
# Audit & Compliance Committee

## May 2016

May 12, 2016

1:15-2:45 p.m.

West Committee Room, McNamara Alumni Center

# AUD - MAY 2016


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# BOARD OF REGENTS
# DOCKET ITEM SUMMARY

**Audit & Compliance** **May 12, 2016**

**AGENDA ITEM:** Review of External Auditor Relationships and Services Provided

| | | | |
|---|---|---|---|
| ☐ **Review** | ☐ **Review + Action** | ☐ **Action** | ☒ **Discussion** |

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

**PRESENTERS:** Michael Volna, Associate Vice President, Finance & Controller

**PURPOSE & KEY POINTS**

To review audit and non-audit services provided to the University of Minnesota by external audit firms and the related fees paid for those services during FY 2015.

**External Auditor Review**

Total Deloitte & Touche (Deloitte) contracted audit and non-audit fees were $3,320,507 for FY 2015 engagements, with actual fees of $3,123,591 paid to Deloitte. All FY 2015 engagements have been completed and final billed. A summary of management's evaluation of Deloitte's performance for FY 2015 is also provided.

**Summary of Audit and Non-Audit Services and Fees (Schedules A & B)**

Total fees of $3,143,816 have been paid for FY 2015 engagements to four different public accounting firms for a variety of audit and non-audit services. A description of the services is included. All audit and non-audit services were reviewed by the Controller for audit independence, and approved by or reported to the Audit & Compliance Committee as specified in Board of Regents Policy: *Audit Committee Charter*.

**Request for Proposal for External Audit Services**

The FY 2016 annual audit will mark the seventh and final year under the contract for audit services with Deloitte & Touche. The University will begin a Request for Proposal process in the fall of 2016 for audit services, following a process similar to that used for the two previous requests for proposals (FY 2005 and FY 2010). A high-level summary of the process is included.

**BACKGROUND INFORMATION**

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

**UNIVERSITY OF MINNESOTA**
**BOARD OF REGENTS AUDIT & COMPLIANCE COMMITTEE**
**MAY 12, 2016**

# External Auditor Review and Summary of External Auditor Relationships and Services Provided

## Background

The Board of Regents is responsible for engaging and overseeing the University's independent external auditors, for reviewing the work of the auditor, and periodically reviewing the fees paid to the audit firm. Effective governance practice recommends that the Audit & Compliance Committee of the Board should conduct such a review at least annually. The Audit & Compliance Committee conducted its last review of audit services and fees in May 2015.

The Controller's Office presents the information below and on the accompanying schedules for the Audit & Compliance Committee's 2016 review of audit, audit related, and non-audit services fees paid to Deloitte & Touche, LLP (Deloitte), the University's independent external auditor. Also included is management's assessment of Deloitte's performance for the FY 2015 engagements.

## Annual Review of External Auditor Relationship and Performance

University management and the Deloitte engagement management team met on April 4, 2016 to review Deloitte's services and performance during the FY 2015 audit. The overall conclusion was that Deloitte did an excellent job during the FY 2015 audit.

Each year of the Deloitte contract, both the University and Deloitte have identified opportunities for improvement and have implemented those improvements. As a result, both sides felt the audit was efficient and the overall process was well managed by both.

Relative to the strengths of Deloitte and the positive aspects of the audit:

- Management felt that the continuity of key Deloitte team members from the prior years' audits contributed to the efficiency of the audit;
- Deloitte's audit approach was consistent to prior years;
- Many of the prior year's recommendations were incorporated into the audit processes, and as a result, efficiencies were seen by both Deloitte and the University staff
- Deloitte has done an excellent job of managing audit fees and costs. Annual audit fees have been within the contract and budget amounts.

Both the University team and the Deloitte team agree that for FY 2016, we need to continue to focus on the improvements that have been made including:

- Continued focus on streamlining the process to continue improving the efficiency of the audit.
- Suggestions for identifying areas that can be tested earlier in the audit process
- Continue to ensure communications between both teams and all audits are consistent and timely.

**Review of Fees Paid to Deloitte & Touche, LLP**

The accompanying Schedule A presents a summary of fees paid to Deloitte for the various FY 2015 audits and other services. The top portion of the fee schedule represents fees paid for the University's annual institutional audits and other audit-related engagements. The contract amounts reported on the schedule are consistent with the amounts agreed to in the fiscal 2015 engagement letters and the firm's fixed price contracts for FY 2015. The total audit fees paid to Deloitte for FY 2015 were $1,804 less than the contract amounts in total, and represent less than expected actual expenses. These amounts are final.

The lower portion of Schedule A contains a breakdown of fees paid to Deloitte for other services. During the year, Deloitte performed other engagements for specific units or activities at the University during FY 2015 outside of the annual audits and agreed-upon procedures engagements, including the following:

- Deloitte was engaged to perform agreed-upon procedures to assist the University's Student Fees Committee and the Office of Student Affairs in determining the proper record keeping and use of the University fees that are allocated to student organizations. Deloitte reviewed thirty-five organizations that received University fees and performed the agreed-upon procedures as outlined by the University Fees Committee and Office of Student Affairs. The related engagement letter was reviewed by the Controller's Office and signed by the Board of Regents. This engagement did not present an independence issue with regard to Deloitte.

- Deloitte was engaged by the University's Student Fees Committee and the Office of Student Affairs to assist in an investigation of an unreconciled cash shortage in the books and records of the Graduate and Professional Student Assembly student group (GAPSA). The related engagement letter was reviewed by the Controller's Office prior to its finalization, consistent with Board Policy. This engagement did not present an independence issue with regard to Deloitte.

- Deloitte was engaged to perform procedures in connection with the University's Bond Offering documents. The related engagement letter was reviewed by the Controller's Office prior to its finalization, consistent with Board Policy. As this engagement was solely to perform attest procedures in connection with the bond offering, it did not present an independence issue with regard to Deloitte.

- Deloitte was engaged by the University's Health Information Privacy and Compliance Office to provide advisory services to the University to demonstrate the University's compliance with HIPAA Security requirements and advise the University on areas that may require further analysis and investigation. The related

engagement letter was reviewed by the Controller's Office and approved by the Board of Regents. This engagement did not present an independence issue with regard to Deloitte.

- Deloitte was engaged to perform analysis, advice and recommendations related to the University's Enterprise Asset Management project. The related engagement letter was reviewed by the Controller's Office and approved by the Board of Regents. This engagement did not present an independence issue with regard to Deloitte.

**Note on Deloitte engagements since the completion of FY 2015 audit work**

The annual review of fees and services is based on a look-back at services and fees for the prior fiscal year. The Audit & Compliance Committee should note that in early FY 2016 (subsequent to the fiscal year covered by this annual review) Deloitte was awarded a contract in the amount of $1,500,000 for a non-audit engagement involving M Health financial due diligence. That engagement was approved by the Board, but because it is an FY 2016 engagement, it does not appear in the amounts being reported on the accompanying schedule. It will be reported to the Audit & Compliance Committee next year, during the review of FY 2016 audit fees and services. The Audit & Compliance Committee discussed the appropriateness of consulting engagements awarded to our external audit firm at the December, 2014 Audit Committee meeting.

**UNIVERSITY OF MINNESOTA**
**BOARD OF REGENTS AUDIT & COMPLIANCE COMMITTEE**
**MAY 12, 2016**

## Schedule A - Fees Paid To Deloitte & Touche, LLP for FY 2015 Engagements

| | *FY 2015 Engagements* | | | *Total FY 2014* |
|---|---|---|---|---|
| ***Annual Audit and AUP Engagements*** | ***Contract Amount*** | ***Billed Amount*** | ***Over/(Under) Budget*** | ***(prior year)*** |
| University consolidated financial statement audit | $ 396,500 | $ 401,296 | $ 4,796 | $ 365,633 |
| RUMINCO financial statement audit | 23,500 | 23,500 | | 23,000 |
| Compliance audits (OMB A-133 and MOHE) | 118,700 | 112,000 | (6,700) | 113,311 |
| NCAA agreed-upon-procedures | 15,100 | 15,200 | 100 | 15,100 |
| Student Organization agreed-upon procedures | 75,000 | 75,000 | | 77,417 |
| Student group investigation | 32,441 | 32,441 | | |
| Audit of Department of Concerts & Lectures | *N/A* | | | 7,886 |
| Audit of Weisman Art Museum | *N/A* | | | 7,874 |
| Total Fees for Audit & AUP Engagements | **$ 661,241** | **$ 659,437** | **$ (1,804)** | **$ 610,221** |
| ***Other Audit Related and Non-audit Fees*** | | | | |
| Consent procedures related to Bond Offerings | 5,000 | 5,000 | | 8,000 |
| HIPAA Security | 293,000 | 293,000 | | |
| Enterprise Asset Management Analysis | 2,361,266 | 2,166,154 | (195,112) | |
| UMN Position Profile analysis | *N/A* | | | 40,000 |
| Total Other Audit Related and Non-Audit Fees *(1)* | **2,659,266** | **$ 2,464,154** | **$ (195,112)** | **$ 48,000** |
| **Total Fees** | **$ 3,320,507** | **$ 3,123,591** | **$ (196,916)** | **$ 658,221** |

*(1)* In FY 2016, Deloitte was awarded a contract in the amount of $1,500,000 for non-audit "due diligence" engagement related to M Health. As of April, 2016 $1,230,387 had been billed on that engagement. See "Note on Deloitte Engagements Subsequent to FY 2015" on preceding page.

## Section II - Review of Fees Paid to All Other Auditing Firms

In addition to the audits performed by Deloitte & Touche, LLP (the University's independent external auditors), other accounting and auditing firms performed a variety of audit and non-audit services at the University during FY 2015. These services are detailed on Schedule B. The comments below provide a brief recap of those services.

- Bradley P. Mickelson, CPA was engaged by the Tweed Museum of Art to perform a yearly report on the Tweed budgets for FY 2015, to be included in an application for Minnesota State Arts Board Grant funds. This contract was previously reported to the Audit Committee

- CliftonLarsonAllen was engaged by the University to assist with facilitation of the internal processes necessary to effectively reach the Definitive Agreements for the restructuring of the relationship between the University of Minnesota, University of Minnesota Physicians, and Fairview Health Services. This contract was previously reported to the Audit Committee.

- Licari Larsen & Co Ltd was engaged by KUMD, the Duluth campus radio station, to perform attest services in FY 2015 in conjunction with the receipt of federal funds from the Corporation for Public Broadcasting. This contract was previously reported to the Audit Committee.

The Office of the Controller reviewed all of the contracts detailed on the attached schedule, consistent with Board policy. None of these engagements resulted in an impairment of independence, in fact or in appearance, for any of the firms.

**UNIVERSITY OF MINNESOTA**
**BOARD OF REGENTS AUDIT & COMPLIANCE COMMITTEE**
**MAY 12, 2016**

## Schedule B - Report of Fees Paid To Audit Firms for FY 2015 Engagements

| | *FY 2015 Engagements* | | | *FY 2014* |
|---|---|---|---|---|
| ***Audit Firm*** | ***Audit Fees*** | ***Non-Audit Fees*** | ***Total Fees*** | ***Total Fees Paid*** |
| Bradley P. Mickelson, CPA | $ 2,000 | | $ 2,000 | $ 1,900 |
| BWK Rogers, PC | | | | 4,000 |
| CliftonLarsonAllen, LLP | | $ 13,025 | 13,025 | |
| Deloitte & Touche, LLP | 659,437 | 2,464,154 | 3,123,591 | 658,221 |
| Licari Larsen & Co., LTD | | 5,200 | 5,200 | 5,200 |
| McGladrey, LLP | | | | 97,296 |
| PriceWaterhouseCoopers, LLP | | | | 789,386 |
| **Total Fees Paid** | **$ 661,437** | **$ 2,482,379** | **$ 3,143,816** | **$ 1,556,003** |

**UNIVERSITY OF MINNESOTA**
**BOARD OF REGENTS**
**AUDIT & COMPLIANCE COMMITTEE**
**MAY 12, 2016**

## Request for Proposal for External Audit Services

Background

The University's 7-year contract with Deloitte & Touche LLP will end upon the completion of the FY 2016 annual audits. In accordance with University purchasing policy the University must utilize a Request for Proposals (RFP) to secure audit services to select a successor firm. Deloitte & Touche is not prohibited from bidding on the next contract.

Selection Process

The Administration is recommending a competitive selection process of about three to four months in duration. Staff from the Controller's Office will develop and issue the RFP, and act as the overall coordinator for the process. Initial screenings of proposals and evaluation of oral presentations will be done by a committee consisting of senior University staff from departments that have significant involvement and interaction with the auditors, due to their system-wide responsibilities.

Board Involvement

As with the prior RFP in 2010, we propose that the Audit & Compliance Committee chair be provided an opportunity to review the responses and rankings of the firms, and confirming the screening committee's recommendation. We would also propose that the Audit & Compliance Committee chair be afforded the option to interview the firm that is recommended for appointment on behalf of the Committee.

Considerations

There are several key aspects of this process that we would like to highlight for the Audit & Compliance Committee:

- We recommend a contract of 4 years, with 3 additional "option" years. This typically provides the winning bidder with sufficient time to learn the University and optimize their performance, without locking the University into an unduly long contract.
- The selection criteria become the basis for the decision to hire a firm. It is important that the Audit & Compliance Committee be comfortable with the selection criteria proposed for inclusion in the RFP.
- The Request for Proposal will be sent to all of the "Big 4" firms, as well as to prominent national and regional firms that may have the expertise and interest in being considered for the University audit. In 2010,
- Timeline - We propose to initiate the process during the fall of 2016. The selection process will be completed by December. The final approval will be sought from the Board at the February, 2017 Board meeting. This will provide ample time for the winning firm to transition smoothly for the June 30, 2017 audit.

# BOARD OF REGENTS
# DOCKET ITEM SUMMARY

**Audit & Compliance** **May 12, 2016**

**AGENDA ITEM:** External Audit Plan

| | | | |
|---|---|---|---|
| ☐ **Review** | ☐ **Review + Action** | ☐ **Action** | ☒ **Discussion** |

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

**PRESENTERS:** Michael Volna, Associate Vice President
Katherine Knudtson, Partner, Deloitte & Touche
Judi Dockendorf, Senior Manager, Deloitte & Touche

**PURPOSE & KEY POINTS**

The external audit plan sets forth the audit scope, objectives, and approach to be used by Deloitte & Touche (Deloitte) for conducting the University's FY 2016 financial and compliance audits. Members from the Deloitte engagement team will provide an overview of the audit plan, including the firm's assessment of audit risks, testing approach, and timelines for the FY 2016 audits.

**BACKGROUND INFORMATION**

This report assists the Audit & Compliance Committee with its audit oversight responsibilities, and is prepared and presented annually in conformity with Board of Regents Policy: *Audit Committee Charter* and Board of Regents Policy: *Board Operations and Agenda Guidelines*.

Deloitte.

# The University of Minnesota

## 2016 Audit service plan

Deloitte.

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May 12, 2016

The Board of Regents Audit and Compliance Committee
University of Minnesota
1300 South Second Street
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Dear Members of the Board of Regents:

We are pleased to present Deloitte & Touche LLP's fiscal 2016 audit service plan for the University of Minnesota (the "University"). First and foremost, we value our role as your external auditor. We understand our responsibility to you as the Board of Regent's chosen representative of the University, and we have developed an audit plan that is specific and candid. This audit plan reflects our commitment to providing you with high-quality, proactive service that is delivered with integrity, objectivity, and independence.

Our audit addresses financial statement and internal control risks through targeted procedures that are responsive to the nature of the risks, including changes in the University, the business environment, and the regulatory landscape. Our procedures include identifying and analyzing issues and facts relevant to our audit conclusions and providing objective challenges to management's judgments and assumptions.

In this document, we describe our plan to serve you, the protocols for communication with the Audit and Compliance Committee of the Board of Regents (the "Audit and Compliance Committee") and management, and other permissible services we provide for the University.

Our organization is dedicated to bringing a high level of quality and service to the audit of the University. We commit to proactively addressing your needs; delivering the right team; and providing understanding, perspective, and industry insights. In addition, in response to your needs and the changing environment in which we operate, Deloitte is investing in transforming the audit through innovation by leveraging new technologies, utilizing big-data analytics, and improving the audit delivery process.

We appreciate the opportunity to serve the University. We hope the accompanying information will be useful to you, and we look forward to answering your questions about our plan.

Please contact Katie Knudtson, lead client service partner, at +1 612 397 4183 if we can be of assistance in any way.

Yours truly,

cc: Management of the University of Minnesota

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# Executive summary

We are pleased to present an overview of our plan to serve the University. We have prepared this document to assist the Audit and Compliance Committee in fulfilling its role in overseeing the financial reporting and disclosure process and the performance of the external auditor.

First and foremost, we value our role as your external auditor. The foundation of our relationship is based on this important role and responsibility to you, as the board of directors' chosen representatives of the University. Our primary responsibility is to plan and perform the audit of the University's consolidated financial statements to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects and whether the consolidated financial statements are free of material misstatements. It is our professional responsibility to challenge significant management assumptions and estimates and to employ an appropriate level of professional skepticism to evaluate them, including related audit evidential matter. We also perform certain permissible services that further develop our understanding of your business; we can leverage this understanding to improve our audit procedures.

**Our reputation is based on:**

**Doing the right thing**

- A high degree of integrity
- Our ability to recognize and act in accordance with our professional responsibilities
- A commitment to objectivity and independence

**Technical excellence**

- Ongoing training in technical matters for all professionals
- Intensive case-based programs for audit partners and managers each year
- A consultative approach to resolving accounting, internal control, auditing, and reporting issues
- Assessment of the quality of our performance against our objectives, service goals, and client service standards
- Dedication to employing the best and serving the best
- Effective systems for monitoring independence

**A robust audit approach**

Below are the key elements that demonstrate our commitment to quality:

- Strong tone at the top
- Comprehensive ethics and compliance programs
- Communication of professional standards and client service standards
- Multifaceted approach to monitoring independence
- Strong industry qualifications
- Robust technical consultation
- National office consultation
- Appropriate technical training for our professionals
- Annual internal and external inspections
- Continuous improvement

## The Deloitte Audit

As your external auditor, we are responsible for gaining a thorough understanding of the applicable auditing standards and for executing our audit in accordance with those standards; thus, the Deloitte Audit is based on auditing standards generally accepted in the United States of America. A critical facet of our audit approach is the risk assessment process. We design the audit to identify and address significant audit risks so that we can conclude whether the consolidated financial statements present fairly, in all material respects, the financial position and the results of operations and cash flows of the University. Our audit approach is designed to continuously respond to the challenges and risks the University is facing on a real-time basis. Responding to University-specific, industry, and economic conditions, we continually align our efforts to the scope and scale of the University's operations to perform an audit in the most efficient and effective risk-based manner.

Designing our audit plan begins with a reassessment of risk areas from our fiscal 2015 audit. Updating our risk assessment is an iterative process performed throughout the audit, and includes consideration of changes in your business objectives and structure, management's risk assessment results, results of procedures related to internal control over financial reporting, and the current state of the industry and the economy.

As a result of this process, we have identified the areas of significant risk for our fiscal 2016 audit. Our professional judgment is central to the application of due care and professional skepticism in these areas of significant risk.

## Engagement team

Our engagement team is led by Katie Knudtson, lead client service partner. Katie is responsible for all services provided to the University and will be supported by a team that includes Scott Erickson, advisory partner, and Chris Terhark, engagement quality control review partner.

## Significant risk areas

Based on our risk-based audit approach and the updated fiscal 2016 risk assessment discussed above, the following preliminary areas of significant risk have been identified:

- **Alternative investments valuation**
- **Management override of controls**

See the Risk Assessment section for further discussion of identified risks of material misstatement and related audit responses.

# Committed to quality

We take our responsibilities to investors and the capital markets seriously, and we are dedicated to building confidence in the independent audit process. The intent of our quality report, **Audit Quality: Our Responsibility, Our Commitment**, is to provide investors, audit committees, regulators, and other market participants with information that will help them understand our commitment to audit quality. The report includes, among other things, information about the steps we have taken in recent years to transform our audit practice, our improved inspection results, actions we are taking to innovate and further strengthen the quality of our audits, and our perspectives on current audit reform proposals.

We hold ourselves to very high standards, and take pride in the important public interest role entrusted to us. To continuously raise the bar on audit quality, we have made substantial, comprehensive investments in our audit practice. Through a combination of these investments, the diligence and dedication of our partners and professionals, and constructive engagement with our regulators, we have made significant, sustained progress toward the achievement of our audit quality objectives. We now have objective evidence that the significant audit quality investments we have made are achieving desired outcomes.

Our commitment to audit quality encompasses the entire range of organizational motivations and behaviors: how we define our role and excellence in auditing; the mindset and mission of the auditor; and the specific capabilities, tools, methods, and standards we apply in conducting audits and managing our practice.

**PCAOB Inspection Reports:** The PCAOB released Part 1 of its 2014 inspection report on May 12, 2015. In May 2016, the PCAOB determined that the remedial actions D&T took in response to Part II of the 2013 report addressed the quality control observations to the satisfaction of the PCAOB, which closes the 2013 inspection cycle and follows similar favorable determinations for the 2012 and 2011 inspection cycles.

**D&T Peer Review:** In 2014, Grant Thorton LLP (GT) completed the most-recent triennial peer review of D&T's system of quality control for our accounting and audit practice applicable to engagements not subject to PCAOB inspection for the year ended March 31, 2014. GT issued a report with a peer review of rating of "pass". A peer review report with a rating of "pass" means that D&T's system of quality control for the accounting and auditing practice applicable to engagements not subject to PCAOB inspection has been suitably designed and complied with to provide D&T with reasonable assurance of performing and reporting in conformity with applicable professional standards in all material respects.

**Audit quality remains our number one priority. As we look forward, we will continue institutionalizing the audit process enhancements we have made throughout our system of quality control to ensure they endure.**

# Engagement team

The engagement team assembled to serve the University represents individuals who have been specifically chosen to meet your expectations and needs. We strive to provide continuity along with a balance of fresh perspective so we can offer high-quality, competent audit and professional personnel who will provide services with quality and distinction.

## Engagement team leadership

Our engagement team is led by Katie Knudtson, lead client service partner. Katie is responsible for all services provided to the University and is in her second year as the lead client service partner for the University. Katie will ensure Deloitte provides a high quality audit, is consistently focused on client service, and communicates in a direct and transparent manner. We encourage you to call on Katie for any needs that arise throughout the year.

Scott Erickson, advisory partner, will work closely with Katie and will serve as a resource to management, the Audit and Compliance Committee, and our team. Annually, Scott will meet with the Chair of the Audit and Compliance Committee as well as members of management. In addition to providing advice, insights, and perspectives based on his extensive experience, Scott will provide access to other specialists and industry leaders.

Chris Terhark, your engagement quality review partner, will be responsible for evaluating and concurring with the significant judgments made by our team and the overall conclusion of the audit, as well as acting as Katie's primary consultation resource. When a matter requires review at a higher level, Katie will work with Deb DeHaas, national office liaison partner for the University. Deb will expedite the resolution of matters that require consultation with our national office, providing immediate access to experienced technical specialists.

## Use of specialists

We recognize the importance of sharing our accounting, reporting, and industry knowledge and experience, and we will provide an enhanced level of skill for the specialized risks and industry issues affecting the University. The Deloitte Audit is distinguished by the use of a broad range of industry and functional specialists who are integral to the audit team and carry a deeper understanding of specific topics. These specialists augment the core audit engagement team in understanding business processes and related risks, and help the audit engagement team apply an appropriate level of professional skepticism to challenge significant management assumptions.

For the University's fiscal 2016 audit, we will use specialist resources to assist in performing our audit procedures for:

- Assessing the design and implementation of information technology and security controls
- Auditing income tax exemption
- Auditing estimates that involve actuarial calculations, such as the pension liability
- Auditing fair value of alternative investments

- Analyzing journal entries to address management override of controls

Our specialists have been actively involved in the planning and risk assessment process, and will be available to the audit team and the University's management year-round to discuss ongoing risk assessment, accounting and financial reporting issues, industry developments, and other matters of interest. These specialists will regularly update management on technical accounting, industry, and other matters that affect the University to minimize surprises and provide timely information to improve your understanding and ability to respond when new standards are issued or accounting developments occur.

See Our Client Service Team Section for more information on the University's engagement team.

# Scope of services

Our responsibility under generally accepted auditing standards will be described to you in our engagement letter. As described in that letter, the objective of a financial statement audit conducted in accordance with generally accepted auditing standards and the standards applicable to financial audits contained in *Government Auditing Standards*, issued by the Comptroller General of the United States, is to express an opinion on the fairness of the presentation of the University's consolidated financial statements for the year ending June 30, 2016, in conformity with accounting principles generally accepted in the United States of America, in all material respects. We consider the University's internal control over financial reporting (ICFR) as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the University's ICFR. Accordingly, we will not express an opinion on the effectiveness of the University's ICFR.

We will also issue certain other reports as described below:

## Reports on financial statement audits

- University of Minnesota Consolidated Financial Statements
- RUMINCO, Ltd (performed by Deloitte Bermuda)

## Compliance reports

- Federal Award Programs (Office of Management and Budget Uniform Grant Guidance)
  - Schedule of Expenditures of Federal Awards
  - Report on Internal Control and Compliance Related to Financial Reporting
  - Report on Internal Control and Compliance Related to Major Programs
- Examination of Management's Assertion of the University's Compliance with the Minnesota Office of Higher Education Audit Guide

## Agreed-upon procedures

- National Collegiate Athletic Association (NCAA) Agreed-Upon Procedures
- Office of Student Affairs and Fees Committee Agreed-Upon Procedures for student groups

Should you require additional attest and compliance-related services, we will work closely with the University to scope such services appropriately.

In addition to our independent auditors' reports, we will report significant deficiencies and material weaknesses identified in internal controls and issue a management letter when opportunities for improvements or efficiencies come to our attention during the audits and a letter to the Audit and Compliance Committee and management summarizing the results of our audits.

# The Deloitte audit approach

Our responsibility to you is the foundation of our role as the University's external auditor. As your external auditor, we recognize that you operate in an environment that demands our objectivity, skepticism, responsiveness, and deep technical skills. A critical facet of our audit approach is the risk assessment. We design the audit to identify and address risks and obtain reasonable assurance regarding whether effective internal control over financial reporting was maintained and whether the consolidated financial statements are free of material misstatement.

Our audit approach is partner-led, focused, interactive, and dynamic, and follows four major steps:

- Assess and respond to engagement risk.
- Select the engagement team.
- Establish terms of the engagement.
- Enhance our understanding of the company's business and environment.
- Enhance our understanding of internal controls and the accounting processes.
  - Entity-level controls.
  - Process-level controls.
- Determine planning materiality.


- Assess risk at the financial statement level and relevant assertion level.
- Prepare and communicate the audit plan.

- Perform the financial statement review.
- Perform subsequent events review.
- Obtain management representations.
- Prepare audit summary memorandum.
- Report.

- Perform tests and evaluate
  - Entity-level controls.
  - Process-level controls.
- Evaluate control deficiencies.
- Perform substantive tests and evaluate results .

Our risk-based approach drives the way we audit, from financial statement line items and disclosures through the internal controls and substantive procedures we perform. Professional standards and our policies require an audit response for each material account and relevant assertion. Performing our risk identification at this level helps us pinpoint risk and develop a well-tailored, integrated response for both significant and normal risk areas.

This means that even at a detailed level, we audit more efficiently by putting more time into the most important areas. Our audit involves using the right resources at the right time to tailor our response to the risks of material misstatement that have been identified.

| The Deloitte audit difference | |
|---|---|
| **Partner and manager involvement in risk assessment and the identification of the underlying risk of material misstatement for significant account balances and disclosures** | **Improved design of control and substantive tests:**<br>• Tailored procedures for the University<br>• Direct linkage between identified risks of material misstatement, controls that respond those risks, and substantive testing<br>• Focus on risks of material misstatement and the elimination of testing that offers little additional audit assurance<br>• A risk-based sampling methodology that enables us to perform appropriate audit procedures<br>• On-the-job training, enhancing our professionals' ability to make well-reasoned professional judgments |

## In applying our audit approach for the University, we will:

- Conduct a partner-led planning process that enhances risk identification and assessment and promotes an appropriate response in controls testing and substantive procedures
- Empower our people to apply professional judgment and an appropriate level of skepticism in evaluating management's significant assumptions, based on a thorough understanding of your business strategies, operations, structure, risks, internal control environment, and accounting policies, paired with an awareness of related industry and economic events
- Leverage our investments in technology to deliver the level of effort needed to address the related risk through the scalability and flexibility of our audit tools and ease of access to comprehensive accounting and financial disclosure literature
- Use the knowledge of your business we have gained through the audit to improve our risk identification and tailored procedures and provide business process and industry insights.

We recognize that the quality of our audit depends on providing a robust challenge to management's significant assumptions, coupled with unambiguous and direct communication. That does not mean the process needs to be cumbersome or tedious. We will focus our service approach on what matters most by providing timelines and involving senior members of our leadership team, including having Katie develop and approve the audit scope and attend meetings with management to discuss key matters.

## Our plan of action includes:

- Avoiding surprises
- Responding to your questions promptly
- Identifying and communicating key issues in a timely manner
- Working with you directly to manage deadlines
- Providing our broader views and perspectives on the University's operations and internal controls, not just in the areas of accounting and financial reporting, but also in the University's operations and other activities as identified during our audit.

The results of our audit procedures will be analyzed, with conclusions drawn based on applicable professional standards. Before rendering our reports, we will conclude whether the scope of the audit was sufficient to support our opinions; the misstatements identified, if any, have caused the consolidated financial statements to be materially misstated; and the control deficiencies identified, if any, represent material weaknesses that would result in the conclusion that ICFR is ineffective.

## Deloitte audit planning process


Accumulated knowledge about your business is the foundation for our audit planning process.

Our top-down risk assessment begins with the financial statements to determine material account balances and disclosures.

Using assertions, we organize and refine the focus of our audit procedures.

All relevant assertions for material account balances and disclosures are addressed in our audit plan.

Our knowledge and understanding of your business allows us to pinpoint risks. We assess each risk and determine whether it is a significant risk or a normal risk.

We develop tailored responses to significant risks and normal risks.

- We consider the effectiveness of the responses and align the budget with risks.
- Using our most current understanding, we reconsider our approach at the end of each audit cycle.

The Deloitte audit includes our year-round involvement, the use of specialists, and a focus on continuous communication with management and the Audit and Compliance Committee throughout the audit process. The fundamentals of our audit approach are rooted in professional standards, but what differentiates our audit practice is the depth of perspective and professional judgment we bring in tailoring our audits to each client's business and risks. We listen carefully to what our clients and the accounting profession indicate are important criteria for enhancing audit quality, and we continuously improve our approach with this understanding to increase the effectiveness of our procedures and achieve an efficient audit process. With this approach, we maximize audit quality while appropriately controlling your audit costs.

Our focus on continuous improvement and our commitment to professional standards come together in the careful planning and knowledgeable execution that characterize the audit. In applying our audit approach and methodology for the University audit, we will:

- Conduct a partner-led planning process that enhances risk identification and assessment and promotes an appropriate response in controls testing and substantive procedures
- Leverage our investments in technology to increase productivity through the scalability and flexibility of our audit tools and ease of access to comprehensive accounting and financial disclosure literature
- Deliver additional value-added services by using the knowledge we gain from the audit to provide business process and industry insights and identify specialist resources who can help address your areas of interest.

**Year-round involvement**—Our audit approach reflects our commitment to providing timely service. This approach includes:

- The constant availability of partners, specialists, and staff
- Meetings with key members of management and the Internal Audit function
- Analysis and auditing of large or complex transactions timely as completed

**Partner-led audit planning and execution**—The Deloitte culture emphasizes the role of our partners in the execution of our services. Experience tells us that an audit plan developed at the direction of engagement leaders yields an audit that has clarity of purpose and is tailored to the University's business. Katie will guide the upfront planning and execution of the audit, using her deep understanding of your organization, your industry, and the professional literature to drive quality throughout the process. She will be assisted by experienced partners and senior managers as needed.

In the current year, we will leverage our experienced personnel at the senior management level in an effort to drive internal development throughout the entire engagement team. Katie will guide the engagement team in identifying risks of material misstatement by considering what could go wrong in significant account balances and disclosures. She will be involved in the detailed audit execution, including assessing which procedures are most responsive to the identified risks, the level of testing required, and the timing of the testing. Katie will continuously challenge the procedures performed to deliver an effective audit.

Under the leadership of Katie, our audit team will anticipate issues, address potential barriers to appropriate financial reporting, and help minimize surprises in the audit—all of which will bring significant value to the University. When issues are identified and warrant discussion with the Audit and Compliance Committee and management, Katie will provide prompt communication of significant developments and findings.

**Open communication**—We are committed to anticipating issues and avoiding surprises. One aspect of our professional responsibility is to bring issues to the attention of management and the Audit and Compliance Committee. We will consult with management and the Audit and Compliance Committee openly and candidly.

## Plan the audit

We plan our audit to parallel the financial reporting and organizational structure of the University based on our understanding of your business. Our planning emphasizes the continuous identification of business, control, and financial risks. Our audit approach is tailored to focus on those risks and is flexible enough to allow for adjustments as risks are identified or modified.

The audit plan allows for constructive, timely feedback to management regarding matters warranting attention, including significant deficiencies or material weaknesses. The majority of our audit procedures are performed throughout the year and updated at year-end.

In developing the audit plan, we plan tests to obtain evidence regarding the design and implementation of relevant controls, and we plan substantive auditing procedures to test for the material misstatement of significant account balances and disclosures. Our procedures focus our attention on risk areas. When necessary, we will devote special attention to areas of interest identified by the Audit and Compliance Committee or management.

## Responding to the changing risk environment

Although our audit plan generally involves a sequential process from planning to perform to concluding, the stages in this process are flexible and adaptable. For example, once the plan has been developed and is being executed, we may become aware of new risks that were unknown during the planning process and require a change in audit scope. Based on new information, we will reassess previous planning activities and adjust the audit plan accordingly. These adjustments will be communicated to management through our weekly audit status updates as well as at Audit and Compliance Committee meetings in May, December, and February, unless other timing is warranted.

## A laser focus on your most significant risks

Our approach is distinguished by a refined view of risk that pinpoints what could go wrong to cause a material misstatement for significant account balances and disclosures. Applying this lens to the University's audit, we will spend time on the areas that matter most and limit testing in areas that provide little or no additional audit assurance. In short, we will perform appropriate, but not excessive, audit procedures. We will develop our audit plan for the University at the financial statement level and relevant assertion level for accounts and disclosures, and craft an audit plan that targets the risks of material misstatement in each area.

| Benefits of pinpointing risk |
| --- |
| Professional standards and our policies require an audit response for each material account and relevant assertion. Performing our risk identification at this level helps us pinpoint risk and develop a well-tailored, integrated response for both significant and normal risk areas. |
| **Our service**<br>• Helps us identify opportunities for the University's management to consider refining its assessment of risks and related controls<br>• Provides insights on industry matters, business issues, and risks that may affect the University<br>**Quality**<br>• Focuses our specialists by identifying and addressing areas of significant risk<br>• Facilitates the identification of more effective audit methods<br>**Efficiency**<br>• Creates a targeted response for significant risk areas and normal risk areas, aligning audit effort with risk |

## Customized procedures

We customize the nature, timing, and extent of the control and substantive procedures we perform by matching the level of risk identified for each material account or disclosure to the relevant assertions. The decisions in these areas are matters of professional judgment. In this regard, Deloitte's depth of resources, understanding of professional standards, and risk-based audit approach come together in an audit that is specifically tailored for the University.

The Risk Assessment sections includes our preliminary detailed risk assessment and our responses to these risks. As we perform our audit procedures, we will update our risk assessment and inform the Audit and Compliance Committee and management of any significant changes.

## Execute the audit plan

The performance of the audit plan includes evaluating the design and implementation of controls and performing substantive audit procedures.

## Testing design and implementation of controls and evaluating deficiencies

An integral part of our audit approach is the consideration of the control environment, which encompasses both manual and automated controls. Our consideration of controls is based predominantly on an analysis of the key business cycles that constitute management's financial accounting and reporting process.

We consider the University's internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the University's internal control over financial reporting. Accordingly, we will not express an opinion on the effectiveness of the University's internal control over financial reporting. Our consideration of internal control over financial reporting

would not necessarily identify all deficiencies in ICFR that might be significant deficiencies or material weaknesses.

## Substantive audit procedures

Our substantive audit procedures consist of a tailored combination of analytical procedures and detailed tests of transactions and balances; these procedures are designed to obtain reasonable assurance that the consolidated financial statements are free from material misstatement. We apply a professional level of skepticism to the evidential matter provided by management to support their assertions in the consolidated financial statements. To obtain this assurance, we accumulate factual and estimated misstatements that were identified while performing substantive auditing procedures and consider those misstatements in relation to the consolidated financial statements as a whole. Misstatements above a certain threshold will be reported to the Audit and Compliance Committee and management.

## Fraud-related procedures

There is continued emphasis on the auditor's responsibility to detect material misstatements resulting from fraud. Our audit procedures related to fraud include evaluating the design and implementation of management's processes for identifying and responding to the risk of material misstatement resulting from fraud, and the programs and controls that management has established to mitigate that risk. In addition, we perform the following audit procedures to address fraud risks:

- Identify unusual trends in account balances and ratios
- Perform tests of journal entries exhibiting possible characteristics of management override of controls, identified using electronic data interrogation techniques
- Evaluate the University's fraud risk assessment and internal controls to mitigate the risks identified
- Consider the potential for bias in judgments and estimates, including performing retrospective analysis
- Evaluate the business rationale for significant unusual transactions
- Engage in periodic fraud discussions with certain members of senior management and others, including the Audit and Compliance Committee
- Evaluate identified audit adjustments (recorded and passed) for potential fraud
- Consider the impact of the results on financial statement and internal control opinions

## Evaluating management override and antifraud programs and controls

Professional standards require us to plan and perform an audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether caused by error or fraud. Our audit procedures include discussing the risk of fraud with various parties to obtain an understanding of fraud risk and the company's programs to prevent fraud. Our inquiries will encompass members of the Audit and Compliance Committee; executives such as the President, chief financial officer, and general counsel; and individuals in the controller's organization and the internal audit function. In addition to these inquiries, we obtain a database of journal entries for all transactions throughout the year and perform various analyses to detect those entries that have characteristics that indicate a greater likelihood of fraud. We test a selection of these journal entries to determine if there is sufficient evidence to support the entry and assess that there is an absence of management override or fraud. Finally, throughout our audit procedures, we challenge management's assumptions and estimates and apply an

appropriate level of professional skepticism in evaluating evidential matter supporting and opposing management's assertions.

## Evaluate financial statement presentation and disclosures

Among the final steps of our audit is the overall evaluation and assessment of the consolidated financial statements' presentation and the related disclosures. Our overall review and evaluation consists of analytical procedures and consideration as to whether the consolidated financial statements are consistent with our knowledge of the University's business, our understanding of individual balances and relationships, and the evidence accumulated throughout our audit. In addition, we review the appropriateness and adequacy of the disclosures required by generally accepted accounting principles.

## Perform subsequent-events review and obtain management representations

Our subsequent-events review will cover the period from June 30, 2016, through the date of our report on the consolidated financial statements. This review is performed to identify any significant matters that would require adjustment of year-end amounts or disclosure in consolidated financial statements.

The consolidated financial statements are the responsibility of management. We obtain written acknowledgment from management of its responsibility for the preparation of consolidated financial statements that are free from material misstatement, whether due to fraud or error. We ask management to affirm its belief that the effects of any uncorrected misstatements are immaterial, both individually and in the aggregate, to the consolidated financial statements taken as a whole. In addition, we request that management confirm certain specific representations that comprise or supplement our audit support in significant areas or with respect to matters for which there may be limited audit evidence available (e.g., a matter affected by management intent and judgment). The final, signed management representation letter will be provided to the Audit and Compliance Committee prior to report issuance.

## Continuous communication and coordination

In the course of the audit issues will be reported to Katie for discussion with the University's management.

Our coordination plan features:

- Onsite supervision of fieldwork by our international partners
- Regular status meetings conducted by Katie throughout the year
- Meetings with your professionals in areas other than finance to continue to build our understanding of your business and further develop our audit procedures.

Our team will coordinate with your financial personnel to make effective use of their time, keep you informed of progress, and provide findings and feedback in a timely manner. We also will provide any insights related to improvements in internal controls and operational efficiencies for management to consider. As your auditor, we will challenge significant financial assumptions, and when questions arise about accounting positions or procedures, Katie will be proactive and candid in discussing these concerns with you. That is our responsibility, and we are committed to fulfilling it.

## Timely consultation on technical matters

We understand that the technical interpretation of accounting matters is frequently necessary and that these questions can range from mundane to difficult. We will discuss the issues with you to evaluate your positions in real time, rather than waiting until the end of the reporting period to judge them.

Katie is responsible for the resolution of all technical matters, has deep experience in dealing with technical matters and has often worked with Deloitte's National Office. Because issue resolution is an art, not a science, deciding which issues require additional consultation is a key part of Katie's role. When a complex technical matter arises, Katie will immediately engage management to understand its views and engage its team as needed, and will keep management informed until the matter is resolved. The Audit and Compliance Committee and management will have full access to those involved in the resolution process, and are welcome to participate in related discussions. We recognize that management owns the consolidated financial statements and we are auditing them. Katie and other team members will seek to clearly understand management's perspective on the facts and judgments underlying each issue with an unbiased and professionally skeptical mind.

Every step of the way, we will help you understand how we are making decisions, provide you with direct access to our specialists, and talk through issues with you. Although the final decision on all matters rests with Katie, she will have timely access to Deloitte's most knowledgeable specialists on those occasions when she believes she would benefit from the experience of others.

We have also assigned a senior technical partner to our team to help evaluate issues of importance to the University. Chris Terhark, your engagement quality review partner, will be responsible for evaluating and concurring with the significant judgments made by our team and overall conclusion of the audit, as well as acting as Katie's primary consultation resource.

The goal of our consultation approach is to reach the right answer—one that will stand up to scrutiny.

## Using technology to increase effectiveness and consistency

To promote audit effectiveness and consistent service, Deloitte uses a uniform audit approach with common documentation standards and enabling software in the audits of financial statements. These tools help us increase audit effectiveness; collaborate with the University personnel more effectively; and execute our audit in a high-quality, reliable, consistent manner. Deloitte invests heavily in technology development and enhancement to meet the changing needs of our engagement teams. We are committed to being the leader in global audit technology.

## Consideration of the University's use of information technology

The University's use of information technology to serve customers, maintain compliance with regulatory requirements, and support day-to-day operations is pervasive. General information technology controls continue to be a major element in the control environment of the University, and our information technology specialists will be involved in assessing the design and implementation of general information technology and automated controls. In addition, these specialists will continue to meet with management to understand planned changes in the IT environment and to assess and test changes as they occur, as deemed appropriate.

## Technology tools for the University audit

The tools described in the accompanying table help us determine audit scope, prepare consistent audit workpapers and files, conduct analytical procedures, select data for testing, accumulate audit results, and monitor progress to provide for the timely completion of tasks. In addition, we intend to make full use of the University's own technologies to gain further efficiencies.

We are keenly aware of the importance of scaling our audit to the University's size and complexity. To do this, Deloitte uses a package of proprietary audit tools, which are discussed later in this section. These tools can be tailored to the specific attributes of companies and the unique accounting and auditing requirements of the University's industry. We will leverage our proprietary tools and programs to tailor our audit plan for your company.

| Technology | Description | Benefits |
|---|---|---|
| **Engagement Management System** | Deloitte's automated workpaper system, incorporating audit-specific templates, reference materials, support documents, and management insights | Rapid and effective electronic transfer of information among audit team members, and real-time progress and status updates on audit results and findings |
| **Deloitte Optix** | Next generation application that applies analytical techniques to client's datasets to identify transactions with characteristics of audit interest. | Leverages data analytical techniques to uncover unusual trends, patterns, and anomalies in large data sets. Helps audit teams focus more effectively on high-risk areas for fraud in journal entry testing analysis; reduces the time necessary to perform profiling and allows for testing that could not have been conducted manually |
| **Deloitte Audit Plus** | An integrated suite of tools, applications, knowledge, content, and industry information that empowers our auditors to respond to the University's unique environment and circumstances | Facilitates easier sharing of knowledge; integrates tools, content, and other resources; connects Deloitte people with specialists around the world; delivers enhanced research and search capabilities; and provides content that is scalable to the University engagement |
| **Audit Command Language (ACL)** | Market-leading technology for data inquiry, analysis, and reporting | Allows unconstrained analysis of your data files |
| **Control Audit Tool (CAT)** | A proprietary, real-time, web-based tool that will be tailored specifically for the University engagement to assist in managing the scope, performance, and documentation of our ICFR procedures | Creates significant efficiencies in the deployment, review, reporting, and overall conclusion on ICFR at the corporate level; CAT is workflow-enabled, which allows for timely communication and the resolution of issues with local management and provides us with continuous visibility regarding the status of our ICFR testing and issue resolution |

| Technology | Description | Benefits |
|---|---|---|
| **Deloitte Technical Library** | A comprehensive online compilation of accounting and financial disclosure literature that allows Deloitte and the University to research specific accounting issues and functions through access to authoritative literature from pertinent regulatory bodies, as well as our interpretations and guidance; this subscription service, which is unique to Deloitte, provides a natural mechanism for integrating our positions into the University's research on accounting matters and helps achieve a high degree of synergy between our organizations | Contains extensive accounting and reporting guidance; supports the quick and efficient research of complex accounting matters by allowing the University access to our accounting information |
| **Deloitte OnLine** | A secure web-based portal that provides a clear view into audit status | Provides a secure workspace to coordinate and share information and utilizes dashboards that provide real-time tracking of information requests, and online logs that provide transparency into audit issues and findings and can facilitate timely resolution |

## Conclude and report

The results of the audit procedures performed throughout fiscal 2016 will be analyzed and conclusions will be drawn based on generally accepted auditing standards. Before rendering our reports, we will conclude whether the scope of the audit was sufficient to support our opinions; the misstatements identified, if any, have caused the consolidated financial statements to be materially misstated; and the control deficiencies identified, if any, represent material weaknesses.

To obtain this assurance, we accumulate factual and estimated misstatements, if any, that were identified while performing our procedures and consider such misstatements in relation to the consolidated financial statements as a whole. Material misstatements that are identified by us and uncorrected misstatements identified by us or the University will be reported to the Audit and Compliance Committee and management.

## Fostering year-round audit quality

The Deloitte audit is an iterative process that responds to changes in the University's business and other developments that have an impact on the scope of our audit. Serving you with distinction means understanding and evaluating the financial reporting implications of events as they happen, identifying emerging risks or trends promptly, pinpointing issues before they become problems, and communicating regularly with the Audit and Compliance Committee and management.

Soon after completing the year-end audit, Katie will lead a planning meeting using knowledge gained during the audit of the University's business, plans, risks, governance, management, internal controls, and performance. We will use this information to tailor our audit plan for the following year and respond to your changing circumstances.

# Risk assessment

Risk assessment is a critical facet of our audit approach and scoping process. We identify risks of material misstatement associated with the University, material account balances and disclosures, assertions, and related controls. We design all phases of the audit to identify and address risks associated with the University and to enable us to respond to the business, regulatory, and economic environment in which the University operates.

In developing our audit plan for each material account balance or disclosure, we consider:

- What could go wrong to cause a material misstatement of the consolidated financial statements
- Control activities that management has identified, documented, and tested
- The nature and extent of substantive testing needed.

For each risk of material misstatement we identify, we perform substantive procedures to address that risk. Our audit approach is grounded in our understanding of your business accumulated from our experience. We begin by gaining a comprehensive perspective on your operations and business objectives, as well as material financial statement accounts and disclosures.

We also consider the knowledge we gained from previous audits, walkthroughs of the University's business processes, inquiries with management, our reviews of your integrated business plan, management's risk management processes, and the risk assessment performed by the internal audit function. We brainstorm, discuss, and evaluate the inherent risks. By performing the analysis in this manner, we focus our testing on material risks of misstatement and the controls that mitigate those risks.

When we speak about risk, we don't mean errors are occurring. Rather, we identify significant areas in the financial reporting process where judgment, complexity, or infrequency of occurrence gives rise to a higher likelihood of misstatements.

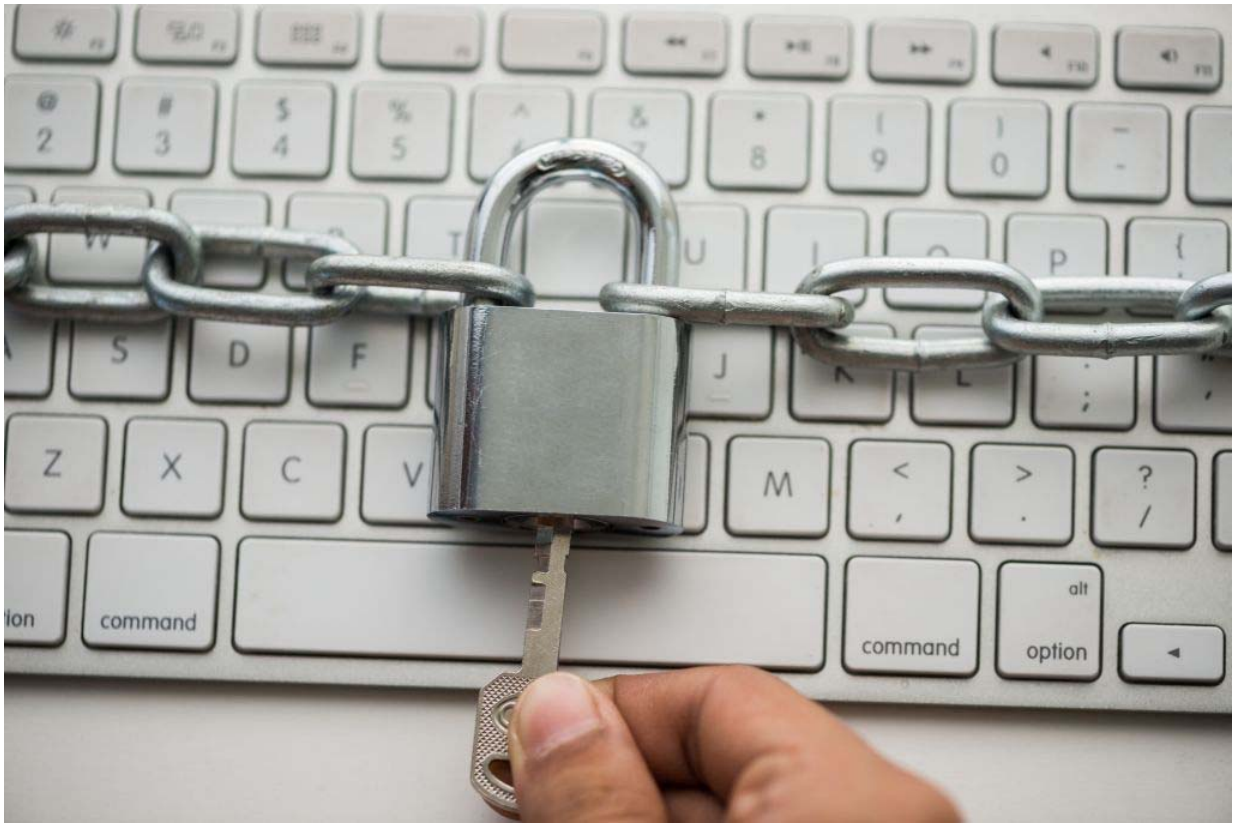
The initial risk assessment will be revisited throughout the audit process. Our monitoring activities are performed in conjunction with our interim review procedures and in our frequent interactions with management. Our team will respond to changes in our risk assessment and implement appropriate audit procedures to respond to the change in risk, as necessary. In addition, our team will address non routine transactions throughout the year. We will inform the Audit and Compliance Committee and management of significant changes to our risk assessment or audit scope as we perform our work.

## Areas of audit focus for 2016

During our risk assessment procedures, we preliminarily identified areas of audit focus and significant risks of material misstatement to the consolidated financial statements, including fraud risks, as documented below, and have provided a high-level summary of our planned responses in those areas, including both internal control and substantive financial statement procedures. In performing our risk assessment, we have considered the risks identified by management and the internal auditors in performing their risk assessment. We will also consider any internal control deficiencies identified during the course of our audit procedures and revise our plan accordingly. Adjustments to our plan may include additional substantive audit testing procedures and may result in the identification of additional significant risk areas. We will deploy more experienced team members to perform audit work for these areas and will separately communicate any significant changes to the planned audit strategy or significant risks during the course of our audit and the reasons for such changes, as necessary.

| Audit focus areas | Description | Planned audit response |
|---|---|---|
| **Cash and cash equivalents**<br><br>**Investments (significant risk)** | • Fair value of investments, particularly those that are not readily marketable<br>• Illiquidity in cash accounts, specifically money market accounts | • Evaluate management's methodology and process for valuing alternative investments<br>• Test the design and implementation of controls surrounding alternative investments<br>• Review support for the valuation of alternative investments for potential impairment<br>• Confirm alternative investment balances with the fund manager and the record-keeper<br>• Obtain and examine the underlying agreements related to alternative investments<br>• Obtain and review the most recent audited financial statements for the alternative investments<br>• Perform substantive analytical detail procedures to test the fair value measurements from the date of the most recent audited financial statements to June 30, 2016<br>• Obtain and review the most recent unaudited financial statements for the alternative investments<br>• Consult with Deloitte professionals with specialized knowledge of auditing alternative investments in designing our audit plan and reviewing the results of our audit<br>• Perform audit procedures surrounding the disclosures included in the consolidated financial statements |
| **Long-term debt** | • Default by counterparties on SWAP agreements<br>• Existence of debt covenant violations | • Obtain an understanding of all SWAP agreements<br>• Review management's analysis and conclusion on accounting for SWAP agreements<br>• Assess the financial condition of the SWAP counterparties<br>• Confirm long-term debt<br>• Assess compliance with debt covenants |
| **Student, tuition and fees — net**<br>**Federal grants and contracts**<br>**Auxiliary enterprises — net** | • Risk of overstatement of student tuition and fees, and other revenues (through premature revenue recognition or recording fictitious revenues)<br>• Risk of understatement of student tuition and fees or other revenues (due to improperly shifting revenues to later periods) | • Review student tuition and fees and other revenue recognition accounting policies and procedures through walk-throughs of revenue cycles during internal control testing<br>• Audit student tuition and fees and other revenues recorded through substantive analytical reviews and/or dual purpose detail testing in conjunction with federal grant compliance work<br>• Reconciliation between federal grant and contracts revenue and our audit of the schedule of federal expenditures |

| Audit focus areas | Description | Planned audit response |
|---|---|---|
| **Management override of controls**<br>**(significant risk)** | • Inherent significant risk under professional standards | • Test the appropriateness of journal entries recorded in the general ledger and other adjustments made in the preparation of consolidated financial statements<br>• Obtain an understanding of the business rationale of significant unusual transactions we become aware of that are outside of the normal course of business for the entity, or that otherwise appear to be unusual given our understanding of the entity and its environment<br>• Test areas of critical management judgment and estimates<br>• Hold discussions regarding the risk of fraud and management override with members of management and the Audit and Compliance Committee |
| **Information management and communication** | • Accuracy of all information generated or stored in the University's financial information systems | • Perform internal control testing around the University's ability to accumulate accurate and reliable information for various departments throughout the University<br>• Assess the system implementation, including that all information was appropriately transferred to the system |



# Our client service team

## Consolidated financial statement audit

**Katie Knudtson**—Lead client service partner
**Scott Erickson**—Advisory partner
**Chris Terhark**—Engagement quality control review director
**Maureen Berggren**—Enterprise Risk Services principal
**Judi Dockendorf**—Audit senior manager
**Matt Jacobson**—Audit manager

## Compliance audits (A-133 single audit and OHE examination)

**Katie Knudtson**—Audit partner
**Chris Terhark**—Engagement quality control review director
**Judi Dockendorf**—Audit senior manager

## Agreed-upon procedures

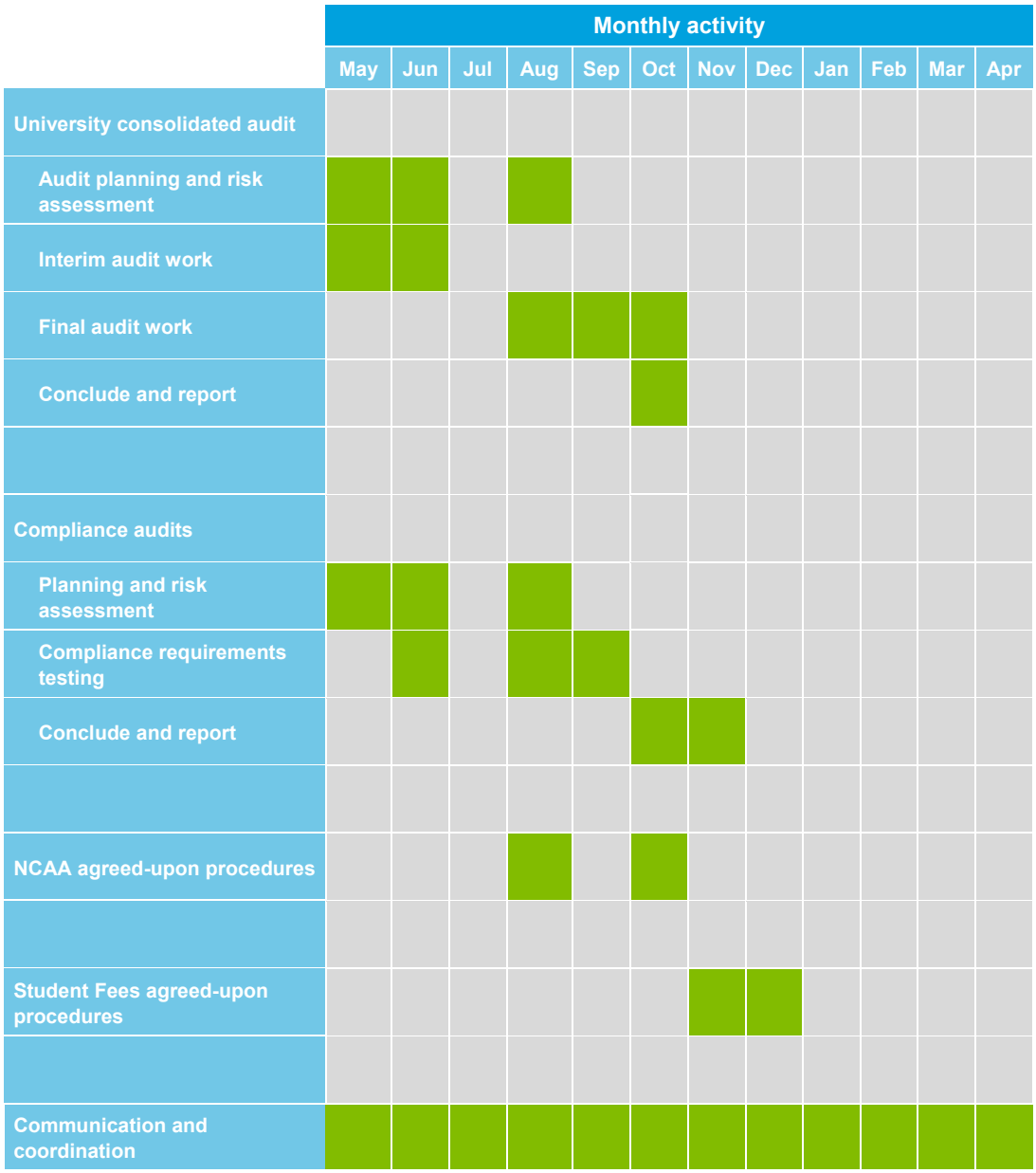
**Katie Knudtson**—Audit partner
**Chris Terhark**—Engagement quality control review director
**Judi Dockendorf**—Audit senior manager

## RUMINCO Ltd

**Muhammad Khan**—Audit partner
**Chris Steele**—Audit manager

# Audit timeline

The performance of audit procedures, in accordance with generally accepted auditing standards (GAAS) and consistent with this audit plan, will be based on the anticipated timing outlined below.



# Recent accounting and industry matters

## Recent GASB Accounting Standards

**GASB Statement No. 72**, *Fair Value Measurement and Application* – effective for **FY2016**

The statement requires a government to use valuation techniques that are appropriate under the circumstances and for which sufficient data are available to measure fair value. The techniques should be consistent with one or more of the following approaches: the market approach, the cost approach, or the income approach. The statement also establishes a hierarchy of inputs to valuation techniques used to measure fair value, which has 3 levels. Further, the statement requires additional analysis of the fair value if the volume or level of activity of an asset or liability has significantly decreased.

**GASB Statement No. 73**, *Accounting and Financial Reporting for Pensions and Related Assets that are not within the Scope of GASB Statement No. 68, and Amendments to Certain Provisions of GASB Statements 67 and 68* – effective for **FY2016 and FY2017**

Establishes requirements for defined benefit pensions that are not within the scope of GASB No. 68, as well as for the assets accumulated for purposes of providing those pensions. In addition, it establishes requirements for defined contribution pensions that are not within the scope of GASB No. 68. It also amends certain provisions or GASB No. 67 and GASB No. 68 for pension plans and pensions that are within their respective scopes.

**GASB Statement No. 75**, *Accounting and Financial Reporting for Postemployment Benefits Other than Pensions* – effective for **FY2018**

This statement establishes new accounting and financial reporting requirements for governments whose employees are provided with other postemployment benefits, as well as for certain nonemployer governments that have a legal obligation to provide financial support for other postemployment benefits provided to employees of other entities.

**GASB Statement No. 82**, *Pension Issues – an Amendment of GASB Statements No. 67, No. 68, and No. 73* – effective for **FY2017**

This statement addresses certain issues that have been raised related to GASB No. 67, GASB No. 68, and GASB No. 73, specifically issues regarding (1) the presentation of payroll-related measures in required supplementary information, (2) the selection of assumptions and the treatment of deviations from the guidance in an Actuarial Standard of Practice for financial reporting purposes, and (3) the classification of payments made by employers to satisfy employee contribution requirements.

## Recent GASB project updates [1]

### Lease Accounting—Reexamination of NCGA Statement 5 and GASB Statement 13

The objective of this project is to reexamine issues associated with lease accounting, considering improvements to existing guidance. This project will provide a basis for the Board to consider whether operating leases meet the definitions of assets or liabilities. Current guidance is provided by National Council on Governmental Accounting (NCGA) Statement 5, Accounting and Financial Reporting Principles for Lease Agreements of State and Local Governments, GASB Statement No. 13, Accounting for Operating Leases with Scheduled Rent Increases, GASB Statement No. 62, Codification of Accounting and Financial Reporting Guidance Contained in Pre-November 30, 1989 FASB and AICPA Pronouncements, and GASB Statement No. 65, Items Previously Reported as Assets and Liabilities. Statement 62 incorporates the provisions of FASB Statement No. 13, Accounting for Leases, as amended and interpreted, into the GASB's authoritative literature. The GASB issued an exposure draft in January 2016 and anticipates issuing final guidance in December 2016.

### 2013 Uniform Grant Guidance

The Office of Management and Budget's *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards* (Uniform Grant Guidance) was implemented in December 2014. The Uniform Grant Guidance supercedes requirements from OMB Circulars A-21, A-87, A-89, A-102, A-110, A-122 and A-133 and is applicable for the University for FY2016.

[1] Information obtained from the Governmental Accounting Standards Board's website at GASB.org.

# Independence

Independence encompasses integrity, professional skepticism, intellectual honesty, and objectivity—freedom from conflicts of interest. No entity or circumstance is compelling enough for us to compromise our ability to serve the public interest or our reputation.

**We employ a comprehensive, multifaceted approach to maintaining independence. Key components include:**

- The commitment of our leaders and a culture that stresses the importance of independence
- Consultation and monitoring processes
- Clearly communicated, comprehensive independence policies and guidance on areas including, but not limited to, personal financial interests, scope of services, business relationships, employment matters, and partner rotation
- A chief ethics and compliance officer who makes presentations regarding compliance to the chief executive officer and the board of directors
- Mandatory training for all partners, principals, and professionals
- A searchable global database of restricted entities, including information about the corporate entity tree and affiliates
- A system to facilitate the electronic tracking of personal financial holdings, including a program designed to enable holdings in brokerage accounts to be automatically imported and updated in the system
- At least annual representations from partners, principals, and employees
- An internal inspection and audit process to evaluate personal compliance with independence policies
- An internal inspection process for compliance with preapproval and scope-of-services policies
- A disciplinary process for noncompliance
- Policies to document the preapproval of any permissible services by the Audit and Compliance Committee, among other matters that might bear on independence
- Regular communications regarding independence matters
- Resources available to answer any independence-related questions.

# Center for Corporate Governance

Expectations for good governance continue to increase as the focus on corporate risk, integrity in financial reporting, and regulatory compliance intensifies. Deloitte's **Center for Corporate Governance** is a resource to assist executives, boards of directors, and the governance community in fulfilling their fiduciary responsibilities. The center focuses on providing thought leadership and activities, including those described in the following section, which provide audit committee members with insights on relevant corporate governance issues. We would be happy to discuss your needs or any additional resources we can provide.

## Deloitte's Center for Corporate Governance encourages dialogue and knowledge-sharing and provides thought leadership on governance issues to advance collaboration among corporations, board members, the accounting profession, academia, investors, and regulatory bodies.

**The Center for Corporate Governance** website includes the latest corporate governance thought leadership by Deloitte professionals and leading third-party organizations. Many of our complimentary publications are housed on the website, including:

- **Audit Committee Brief**—This monthly publication provides recommendations and overviews on corporate governance, regulatory and legislative topics, and technical updates affecting audit committees.
- **Audit Committee Resource Guide**—This overview of audit committee regulatory requirements covers common practices and specific steps for audit committees to consider. It also provides relevant tools and resources, such as an audit committee calendar of activities to help with planning and a financial literacy assessment tool.

### Governance thought leadership and resources

Research and thought leadership by the Center for Corporate Governance focus on issues relevant to boards of directors and governance leaders. The **Deloitte Digest—Board of Directors** is a monthly Deloitte communication, that consolidates board-related content into a single, succinct email.

The center also focuses on developing and maintaining strong relationships with third-party organizations and public policy groups. Collaborations include conference sponsorships, contributing authorships, and peer exchange roundtables.

Deloitte's Governance & Risk Dbriefs webcasts feature Deloitte leaders and guest presenters who provide information on timely governance issues and trends.

### Directors' Series I: Continuing the Dialogue

These board-level, invitation-only programs feature prominent guest speakers who represent the CEO, board member, investor, and regulator perspectives, as well as Deloitte subject matter resources. Speakers discuss a wide range of relevant business and corporate governance topics. Interactive simulcasts and live roundtables are offered in select locations across the United States and provide a unique educational opportunity for board members to engage in discussions with peers and Deloitte leaders on emerging governance matters.

### Board and audit committee education programs

Our permissible and customized board development education programs cover topics such as the role of the board, setting the strategic agenda, talent management and succession planning, executive compensation, risk oversight, ethics and compliance, regulatory updates, the economic outlook, cyber risk, FCPA and anti-money laundering, and board composition, to name a few. We offer education sessions specific to the audit committee, including audit committee leading practices, risk oversight, interaction with internal audit, anti-fraud programs and controls, enterprise compliance, the tax landscape, technical accounting activity, mergers and acquisitions, and valuation.

# BOARD OF REGENTS
# DOCKET ITEM SUMMARY

**Audit & Compliance** **May 12, 2016**

**AGENDA ITEM:** Update on Implementation of Human Participant Research Protection Plan

| | | | |
|---|---|---|---|
| ☐ **Review** | ☐ **Review + Action** | ☐ **Action** | ☒ **Discussion** |

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

**PRESENTERS:** Brian Herman, Vice President for Research

**PURPOSE & KEY POINTS**

The purpose of this item is to discuss progress made on the Board Resolution related to Human Research Protection Program work plan implementation. Topics presented at this meeting have occurred since the implementation received Board approval in June 2015.

In general the implementation work remains on schedule and a more detailed analysis of progress against the original external review panel recommendations has been completed. Work areas remain engaged with key stakeholders, and consult their work broadly to ensure engagement and adoption of the changes.

Recently in March, University Leadership provided updates on the Advancing Human Research Protections implementation work to both the Senate Higher Education Committee and the House Higher Education Committee. Both sessions were productive discussions that highlighted both progress and continued need to make changes, communicate transparently, and rebuild trust with the community. One outcome of the Senate hearing is a new Advancing HRP implementation organizational chart to help clarify the new processes and accountability lines and is available on the Advancing HRP website.

Highlights of significant progress includes:

**Department of Psychiatry**

- Psychiatry Leadership transition – New department head, Dr. Sophia Vinogradov, starts July 31, 2016, though is already engaging with the University community.
- Department faculty have adopted new policies: requiring Good Clinical Practice (GCP) standards for all studies, implementation of a new checklist to ensure better collaboration with clinical staff, and a requirement that a treating clinician of a potential study participant cannot be involved in consent for a research study.

- The department endorsed Clinical and Translational Science Institute (CTSI) management of all clinical trials and began that transition.
- A full-time CTSI research project manager, already embedded in Psychiatry, is working with investigators on all aspects of design and execution of clinical trials.
- New accountability standards require that any problems identified with studies and not quickly corrected by the Principal Investigator are reported to the department head and then, if still not corrected, to the Vice President for Health Sciences/Dean of the Medical School and Vice President for Research.
- The department continues to work with the Center on Bioethics on recruitment and other ethical issues.

**Internal Review Board (IRB)**

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

**New Oversight Structure**

- Research Compliance Office (RCO) – Now has responsibility for conducting for-cause investigations to ensure separation from the IRB.
- Fairview University Research Oversight Committee (FUROC) – This committee is composed of leaders of the University and Fairview Health Services to ensure better communication about and oversight of research in Fairview facilities and involving Fairview patients and staff. The committee is co-chaired by the University's Vice President for Health Sciences/Dean of the Medical School and Fairview's Chief Medical Officer.
- Community Oversight Board (COB) – The COB was created to allow for greater community input into research involving human participants at the University on ethics, community engagement, policies, communication and dissemination of research finding. The board is chaired by Paul Mattessich of Wilder Research and has a diverse membership representing health care providers, patient advocates, the University, and the non-profit community.
- External Advisor – External advisor Dr. David Strauss continues reviewing progress with each of our work teams and spent time on campus in March consulting and discussing work accomplished to-date.

**Education and Training**

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

**Culture**

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

More detail is available in the progress summary, included in the docket.

**BACKGROUND INFORMATION**

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

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

The Team was chaired by Dr. William Tremaine, Professor of Medicine, Mayo Clinic and Director, Mayo Clinic IRB. During the time of the Team's work, two additional reports were made available: 1) a May 5, 2015 draft report from the Office of the Legislative Auditor, which presented findings from all industry-sponsored studies at the University from 2004-2014; and 2) *Final IRB Investigation Report Into Fairview Concerns Regarding Psychiatry Research Studies at the University of Minnesota*, referred to as the "Oakes report." Team members considered the information from these reports in their recommendations. Report #2 above is publically available on the Advancing Human Subjects Research website.

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

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

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

Key components of the report were:

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

The Team received over 60 comments to the draft report. The comments reflected concerns about undue burden and the proposed policy change regarding Conflict of Interest; suggestions for community engagement; concerns about changes to scientific review; and questions about the applicability to the Social and Behavioral IRB. The final report reflects those submissions.

At its June 2015 meeting, the Board reviewed and discussed the final work plan's key recommendations and passed a resolution endorsing the final work plan. The Board also stated it would take an active role in providing ongoing oversight and monitoring of these activities by receiving regular progress reports through its Audit Committee at each of the committee's meetings until the work plan has been fully implemented. Those progress reports are online at the Advancing HRP website.

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

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

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

Continued monthly reporting to the Legislature included updates about:

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

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

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

**AdvanceHRP Implementation**
**http://research.umn.edu/advancehrp/index.html**
**Progress Summary & Recommendations Alignment Table (vApril2016)**

| Work Plan Section | Lead(s) | Percent Complete* | Work Scope (Responsible Officer) | External Review Panel Recommendation | Completed Deliverables (Progress Reporting to BOR and Legislature including date reported) |
|---|---|---|---|---|---|
| IRB Membership | Billings, Biros | **80%** | Recruit membership, form new committees. Set compensation structure & policy **(VPs Herman and Jackson)** | - Implement guidelines regarding IRB meeting attendance in order to ensure that a larger, more critical mass of members are present at each meeting.<br>- 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.<br>- 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. (page 27) | **Final Report Submitted and Posted on Website**<br>-September 2015 Developed four medical IRB rosters that more closely align expertise with submission type.<br>-September 2015 Proposed a minimum IRB meeting attendance requirement of 65%. Each medical roster will have 13 members including at least one non-scientific member. A majority must be present for each review.<br>-January 2016 Further developed a compensation plan that conforms to federal guidance and incorporates the recommendations of the implementation team.<br>-New and existing IRB members received confirmation notices the last week of February and the HRPP anticipates the rosters for the four medical panels will be complete and new members will begin training in the next few weeks.<br>-Orientation meetings for all IRB members will begin in April 2016. New members meeting scientific reviewer qualifications will be engaged in scientific review beginning in April.<br>-March 2016 The HRPP office conducted outreach activities with community organizations, such as a Parent Advisory Board, the National Alliance for Mental Illness (NAMI), and the Ombudsman for Mental Health and Developmental Disorders for recruiting members of the community. Significant progress was made on committee membership mapping and panel definition during March. Remaining expertise gaps will be filled during April.<br>-April 2016 Unanticipated challenges have been identified during preliminary implementation of the work plan recommendations related to IRB membership. In collaboration with experts from Huron Consulting Group, an alternative plan that meets the spirit of recommendations as noted in the work plan is currently underway. The HRPP office continues to monitor IRB membership and engage other groups, including the Community Oversight Board, to assist with recruiting a more diverse member base reflective of the community of research participants. |
| FUROC | Herman | **100%** | Establish committee | -Fairview staff should be involved in protocol review, in gatekeeping | -August 2015 Fairview University Research Oversight Committee (FUROC) |

| Work Plan Section | Lead(s) | Percent Complete* | Work Scope (Responsible Officer) | External Review Panel Recommendation | Completed Deliverables (Progress Reporting to BOR and Legislature including date reported) |
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| | | | **(VP Herman)**<br><br>Committee leadership **(VP Jackson and Thomas/Fairview CMO)** | functions, and in research monitoring. (page 84) | chairs charged and membership finalized. First meeting September 2015.<br>-February 2016 FUROC reconstituted to include Beth Thomas, DO, Chief Medical Officer of Fairview, and Debra Cathcart, Chief Nursing Executive for M Health. At February's meeting the group agreed to meet bimonthly and focused on communication with the OVPR/IRB and increased collaboration between clinical and research staff as priorities. Between meetings a small group agreed to develop possible policies and practices to discuss further.<br>The next meeting is scheduled for April 2016. |
| For Cause Investigations | Webb | **90%** | Establish Research Compliance Office **(VP Herman)** | N/A | **September 2015 Final Report Submitted and Posted on Website**<br>Research Compliance Office (RCO) structure and operations became effective 10/2/15.<br>The Research Compliance Office now has responsibility for conducting *For-Cause Investigations* (see below) |
| | Waldemar | **90%** | Transition For Cause Investigations **(VP Herman)** | - 3.2.8 Reconsider the reliance on IRB membership to staff ICs [investigative committees] 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.<br>- 3.2.9 More rigorously make use of other internal resources (such as the PAR Monitoring Program discussed in section 3.3.3) and external resources to supplement the work of the ICs.<br>- 3.2.10 Evaluate the mechanisms through which IC findings and any corrective action required are disseminated, particularly with regard to follow-through with complainants. (page 34) | **September 2015 Final Report Submitted and Posted on Website**<br>Deliverables related to plans 3.2.8 and 3.2.9 have been completed.<br>Some deliverables related to 3.2.10 remain to be completed and they involve the revision of procedures about the actual investigation and the processes for dissemination of findings and management of any related corrective action requirements. The revised policy and procedures are in process. |
| Community Oversight Board | Herman | **100%** | Establish board structure and finalize membership **(VP Herman)** | N/A | October 2015 Appointed Paul Mattessich as chair of the newly established Community Oversight Board. Membership has been invited, accepted and first meeting held.<br>-The COB had its inaugural meeting on February 8. The first meeting included |

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| | | | | | background information and discussion with Vice President Herman, a dialogue with the chair, Paul Mattessich, on how to begin creating a process to address the COB's charge, and an initial discussion on the composition of the board. The COB plans to meet quarterly and the next meeting will be scheduled for May 2016.<br>-March 2016 The COB met with Dr. David Strauss. |
| External Advisor | Herman | **100%** | Hire external advisor: external review panel member<br>**(VP Herman)** | N/A | -August 2015 Engaged Dr. David Strauss, member of the external review panel, to work with the University on implementation rollout.<br>-External advisor Dr. David Strauss has reviewed and provided feedback on the following implementation work products: For cause investigations, the Research Compliance Office, updates to the IRB review process, changes to scientific review, Compass Point Research review and the consultant report on the Department of Psychiatry.<br>-Dr. David Strauss, was on campus March 30 and 31 to review progress with each of our work areas. Dr. Strauss also met with faculty and University senior leaders. We expect a report from him summarizing his visit. Dr. Strauss will continue his engagement with the University through June and will provide a final report. |
| Scientific Review of Studies | Billings, Biros | **100%** | Change policy-eliminate dept. review, define HRPP process<br>**(VP Herman)** | - 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. (page 47)<br>- Carefully consider whether a robust review at the department level is feasible for each department, taking into consideration the size of the department, reporting relationships, and the volume of research. (page 47)<br>- 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. (page 47) | **December 2015 Final report submitted.**<br>-The policy on scientific review of study protocols was revised and posted in March 2016. IRB application forms were revised and communications were sent to researchers to indicate that departmental review is no longer accepted. Current and new IRB members will begin to conduct scientific assessments of research protocols in April 2016. |

| Work Plan Section | Lead(s) | Percent Complete* | Work Scope (Responsible Officer) | External Review Panel Recommendation | Completed Deliverables (Progress Reporting to BOR and Legislature including date reported) |
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| | | | | - 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. (page 47)<br>- 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. (page 47)<br>- 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. (page 47)<br>- 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. (page 49)<br>- 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. (page 49) | |
| Cultivating A Culture of Ethics | Aronson, Wolf, Zentner | **50%** | Communications: Commitment Statement, Culture: campus conversations, education Hierarchy of accountability **(VPs Herman and Jackson)** | - 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. (page 20)<br>- 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. (page 20)<br>- 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. (page 20) | Dec. 2, 2015 University hosted conference entitled "Research with human participants: The National Debates". Large national audience including external experts participated. Videos available online.<br><br>September 2015 To address the "two task force" recommendation, the implementation team designed a structure where this would be a shared responsibility between the Community Oversight Board and FUROC.<br><br>December 2, 2015 Building on the momentum and success of the University's conference, Research with Human Participants: The National Debates, conference organizers are now making plans to hold an annual half-day |

| Work Plan Section | Lead(s) | Percent Complete* | Work Scope (Responsible Officer) | External Review Panel Recommendation | Completed Deliverables (Progress Reporting to BOR and Legislature including date reported) |
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| | | | | - Incorporate the University's stated commitment to, and plans for strengthening, research ethics and research participant protections in future strategic planning. (page 21)<br>- 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. (page 21)<br>--Consider efforts to engage the local community of patients and prospective subjects with programs on the ethics of research and the University's HRPP (page 40)<br>- 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. (page 89)<br>- 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 (page 90)<br>- 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. (page 90) | conference on research ethics. The Consortium on Law and Values, which hosted the initial conference, will lead the planning efforts for a spring 2017 conference as well.<br><br>Dec. 11, 2015 Vice President for Research incorporated a stated commitment to ethical culture into the research strategic plan and presented during annual report to the Board of Regents. In addition, the 2015 University Accountability report (pg. 80) includes a similar ethics statement about meeting, upholding and exceeding the highest ethical standards in research practices involving human subjects.<br><br>February 2015 The Cultivating a Culture of Ethics leadership team has drafted a University Statement of Core Commitments and is currently presenting that language to key stakeholder groups across campus for feedback. The planned use for the statement aligns with the external review panel's recommendations that include engaging the University community in ethics focused conversations and increasing awareness about our value system as well as University policies and procedures. The key stakeholder groups include department heads, clinical department faculty, faculty governance, and an open call for comments using the AdvancingHRP website.<br><br>March 2015 Began work on developing a messaging campaign that communicates the University core commitments to a culture of ethics (above) and offers a way for people to voice concerns and find more information.<br><br>-December 2015 Through conversations with national experts, an evaluation tool called the Survey of Organizational Research Climate (SOuRCe) was identified. This survey instrument is described at http://ethicscenter.csl.illinois.edu/sorc/. To our knowledge it is the only validated instrument in the U.S. for assessing the perceived climate of research |

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| | | | | | integrity. To guide UMN customization and administration of the SOuRCe, an Advisory Committee has been assembled and will include collaboration of Brian Martinson, PhD, a co-developer of the SOuRCe.<br><br>**OTHER AREAS CONTRIBUTING WORK**<br>- Hierarchy of accountability for human research ethics: an accountability org chart was created for the March 2016 legislative hearings and will serve as the basis for this hierarchy. [AdvancingHRP Communications]<br><br>- HRPP is working with OVPR communications on website upgrade to include a "one-stop" concept. This work will be done in partnership with the AdvancingHRP communications team and the IRBRenew project implementation. [HRPP and OVPR Website Redesign] |
| IRB Protocol Review Process | Dykhuis | **80%** | eIRB, new forms & procedures, new FTEs, benchmarking visits **(VP Herman)** | - 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. (page 30)<br>- 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. (page 30)<br>- 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. (page 30)<br>- 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. (page 31) | -IRB staff conducted benchmarking visit in July 2015 visit to Penn State.<br>-August 2015 Enhanced the pre-review process to more appropriately utilize non-meeting IRB review (referred to in regulations as "Expedited Review") for applicable submissions.<br>-August 2015 Established meeting agenda "caps" on number of items reviewed<br>- September 2015 Revised IRB minutes and meeting management. More closely aligned practices for documenting controverted issues with regulatory requirements & accreditation standards by revising the meeting minutes template to enhance and facilitate IRB deliberations.<br>September 2015 -Doubled total number of IRB continuing review meetings and increased number of medical meetings.<br>-January 2016 Hired reliance agreement position into HRPP operations.<br>-December 2015 The HRPP continues to make progress on implementing an electronic system to manage documents and processes for the IRB (IRB Renew). The first phase of this project officially launched on January 4 and is anticipated to last six weeks. During this phase, the IRB Renew Project team members will work closely with Huron Consulting and a small number of |

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|---|---|---|---|---|---|
| | | | | | institutional stakeholders to gather and document the requirements of the U's IRB and HRPP. The second phase of the project launched on March 28, 2016. This phase will consist of customization and implementation of the Huron Toolkit, redefining organizational structure and augmentation of staffing resources and training/mentoring of IRB staff and members on the effective utilization of new SOPs, checklists, worksheets and training guides. The third and final phase, which will run concurrently with implementation of the toolkit, will be configuration and the launch of the online submission system.<br>-HRPP hired an expert consultant who is attending IRB committee meetings to provide consultative support for the committee.<br>-The HRPP enhanced the continuing review meeting documentation procedures which includes a revised IRB review worksheet. |
| Monitoring of Studies | Dykhuis | **50%** | New FTEs, reengineer PAR function + external advisor<br>**(VP Herman)** | - 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.<br>- 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.<br>- 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.<br>- 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.<br>- In the context of ongoing concerns about problems related to subject | -Two new monitoring staff hired in HRPP to address expanded monitoring.<br>-Development of new tools is underway to use during the performance of live consent monitoring. In addition, creation of tools to facilitate engagement of research participants during the assessment of informed consent and development of tools to enhance understanding of informed consent is underway. The PAR team is also evaluating use of existing, validated survey tools that could be deployed following informed consent of participants to assess the quality and effectiveness of informed consent.<br>- PAR staff are preparing for collaboration with work plan leads related accountability metrics and reporting. Effort is being spent compiling data for monthly reports of quality improvement and quality assurance initiatives, including assessment of IRB review process/functioning, that will facilitate development of more transparent reporting mechanisms with key stakeholders as recommended by the external review panel and as detailed in the work plan.<br>- Enhanced methodology for monitoring. Engagement of an external clinical and translational research management and consulting firm (Compass Point |

| Work Plan Section | Lead(s) | Percent Complete* | Work Scope (Responsible Officer) | External Review Panel Recommendation | Completed Deliverables (Progress Reporting to BOR and Legislature including date reported) |
|---|---|---|---|---|---|
| | | | | recruitment and consent in psychiatric studies, PAR should include live consent monitoring of such studies in its repertoire of subject safeguards.<br>- Separate reporting chains for IRB review and Post-Approval Review should be considered. (page 54) | Research) submitted a final report in March 2016 that included PAR methodology recommendations. |
| Human Research Participants Who Have Impaired or Fluctuating Capacity to Consent | Miles, Dykhuis | **50%** | Implement tool to assess capacity.<br>Train and communicate researchers<br>**(VP Herman)** | - 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. (page 65)<br>- 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. (page 65)<br>- 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. (page 65)<br>- 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;<br>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. (page 66)<br>-Develop standards that protect against real or perceived coercion in psychiatric treatment settings in which individuals may fear involuntary court proceedings.<br>- 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. | September 2015 IRB Policies Amended:<br>IRB Policy 501: Vulnerable Populations<br>IRB Policy 506: Adults Lacking Capacity and/or Adults with Diminished Capacity to Consent<br><br>Held Informed Consent training session designed for research coordinators in March 2016. Recording of "Informed Consent: Enhancing Participant Understanding" is available on the IRB training page http://mediasite.ahc.umn.edu/Mediasite/Catalog/catalogs/ovpr-hrpp<br><br>A new course is being offered spring semester 2016 at the University of Minnesota. This fifteen week lecture series, Standards for Research with Human Participants, is offered through the Center for Bioethics and is taught by Steven Miles, M.D., professor in the Department of Medicine and Maas Family Endowed Chair in Bioethics in the Center for Bioethics. |

| Work Plan Section | Lead(s) | Percent Complete* | Work Scope (Responsible Officer) | External Review Panel Recommendation | Completed Deliverables (Progress Reporting to BOR and Legislature including date reported) |
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| | | | | (page 68)<br>- 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.<br>- 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. (page 69) | |
| | Dykhuis | **50%** | LAR policy changes<br>72-hour hold policy<br>**(VP Herman)** | - Policies and procedures related to the use of LARs must be comprehensively re-assessed in accordance with the foregoing observations and conclusions.<br>- The OVPR and HRPP leadership should consider consultation with OHRP or DHHS on this topic. (page 71) | December 2015 HRPP hired an expert IRB consultant to facilitate revision of LAR policies.<br><br>-The HRPP is evaluating interest in establishing a community wide workgroup to gain consensus on the definition and interpretation of the Minnesota statute regarding the role of the legally authorized representative in research.<br><br>-The HRPP is evaluating validated capacity (to consent) assessment tools.<br><br>-The post approval review team is developing draft tools to perform consent monitoring activities including a brochure for use with LARs to facilitate the informed consent process. |
| | | **50%** | | -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.<br>-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. (page 73) | -September 2015. Implemented no recruitment of individuals/patients on 72-hour hold. Changes documents in revisions to Appendix I and HRPP Policies 501 and 506 related to the 72-hour hold policy were released in April. |
| Dept. of Psychiatry | Paller | **70%** | Clinical & Translational Science Institute (CTSI) management of trials. | - IRB membership, expertise and training should more effectively address risk evaluation and management for psychiatric research.<br>- Best practices regarding consent and capacity to consent should be | - Dec 2015 IRB website http://www.research.umn.edu/irb/ updated so that departments or academic instructors may request basic or advanced training tailored to individual needs and meet the greater goal supporting culture |

| Work Plan Section | Lead(s) | Percent Complete* | Work Scope (Responsible Officer) | External Review Panel Recommendation | Completed Deliverables (Progress Reporting to BOR and Legislature including date reported) |
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| | | | Engage consultant for climate assessment plan.<br><br>Enhance culture of inclusion and mutual trust.<br>**(VP Jackson)** | introduced and made routine.<br>- Fairview staff should be involved in protocol review, in gatekeeping functions, and in research monitoring.<br>- [The investigators] as the focus of ongoing concern and criticism, should receive supervision, coaching in leadership, and advanced training in human subjects protections. (page 84) | change.<br>- The Implementation Team work plan included a recommendation that the Clinical Translational Science Institute (CTSI) assume management of interventional drug and device trials in the Department of Psychiatry. CTSI contracted with Clinical Research and Compliance Consulting in response to that charge, and the consultant's final report and CTSI management plan were shared with the Board of Regents Audit and Compliance Committee on February 11.<br>-The Department of Psychiatry and the Clinical Translational Science Institute (CTSI) are moving forward on implementing the management plan of clinical trials finalized in January. The management plan describes how the CTSI will assume management of interventional drug and device trials in the Department of Psychiatry. The CTSI has posted positions for a new Clinical Research Manager and a Regulatory Specialist, as well as two additional clinical trial monitors.<br>- With CTSI, the Department of Psychiatry has begun the changeover to OnCore Clinical Trials management system.<br>- The Department endorsed using GCP for all clinical trials. CTSI is continuing their progress with the Department of Psychiatry's investigators to implement the required GCP. There is a full time CTSI staff working with psychiatry investigators.<br>- The Department has worked with Fairview to **adopt a new checklist** to ensure more and better interactions between research and clinical staff from the study design through implementation. This had been adopted by both the Department and Fairview.<br>- Of the two investigators identified in the external panel review, one has retired from the University and one is no longer engaged in clinical research. To reengage in research, the investigator is aware that he must complete the required training and literature review. To date he has participated in the OVPR summit and has engaged in departmental discussions regarding |

| Work Plan Section | Lead(s) | Percent Complete* | Work Scope (Responsible Officer) | External Review Panel Recommendation | Completed Deliverables (Progress Reporting to BOR and Legislature including date reported) |
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| | | | | | interactions with clinical staff, consent processes and conflicts of interest. |
| Engaging Research Participants | Eder | **70%** | -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<br>-Create and publicize mechanisms for participants and families to provide confidential feedback and report concerns, develop a small handout<br>-Create and publicize procedures for handling concerns and for notifying reporter when they have been handled<br>-Create position of Community Liaison Officer<br>-Create link to Community Oversight Board | - 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.<br>- Develop mechanisms to regularly solicit, evaluate, and respond to research participant feedback. (page 58)<br>- 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. (page 58)<br>- 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 | -The Engaging Research Participants work area gathered research participant surveys from other Clinical and Translational Science Award (CTSA) institutions across the country and is crafting a survey to assess research participants' experiences (Jan – March); two drafts of the survey have been reviewed by the work group (March – April). Expectation is to have a final version in late May or early June.<br>- The group is drafting recommendations for research dissemination to participants and the public that reflect community preferences.<br>- The group has developed recommendations related to the informed consent process, particularly emphasizing consent as an ongoing or continuous process. The recommendations will be complete in early May.<br>- The group is working with Human Research Protection Program (HRPP) office to design and implement a participant contact card for study staff to give to participants and families. A final version of the card will be available in early May.<br>- The group drafted a Community Liaison Officer (CLO) position description and anticipates posting the position in April. A final version of the job description has been shared with University leadership in April with the expectation of its posting in the next month. Key responsibilities of the CLO will be supporting the Community Oversight Board, implementing the research participant survey, and compiling information to report on the University-community relations around research. |

| Work Plan Section | Lead(s) | Percent Complete* | Work Scope (Responsible Officer) | External Review Panel Recommendation | Completed Deliverables (Progress Reporting to BOR and Legislature including date reported) |
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| | | | **(VP Herman)** | concern. (page 59)<br>- 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. (page 59) | |
| Education and Training of Investigators | Ingbar, Schacker | **75%** | Integrate and coordinate human research protection training: curriculum development, training delivery<br>**(VP Herman)** | -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 (page 39)<br>-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 (page 39)<br>-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 (page 39)<br>-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 (page 39)<br>-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 (page 40) | Dec. 2015 CTSI hires consultant to perform human research protection education and training gap analysis and curriculum design plan based on national CTSA consortium information.<br><br>March 2016: Draft summary of existing UMN resources and Education & Training gap analysis with recommendations completed.<br><br>April 2016 - Education & Training gap analysis with recommendations accepted by work group, meeting with Drs. Herman and Jackson to present a comprehensive plan on April 20 and includes need for longer time horizon (18 rather than 12 months) to develop analysis, recommendations and plan for implementation. Implementation will commence based on results of that meeting.<br><br><u>OTHER AREAS CONTRIBUTING WORK</u><br>Sept. 2015 HRPP program education and outreach specialist hired and has created an education structure for new IRB members, expanded communication and education issues, and launched a training tracker to document HRPP and IRB training.<br><br>Dec. 2015 - Center for Bioethics releases fifteen week lecture series spring semester entitled, "Standards for Research with Human Participants". |

| Work Plan Section | Lead(s) | Percent Complete* | Work Scope (Responsible Officer) | External Review Panel Recommendation | Completed Deliverables (Progress Reporting to BOR and Legislature including date reported) |
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| | | | | -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 (page 40)<br>-Consider ways to involve the University's Center for Bioethics in the educational programs focusing on human subjects research (page 40)<br>-Consider efforts to engage the local community of patients and prospective subjects with programs on the ethics of research and the University's HRPP<br>-Upgrade and professionalize education in, among other subjects, the responsible conduct of research and research ethics. (page 40) | Dec. 2015 IRB Website http://www.research.umn.edu/irb/ now includes advanced training opportunity, tailored training and new IRB Newsletter designed to deliver timely updates about policy, procedure and training opportunities.<br><br>Center for Bioethics: Standards for Research with Human Participants Spring Semester, Jan 19 - May 6, 2016 |
| Accountability Metrics | Waldemar | **60%** | RCO track and report accountability metrics. Create reporting mechanism to Community Oversight Board and FUROC. **(VP Herman)** | N/A | - Portfolio of identified items being finalized. Metrics team has been identified. Meetings with stakeholders and data analysts are being scheduled. Data collection slated to commence July 1 while work continues on data presentation, level of detail, infrastructure requirements (queries, tables, access, etc.). |
| Conflict of Interest | Durfee | **80%** | Revise COI policy **(Chief of Staff/Office of Inst. Compliance Director)** | N/A | -Revisions to the Conflict of Interest policy are now in the final stages of consultation and review. Policy will be discussed, and possibly voted on, at the May University Senate meeting. Even if voted upon by the Senate, the new policy will not be put into place until after the faculty union vote, which will likely be sometime this Fall. Once passed, the University will be one of only three institutions (including UCSF and Mayo) to have a policy requiring no personal income from a company while working as a PI on a study funded by the same company. |
| Other: BOR | Herman | | Suspended enrollment of psychiatric | N/A | -Hired Quorum IRB to review 15 psychiatric studies suspended and 3 psychiatric studies not yet approved by IRB. |

**AdvanceHRP Implementation**
**http://research.umn.edu/advancehrp/index.html**
**Progress Summary & Recommendations Alignment Table (vApril2016)**

| Work Plan Section | Lead(s) | Percent Complete* | Work Scope (Responsible Officer) | External Review Panel Recommendation | Completed Deliverables (Progress Reporting to BOR and Legislature including date reported) |
|---|---|---|---|---|---|
| or Senior Leadership Assigned | | | 2015 AAHRPP Accreditation, interventional drug studies outsourced, engage external consultant to review protocols **(VPs Herman and Jackson)** | | -All new Psychiatry interventional drug trial applications continue to be outsourced to Quorum *IRB*.<br>- June 2015 AAHRPP reaccreditation site visit and follow-up draft comments. Sept. 2015 Final site visit report and pending accreditation status received. Quarterly improvement plans required through Aug. 2016.<br>-President Eric Kaler, Vice President Brian Herman, and Dean/VP Brooks Jackson provided updates on the Advancing Human Research Protections implementation work to both the Senate Higher Education Committee and the House Higher Education Committee.<br>-One outcome of the Senate hearing is a new Advancing HRP implementation organizational chart to help clarify the new processes and accountability lines.<br>-The Office of the Legislative Auditor is meeting with key stakeholders on campus to do a follow-up review. The OLA is focused on consent, recruiting and participation of vulnerable participants, conflict of interest, communication with family and friends of study participants, appropriate delegation of study tasks, IRB review, documentation of adverse events and communication between researchers and the IRB. We expect a report from Auditor Nobles in May. |

***Percent Complete = percent complete of external review panel recommendations. Work scope could include additional items described in the Implementation Team's Final Report that go beyond the external review panel recommendations.**

# Advance HRP Implementation

**MAY 2016 Progress Report**

| Work plan Section | Status | Lead | Scope |
|---|---|---|---|
| **IRB Membership** | √ | 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** | √ | Webb | Establish Research Compliance Office (RCO) |
| | | Waldemar | Transition For Cause Investigations to RCO; establish more robust procedures specific to complainant and adverse event reporting |
| **Community Oversight Board** | √ | Herman | Establish board structure and guidelines |
| | | | Finalize membership; appoint chair |
| | | | Invite members; convene first meeting |
| **External Advisor** | √ | Herman | Hire external advisor (external review panel member); 2015 AAHRPP Accreditation; Compass Point compliance review. |
| **Scientific Review of Studies** | √ | Billings, Biros | Eliminate department reviews and move to Human Research Protection Program (HRPP) office. |
| | | | Define a new IRB process and policy in consultation with other required scientific reviews |
| **Cultivating a Culture of Ethics** | O | Aronson, Zentner, Wolf | Create language explaining the University's commitment to research participant protection |
| | | | Clear statements on key 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 – IRB Renew |
| | | | Implement Huron Toolkit IRB forms and procedures |
| | | | Add new FTEs |
| | | | Complete benchmarking visits |
| **Monitoring of Studies** | O | Dykhuis | New post-approval review FTEs |
| | | | Reengineer post approval review function; Includes work with Compass Point to further refine methodology. |
| **Human Research Participants Who Have Impaired or Fluctuating Capacity to Consent** | O | Miles | Implement tool to assess capacity |
| | O | | Train and communicate change to researchers |
| | O | Dykuis | Implement LAR policy changes |
| | √ | | Implement 72-hour hold policy |
| **Department of Psychiatry** | O | Paller | Transition to Clinical & Translational Science Institute (CTSI) management of trials |

| | | | |
|---|---|---|---|
| | | | Engage consultant for climate assessment plan. Enhance culture of inclusion and mutual trust. |
| **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 human research protection training |
| | | | Curriculum development |
| | | | Training delivery |
| **Accountability Metrics** | O | Waldemar | Track and report accountability metrics |
| **Conflict of Interest** | O | Durfee | Implement updated COI policy |

√ = Completed

O = In Progress/some items completed

= 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

# ADVANCING HUMAN RESEARCH PROTECTIONS

Brian Herman, Vice President for Research

May 12, 2016

Audit Committee

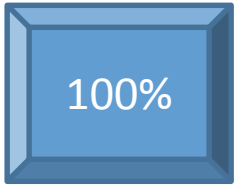
# KEY POINTS

- Progress to date
- Near term: next two months
- Long term: 07/01/16 and after

# PROGRESS TO DATE

% complete

# FAIRVIEW UNIVERSITY RESEARCH OVERSIGHT COMMITTEE (FUROC)




- ✓ Establish committee membership

  (VP Herman)

- ✓ Charge committee leadership

  (VP Jackson and CMO Thomas/Fairview)

**Next:** FUROC meets every other month to consider research issues affecting Fairview patients and staff and to improve communication between the organizations. FUROC will oversee a climate survey related to research conducted at Fairview.

# COMMUNITY OVERSIGHT BOARD


- ✓ Establish board structure and finalize membership

  (VP Herman)

**Next:** Board meets on May 12 to discuss Psychiatry Assessment and Compass Point reports, role of the COB, and the University Statement of Core Commitments

**Charge:** 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.

# EXTERNAL ADVISOR


- ✓ Hire external advisor: external review panel member

  (VP Herman)

**Next:** Dr. David Strauss will continue working with the teams, evaluating and providing feedback.

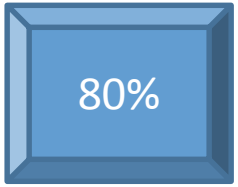
# SCIENTIFIC REVIEW OF STUDIES


- ✓ Change scientific review policy-eliminate dept. review
- ✓ Define HRPP process

(VP Herman)

**Next:** Current IRB members began conducting scientific assessments of research protocols in April 2016.

# IRB MEMBERSHIP

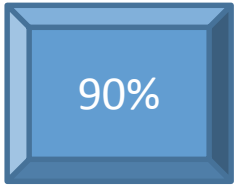



- ✓ Recruit membership, form new committees
- ✓ Set compensation structure and policy

  (VPs Herman and Jackson)

**Next:** Adjusting membership structure to fill open positions and align with eIRB tool kit. New committees will all be formed by 07/01/16.

# FOR CAUSE INVESTIGATIONS

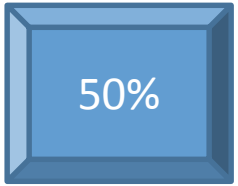



- ✓ Establish Research Compliance Office
- ✓ Transition For Cause Investigations

  (VP Herman)

**Next:** Finalize compliance review policy and procedures which are currently in the University Administrative policy leadership approval step.

# CULTIVATING A CULTURE OF ETHICS



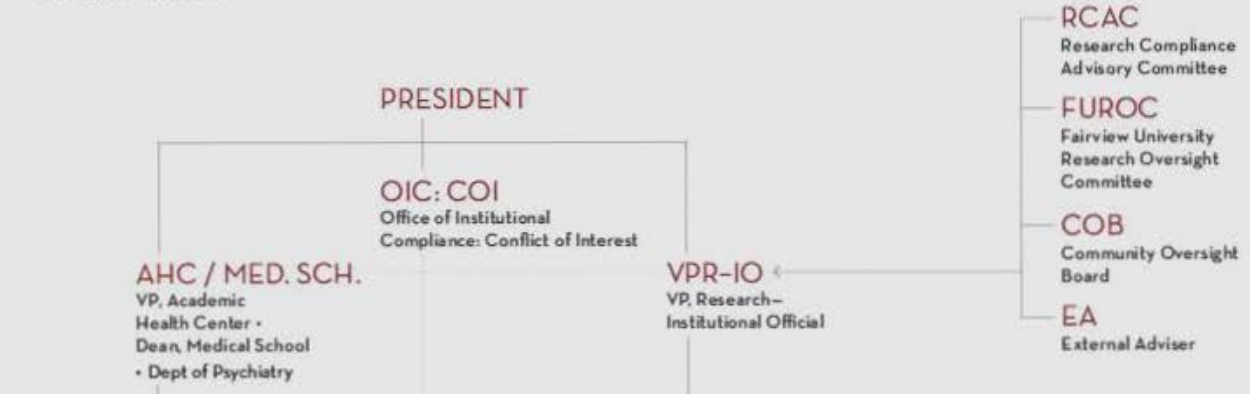

- ✓ Communications: Commitment Statement
- • Culture: Campus conversations, education
- ✓ Hierarchy of accountability

  (VPs Herman and Jackson)

**Next:** Will finalize ethics commitment statement conversations, publications, and education by 06/30/16. Continued planning for Spring 2017 AdvancingHRP conference (1/2 day) and local education component (1/2 day). Source Survey implementation by Fall 2016.

# Hierarchy of Accountability

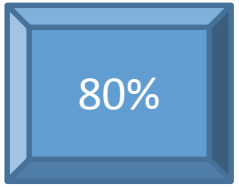
UNIVERSITY OF MINNESOTA
**Driven to Discover℠**




**ADVANCING HUMAN RESEARCH PROTECTIONS: IMPLEMENTATION ORGANIZATIONAL CHART**

The University of Minnesota is in the midst of a university wide initiative to strengthen its human research protections and establish a program that keeps the well-being of research participants at the center of its policies and procedures. This organizational chart represents the University leaders, units and external partners directly involved in this effort. Learn more at research.umn.edu/advancehrp

# IRB PROTOCOL REVIEW PROCESS

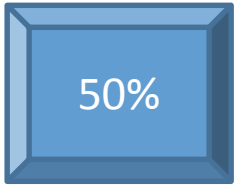



- ✓ Benchmarking visits (Penn State, U Wisc. Madison)
- Implement new eIRB system including Toolkit and ClickIRB (planned implementation through December 2017)
- Implement Huron Toolkit (new forms & procedures, new FTEs)

  (VP Herman)

**Next:** Huron Toolkit implementation will be completed 06/30/16. The toolkit includes organizational structure, policy, procedures, forms and business process. The Click IRB software implementation will continue through December 2017.

# MONITORING OF STUDIES

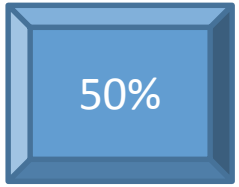



- ✓ Hire new FTEs
- Reengineer PAR function + external advisor (Compass)

  (VP Herman)

**Next:** Implement Compass Point Research methodology as described in its March 2016 final report. Align monitoring functions between HRPP, CTSI and the Research Compliance Office (RCO) by 06/30/16. Fully implement new Compass Point monitoring methodology by Fall 2016.

# HUMAN RESEARCH PARTICIPANTS WHO HAVE IMPAIRED OR FLUCTUATING CAPACITY TO CONSENT

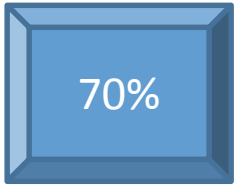



- ✓ 72-hour hold policy
- Implement tool to assess capacity (in progress)
- Train and communicate researchers
- LAR policy changes

(VP Herman)

**Next:** IRB Polices 501 (Vulnerable Adults) and 506 (Diminished Capacity) revisions in process and will be implemented by 06/30/16. Assessment tool selected and will be implemented within the framework of the IRB policies and Huron toolkit.

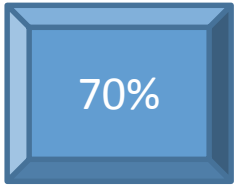
# ENGAGING RESEARCH PARTICIPANTS




- ✓ Create Community Liaison Officer position, create link to Community Oversight Board
- Create research participant satisfaction survey and 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

(VP Herman)

# ENGAGING RESEARCH PARTICIPANTS (CONT.)



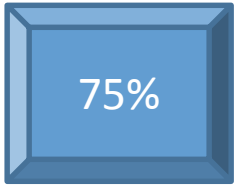

Next:

Templates of the contact card have been drafted and will be made available on the IRB forms page of the website by 06/30/16.

HRPP/IRB facilitated an informed consent session to promote participant engagement in the consent process. Second session planned for June. Includes information about how the IRB protocol should include a dissemination plan.

Draft version of the survey will be ready to share outside of Engaging Research Participants work group in May. Survey implementation planned after work group and VPR approval in June.

# EDUCATION AND TRAINING OF INVESTIGATORS



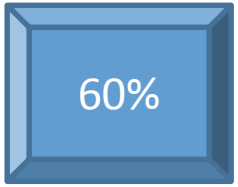

Integrate and coordinate human research protection training.
Draft final report submitted that included recommendations for:

- ✓ Gap analysis
- Curriculum development (advanced training)
- Training delivery
- Oversight

(VP Herman)

**Next:** Creation of an education advisory board that will finalize roles and responsibilities based on gap analysis and team recommendations by 06/30/16. Training delivery remains ongoing.

# ACCOUNTABILITY METRICS

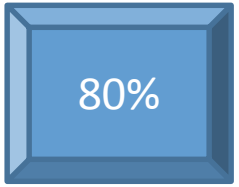



- Track and report accountability metrics
- Create reporting mechanism to Community Oversight Board and FUROC

  (VP Herman)

**Next:** Accountability metrics are drafted and a plan to consult these metrics with the COB and FUROC confirmed. Metrics will be finalized in June once all final reports are received and approved by the VPR.

# CONFLICT OF INTEREST

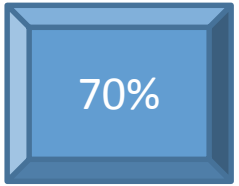



- Revise COI policy

  (Chief of Staff/Office of Inst. Compliance Director)

**Next:** Policy was discussed and voted on at the May 2016 University Senate meeting. The new policy will not be put into place until after the faculty union vote, which will likely be sometime fall 2016.

# DEPARTMENT OF PSYCHIATRY

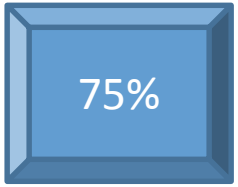



- ✓ Clinical & Translational Science Institute (CTSI) management of trials
- Engage consultant for climate assessment plan
- Enhance culture of inclusion and mutual trust

  (VP Jackson)

**Next:** FUROC will take responsibility for a climate assessment. The Department continues to work on the culture of inclusion and has implemented a new checklist to ensure communication and collaboration with Fairview clinical staff.

# REGENTS OR UNIVERSITY SENIOR LEADER ADDITIONS




- ✓ Interventional drug studies outsourced to Quorum IRB
- ✓ Engage external consultant to review protocols (Compass)
- 2015 AAHRPP accreditation

  (VPs Herman and Jackson)

# NEXT TWO MONTHS AND BEYOND

# OUTCOMES EXPECTED NEXT TWO MONTHS

- Work teams wrap up work
- Final reports to VPR for review
- Transition to operational unit responsibilities
- Outcome/accountability measures benchmarked
- Progress report to Board of Regents in June

# POST JUNE30

- Operational transitions completed
- Review outcomes and evaluate impact
- Adjust or re-align resources
- Trend accountability metrics
- Huron Toolkit and ClickIRB technology implementation (eIRB implementation goes through 2017)

UNIVERSITY OF MINNESOTA

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# BOARD OF REGENTS
# DOCKET ITEM SUMMARY

**Audit & Compliance** **May 12, 2016**

**AGENDA ITEM:** Update on Remediation of Information Technology Audit Findings

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

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

**PRESENTERS:** Gail Klatt, Associate Vice President, Internal Audit
Bernard Gulachek, Interim Vice President and Chief Information Officer

**PURPOSE & KEY POINTS**

The purpose of this item is to provide an update on the initiatives underway to remediate outstanding information technology (IT) audit findings and recommendations, and to reduce the number of future control vulnerabilities. Specific strategies and tactics underway include:

- Create IT "Centers of Excellence." Centralize technology services by leveraging areas of IT expertise. Work includes the definition of centralization, service sourcing, and formal delegation of service authority and accountability.
- Establish Information Technology Compliance Function. Implement an information technology compliance function serving as a liaison between University technologists and University Audits in support of resolving current – and eliminating future – IT audit findings.
- Continue to leverage the institution's standardized, common-good IT services and infrastructure in support of locally specialized technology needs.
- Reduce audit findings through continuing development and communication of IT policy, centralization of IT services, and incentives/disincentives for embracing IT standardization.

**BACKGROUND INFORMATION**

The Audit & Compliance Committee has raised concerns about the increasing number of audit findings that involve information technology, and the length of time to resolve them.

# BOARD OF REGENTS
# DOCKET ITEM SUMMARY

**Audit & Compliance** **May 12, 2016**

**AGENDA ITEM:** Institutional Compliance Officer Semi-Annual Report

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

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

**PRESENTERS:** Lynn Zentner, Director, Office of Institutional Compliance

**PURPOSE & KEY POINTS**

The Director of Institutional Compliance typically reports on compliance-related matters twice each year. This report focuses on:

1. Continuing the focus on the University's commitment to ethical conduct
2. Particular compliance-related matters
3. Report of the Institutional Compliance Function review
4. Ureport statistics for the period May 2015 through April 2016

**REPORT OF THE DIRECTOR, OFFICE OF INSTITUTIONAL COMPLIANCE,**
**FOR THE AUDIT COMMITTEE OF THE BOARD OF REGENTS**
**ON THE UNIVERSITY COMPLIANCE PROGRAM**
**May 12, 2016**

## *INTRODUCTION*

This report addresses the following: (I) Continuing the Focus on the University's Commitment to Ethical Conduct; (II) Particular Compliance-related Matters; (III) The Report of the Institutional Compliance Function Review; and (IV) UReport Statistics for the Period May 2015 through April 2016. Additional information regarding the University's Office of Institutional Compliance is available on the Office's website. Links to relevant resources are also provided. http://www.compliance.umn.edu/complianceHome.htm.

## *I. CONTINUING THE FOCUS ON THE UNIVERSITY'S VALUES AND COMMITMENT TO ETHICAL CONDUCT*

The Director's Report for both May and December 2015 began with a focus on the University's Code of Conduct (the Code) and efforts that would be pursued to bring the values of the Code to life for each member of the University Community. Since then, the University's faculty and staff portal page has addressed one of the ten standards of the Code monthly, providing examples of the conduct expected of all members of the University Community. As mentioned, this initiative has been titled: Know the Code. Posters have been disseminated to more than 300 locations around the University, on all campuses, and postcards have similarly been disseminated.

The work of the Implementation Team and the All Leads subgroups, led by Vice President Brian Herman, continues. These groups include representation from the Office of the Vice President for Research, the Office of Institutional Compliance, University Relations, several faculty, and Medical School leadership. Some teams have completed their assignments while others continue to meet regularly to complete the assigned work. Dr. David Strauss, Columbia University, an external adviser to the Implementation Team, visited the University in March and met with members of the Implementation Team Leads to provide insights and respond to questions posed by this group. It was a rich opportunity for members of the Implementation Team to have the benefit of Dr. Strauss' views.

In addition to the work of the Implementation Team, the Consortium on Law and Values, in Health, Environment & Life Sciences sponsored a conference in early December 2015 titled Research with Human Participants: The National Debates. This event was spearheaded by Susan Wolf, McKnight Presidential Professor of Law, Medicine & Public Policy. The speakers included experts from several institutions of higher education, as well as industry. While this was an all-day event, future conferences on this topic will likely be half day events with the second half of the day devoted to discussions among faculty in their respective Departments. Approximately 1600 individuals attended the conference in person at Coffman Union or via a webcast.

The University is also exploring the use of a University-wide survey on organizational research ethics and integrity. The University has recently gathered information regarding a tool titled the

Survey of Organizational Research Climate (SOuRCe). This survey instrument was developed with NIH funding by a Professor at the University of Illinois. It is the only validated survey instrument in the United States for assessing the perceived climate of research integrity. Professor Wolf has recently convened a SOuRCe Advisory Committee to consider and address how this instrument might be used at the University.

## *II. PARTICULAR COMPLIANCE-RELATED MATTERS*

### *A. THE INDEPENDENT REVIEW OF 100 ACTIVE IRB STUDIES CONDUCTED BY THE COMPASS POINT RESEARCH FIRM*

As a result of the external evaluation of human research protections at the University, a March 2015 resolution passed by the Board of Regents included a plan to sample additional interventional clinical studies to determine whether ongoing activities are appropriate and consistent with approved protocols. The University engaged Compass Point Research (CPR), an independent, external full-service clinical and translational research management and consulting firm, to conduct a review of 100 active studies with at least one participant currently enrolled. Under the direction of the Vice President for Research and the IRB Executive Committee, the continuing review procedures of the IRB were expanded in 2011 to include a Post Approval Review (PAR) function. This function was developed to meet FDA requirements. CPR previously conducted a comprehensive review in 2014. Vice President Brian Herman will report the results of this review to the Audit and Compliance Committee on May 12, 2016.

### *B. REVISIONS TO THE ADMINISTRATIVE CONFLICT OF INTEREST POLICY*

The University has had conflict of interest policies in effect since 1994. The policy adopted in 1994 was a Board of Regents Policy. In 2005, an administrative conflict of interest policy was adopted to further implement the Board of Regents Policy. Substantial revisions were made to two administrative individual conflict of interest policies in 2010 and 2011 and additional revisions are undergoing review today. The significant proposed revision that is currently under review by faculty governance groups arises out of the document titled “Implementing the Recommendations of the External Review of the University of Minnesota Human Research Protection Program” (Work Plan), dated June 11, 2015. This proposed revision prohibits investigators, while participating in a human participant research study requiring IRB approval, from accepting remuneration from a company that is sponsoring the study or from a company whose product, device or other technology may be evaluated during the course of the study.

If adopted, this provision reflects a significant change for affected University faculty because, in the past and currently, the University has focused on managing conflicts of interest rather than precluding the receipt of income from industry. The University, however, has limited the amount of income an investigator can earn from industry while serving as a Principal Investigator on a human participant protocol. During the 2015-2016 academic year Conflict of Interest Program staff, together with Professor Will Durfee, have consulted this proposed revision to the Individual Conflict of Interest Policy with 13 separate committees and departments, and twice has participated in discussions with the University Senate. A vote by the University Senate is expected on May 5. The revised policy, if approved by the President's Policy Committee, will not be implemented until the faculty unionization matter is resolved and the status quo order lifted.

Additional key changes to the policy include the following:

- The two individual conflict of interest policies that have been in effect since 2010 and 2011 have been merged into one. In the past, one policy governed those involved in clinical health care and the second policy applied to everyone else. The separate policy that applied to those involved in clinical health care will be retired.
- The proposed revised policy also clarifies standards governing relations with business entities to include prohibited activities, gifts, and consulting agreements.
- Some provisions have been revised to align with Board of Regents policies and Public Health Service Conflict of Interest regulations.

### *C. EXTERNAL REVIEW OF MATTERS RELATED TO THE ATHLETICS DEPARTMENT THAT INCLUDED RECOMMENDATIONS FOR THE OFFICE OF EQUAL OPORTUNITY AND AFFIRMATION ACTION*

In December 2015, a report created by attorneys from the Fredrickson law firm identified ways in which the work of the Office of Equal Opportunity and Affirmative Action (EOAA) could be strengthened. The Director of EOAA convened a committee to review those recommendations. In addition to EOAA, the committee membership represented the following offices and departments: Office of the General Counsel, Office of Institutional Compliance, Office for Human Resources, College of Education and Human Development, Provost's Office, Intercollegiate Athletics, and Office for Conflict Resolution. The Committee met twice in January 2016. Below are some of the most significant recommendations that EOAA will implement as a result of this review:

- Continue regular reviews of planned presentations and evaluations, including role playing and discussions with governance groups. With regard to the implementation of mandatory sexual harassment training and the development of future training, add a role for the Athletics Department in the delivery of the training. Continue discussions with faculty and employee governance groups about the implementation of this training for all employees, including faculty.
- Continue to register this training through ULearn (the University's learning management system) and inject evaluative questions into the training.
- Revise current University policy to require that all supervisors and advisors report to EOAA all instances of sexual harassment that come to their attention.
- Investigate the value of obtaining an automated project management system and explore the addition of two investigators to EOAA staff in order to shorten timelines on the completion of investigations.
- Review current policies to ensure full compliance with state and federal laws.
- Establish a process for contacting, or attempting to contact, all individuals who report sexual harassment including those who are not members of the University Community.
- Explore how local Human Resources and OHR can support investigations in collaboration with EOAA.
- Provide information to relevant parties explaining that determinations are governed by a "preponderance of the evidence" standard for purposes of adjudicating an allegation.

- Continue to communicate with reporters through UReport throughout the duration of the investigation. Review existing policies to ensure that sufficient notice is being provided to the reporters and subjects regarding the outcome of investigations.
- Follow up with responsible administrators in colleges and academic units to determine whether the recommendations made by EOAA have been implemented.

### *D. NEW CLERY COMPLIANCE COORDINATOR*

Beginning in November 2015 responsibility for the University's Clery Compliance Program was transferred from the University of Minnesota Police Department (UMPD) to the Office of the General Counsel (OGC). OGC then hired the University's first Clery Compliance Coordinator, Daniel Alberts. Mr. Albert's initial evaluation of the Clery Compliance Program revealed two high-risk compliance concerns, namely the need to: (1) identify and train all Campus Security Authorities (CSAs) and (2) properly identify the "Clery Geography" on the Twin Cities campus. A Clery Compliance Committee has been created and its membership will assist with addressing these concerns and the implementation of the CSA Program. The Space Management and Real Estate Offices will produce an annual report of all property owned or controlled by the University. This report will be reviewed jointly by the Clery Compliance Coordinator and a representative from Space Management and Real Estate Offices to ensure its accuracy and completeness. Mr. Alberts is currently working to add Campus Security Authority Training to ULearn, with plans to launch this training program by fall 2016. This training will be required annually for all CSAs.

### *E. MONITORING INITIATIVES*

At the November 2015 meeting of the Executive Oversight Compliance Committee, the membership agreed that routine monitoring of medium and high risk compliance areas should be conducted on a regular basis. Some administrative units have robust monitoring programs in place while others are currently in the process of implementing a more formal approach. This initiative was emphasized during communications with the Compliance Partners in January and February. Going forward, this issue will be addressed during the Legal Compliance reporting reviews.

## *III. THE REPORT OF THE INSTITUTIONAL COMPLIANCE FUNCTION REVIEW*

In August 2015, President Kaler charged Bill Donohue, General Counsel, Gail Klatt, Internal Audit, and Amy Phenix, Chief of Staff with the implementation of a Compliance Function Design Review. In his charge, President Kaler asked these individuals to:

- Review compliance models at peer institutions to identify other approaches that the University may want to adopt;
- Gather input from key campus leaders and stakeholders, including the Board of Regents and faculty governance leaders, about both our current compliance structure and proposed recommendations for change;
- Identify the most effective reporting line for the compliance function;
- Review the staffing and resource needs, including considering whether our decentralized approach is a best practice and the most practical for the University;
- Review effective executive oversight and responsibility for compliance activities;

- Advise whether our Conflict of Interest Program should be separated from the Compliance Office and, if so, recommend an alternative management structure for that function;
- Provide recommendations for creating greater accountability for promoting an ethical culture, strengthening that culture across the University system, addressing unethical behavior when it occurs, and defining the role of senior leaders in advancing an ethical culture; and
- Develop recommendations for indices the University could adopt to assess the extent to which we have successfully promoted an ethical culture.

I provided staff support and subject matter expertise to that effort.

Chief of Staff Amy Phenix and Internal Auditor Gail Klatt presented the recommended outcomes of this effort to this Committee on February 11th of this year. I take this opportunity to share my observations.

I fully support the recommendation that the leader of the Office of Institutional Compliance (OIC) continue to report to the President, the continued access to the Board of Regents through the semi-annual engagement with the Audit and Compliance Committee, the change in title to Chief Compliance Officer (CCO), the elimination of the dotted line to the General Counsel, and the inclusion of the CCO on the President's Senior Leadership Team. I also am pleased that a recommendation has been made to add a semi-annual meeting between the Chair of the Board, the Chair of the Audit and Compliance Committee and the CCO and to develop with the Chair of the Board's Audit and Compliance Committee a process for sharing information outside of the semi-annual reporting framework.

The decentralized approach to the Compliance Partner structure works well and always has. The recommendation for the development of MOUs to govern these relationships will serve to strengthen the current infrastructure. Similarly, regularly scheduled meetings with the President will both elevate the stature of the program and strengthen that relationship as well.

In order for the Compliance Officer to be fully attuned to all compliance related matters, strengthening the relationship with senior leaders is extremely important. With full appreciation for their demanding schedules, I suggest there would be significant value in having the CCO meet individually with senior leaders two times each year.

The recommendation to create and add an Ethics Program to the Compliance Office is, from my perspective, the most compelling recommendation that results from this review. As a compliance professional I have learned from my colleagues in industry (e.g. Cargill, Medtronic, and Health Partners), from other institutions of higher education (e.g. Penn State, Ohio State, and Indiana University), as well as professional organizations (e.g. Society for Corporate Compliance and Ethics, and the National Association of College and University Attorneys) the importance of defining and maintaining an ethical culture. This work requires an institution- wide commitment from the President and leaders at all levels across the University. The Office of Institutional Compliance is committed to establishing an ethics program and building an infrastructure for the University.

Finally, I strongly support the recommendation that Compliance Training reside in OIC. Moving compliance training into a centralized system in a manner that is similar to the University's

Policy Program would lead to enhanced efficiencies and effectiveness. While this would likely require additional staff for the Compliance Office, the benefit to the University at large would, from my perspective, justify this investment.

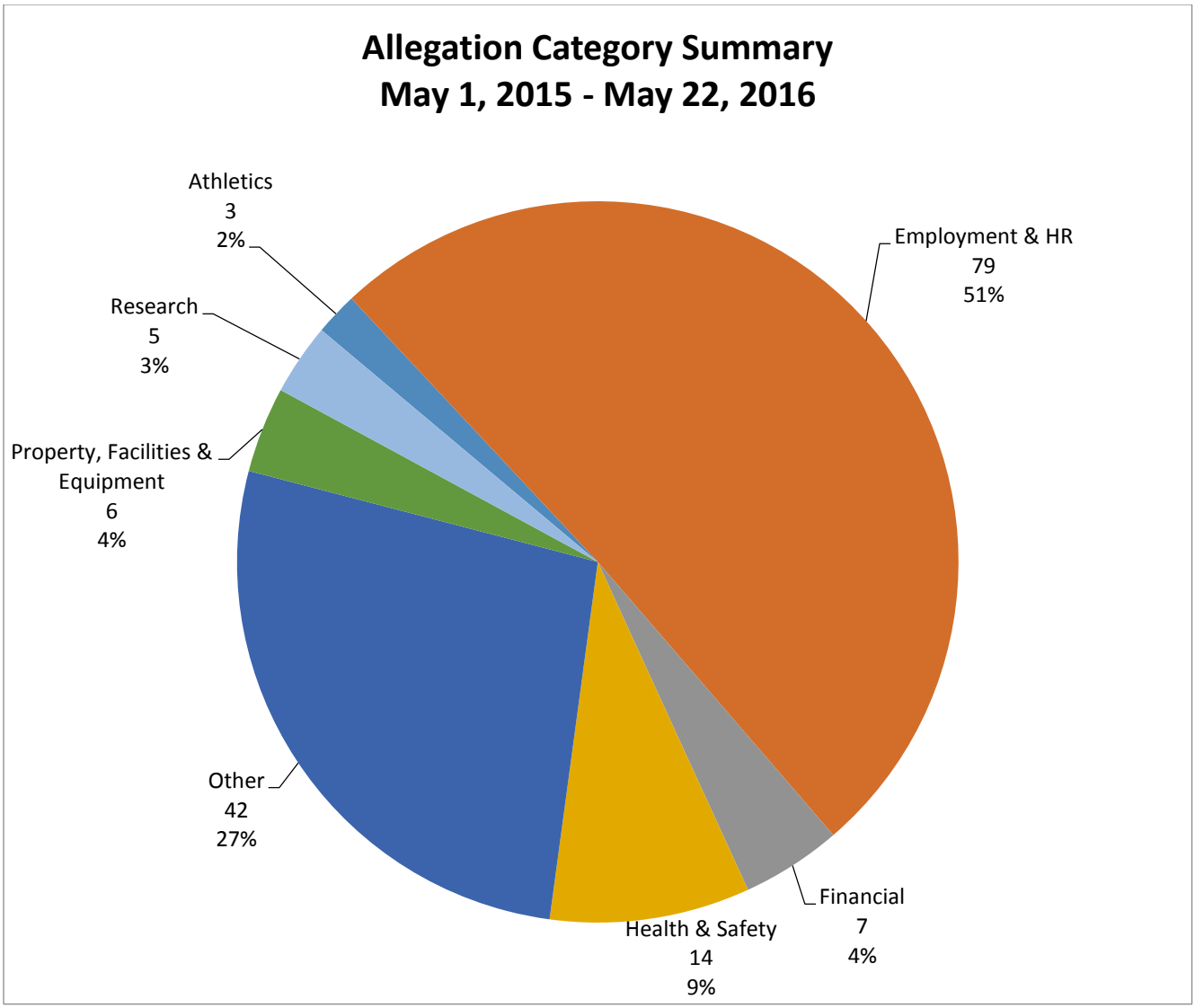
## *IV. UREPORT STATISTICS FOR THE PERIOD MAY 1, 2015 THROUGH APRIL 22, 2016*

UReport is the University's confidential web-based reporting service. This reporting service is provided by Navex Global, an independent company that provides similar services for hundreds of companies and universities. UReport is intended to be used to report violations of local, state and federal law as well as violations of University policy. This reporting system is not intended to be used for employment concerns that do not involve legal or policy violations or that involve purely student concerns, except with respect to Medical School students, or issues for which the University is not responsible. We are coordinating efforts with the office of Equal Opportunity and Affirmative Action to, in the near future, include allegations of bias as a category in the UReport system. Reporters may submit reports either via a hotline or the web. Reports may also be submitted anonymously. Those who submit reports are expected to report good faith concerns and to be truthful and cooperative in the University's investigation of allegations. UReport has been in existence at the University since 2005. Since its inception, a total of 1418 reports have been submitted, averaging approximately 135 per year. During the 12 month period, May 1, 2015 through April 22, 2016 156 reports were submitted. Seventy two percent of the reports were anonymous. Just over 50% of the reports involve claims regarding:

- Hiring, advancement, discipline or termination
- Discrimination, harassment and/or equal opportunity
- Abuses in wage, benefits, vacation, overtime, and leaves
- Other employment concerns

Ninety-two percent of the reports were received via the internet. Forty-six percent of anonymous reporters and thirty-nine percent of reporters who provided their identity checked back to determine the status of the follow up conducted regarding the concerns they described. The graphs below illustrate these figures.

| Issue | | Running Total from Launch (August 2005) | May 1, 2015 to April 22, 2016 |
|---|---|---|---|
| Total Reports | | 1418 | 156 |
| Report Sources: | | | |
| | Internet | 89% | 92% |
| | Call Center | 11% | 8% |
| | Other | <1% | 0% |
| % Anonymous | | 73% | 72% |
| Reporter "check back rate" for anonymous reports | | 50% | 46% |
| Reporter "check back rate" for non-anonymous reports | | 40% | 39% |
| Percentage Substantiated (reflects that an individual was coached, counselled, or disciplined) | | | 34% |


Allegation Category Summary
May 1, 2015 - May 22, 2016
Athletics
3
2%
Research
5
3%
Property, Facilities & Equipment
6
4%
Other
42
27%
Health & Safety
14
9%
Financial
7
4%
Employment & HR
79
51%

# BOARD OF REGENTS
# DOCKET ITEM SUMMARY

**Audit & Compliance** **May 12, 2016**

**AGENDA ITEM:** Information Items

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

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

**PRESENTERS:** Michael Volna, Associate Vice President

**PURPOSE & KEY POINTS**

**Extension of M Health Due Diligence Scope of Services**

The University, Fairview Health Services, and University of Minnesota Physicians are finalizing definitive agreements for the creation of a new entity called M Health. The University had previously contracted with Deloitte for financial diligence services.

Due to recent developments involving the potential merger of U Care MN with Fairview Health Services, the University would like Deloitte to perform limited diligence procedures on U Care to assess the potential financial impact of the merger on the new M Health entity. The additional scope has been reviewed by the Controller, and does not impair Deloitte's independence with respect to audits performed for the University. As this is an extension of scope under the current due diligence contract with Deloitte and not a new engagement, the additional scope is being reported to the Board of Regents as an information item rather than an approval item.

Deloitte's proposal includes a fee estimate of $110,000-125,000. Purchasing Services has determined the increase in fees does not constitute a purchasing contract amendment requiring Board approval.

**BACKGROUND INFORMATION**

The Board of Regents, by emergency action, approved a contract with Deloitte for financial diligence services in November 2015 for an estimated $1,500,000. The emergency approval was reported to the Board after the fact at the December 2015 Board meeting.