our Audit practice since 2011 and has practiced in our Minneapolis office her entire career.

- Prior to joining the partnership, Katie served as the senior manager for many of the engagements she is now serving as the engagement partner, demonstrating a longstanding history of quality client service.

- Regularly, Katie has works closely with Deloitte's national office and industry leaders on emerging technical accounting and reporting matters in various industries. Katie is recognized by her clients for her strong leadership and clear communication skills. Katie also has significant experience in resolving technical matters.

- For the last four years, Katie has served as the engagement partner for several University of Minnesota attest engagements. During this time, she has demonstrated a collaborative approach serving the University, focusing on a high level of audit quality. Her service demonstrated her effective communication skills throughout all levels of the University, including the Audit Committee.

Education
University of Iowa
Bachelor of Science in Business Administration - Accounting

Professional and Community Activities
Member American Institute of Certified Public Accountants
Member Minnesota Society of Certified Public Accountants
Certifications include: CPA (Minnesota)
Board Member and Finance Committee Member of the Girl Scouts of Minnesota and Wisconsin River Valleys
Member United Way's Women's Leadership Council

Personal
Katie is married and has two children, Will (8) and Chloe (4). Katie enjoys running and spending time with friends and family.