Audit Committee

May 2015

May 7, 2015

7:30 a.m. - 9:00 a.m.

East Committee Room, McNamara Alumni Center

AUD - MAY 2015

BOARD OF REGENTS
DOCKET ITEM SUMMARY

Audit **May 7, 2015**

Agenda Item: External Auditor Review & Summary of External Auditor Relationships & Services Provided

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

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

Presenters: Michael Volna, Associate Vice President

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 2014 (through March 2015).

External Auditor Review (Section I)
Total Deloitte & Touche (Deloitte) contracted audit and non-audit fees were $678,300 for FY 2014 engagements, with actual fees paid of $658,221. All FY 2014 engagements have been completed and final billed. A summary of management's evaluation of Deloitte's performance for FY 2014 is also provided.

Deloitte completed a partner rotation at the conclusion of the FY 2014 audit engagements. The new Deloitte engagement partner will be introduced to the Audit Committee.

Summary of Audit and Non-Audit Services and Fees (Section II)
Total fees of $1,556,003 have been paid for FY 2014 engagements to six 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 Committee as specified in Board of Regents Policy: *Audit Committee Charter*.

Background Information

This report is prepared and presented to the Board of Regents Audit 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 COMMITTEE
MAY 7, 2015

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 Committee of the Board should conduct such a review at least annually. The Audit Committee conducted its last review of audit services and fees in May 2014.

The Controller's Office presents the information below and on the accompanying schedules for the Audit Committee's 2015 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 2014 engagements.

Section I - Annual Review of External Auditor Relationship and Performance

University management and the Deloitte engagement management team met on March 23, 2015 to review Deloitte's services and performance during the FY 2014 audit. The overall conclusion was that Deloitte did an excellent job during the FY 2014 audit.

The University and Deloitte had each prepared an assessment of the engagement, identifying both positives and opportunities for improvement and increased audit efficiencies. The teams met to compare notes and identify opportunities for improvement.

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 FY 2013 audit 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 identified opportunities for improving next year's audit process. These included:

- 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.

With respect to the annual A-133 compliance audit, the University and Deloitte reviewed the testing requirements and fee schedule as recommended in the FY 2013 review, to better match the fees with the testing work.

Audit Partner Rotation

Upon completion of the FY 2014 audit engagements, Kirsten Vosen, the Deloitte partner serving the University since 2010, rotated off the engagement. Tom Roos, an audit partner who worked on past University audit engagements earlier in his career, was selected as the lead engagement partner for the University. The University team is delighted to have Tom join the engagement. There should be no impact to the audit work, and we look forward to Tom continuing the quality service that Ms Vosen provided to the University engagement for 5 years.

Review of Fees Paid to Deloitte & Touche, LLP

The accompanying schedule presents a summary of fees paid to Deloitte for the various FY 2014 audits and other services. The top portion of the fee schedule represents fees paid for the University's annual institutional audits and audit-related engagements. The contract amounts reported on the schedule are consistent with the amounts agreed to in the fiscal 2014 engagement letters and the firm's fixed price contract for FY 2014. The total audit fees paid to Deloitte for FY 2014 were $21,056 less than the contract amounts in total, and represent less than expected actual expenses. These amounts are final.

The lower portion of the schedule contains a breakdown of fees paid to Deloitte for other services. During the year, Deloitte performed five other engagements for specific units of the University. In order to reduce audit costs and maintain greater oversight of audit and audit-related engagements across the University, the Controller's Office is working closely with Deloitte and University departments to use Deloitte whenever possible for additional external audit or attest services.

Services performed by Deloitte during FY 2014 that were not part of the annual audits and NCAA agreed-upon-procedures of the University included:

- Deloitte was engaged to audit the statement of activities for the Department of Concerts and Lectures. This engagement was the result of an external funder's stipulations that require the Department of Concerts and Lectures to prepare and submit financial statements of their activity. 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 provide an audit opinion, it did not present an independence issue with regard to Deloitte.

- Deloitte was engaged to perform an audit of the Weisman Art Museum. This engagement was the result of an external funder's stipulations that require the Weisman Art Museum to prepare and submit financial statements of their activity. 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 provide an audit opinion, it did not present an independence issue with regard to Deloitte.

- 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 twenty-three 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 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 to provide annual support for the University's Profiles. The profiles were upgraded in FY 2013 from Beta Profiles to Profiles Version 1.0.3. The 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.

Note on Deloitte engagements subsequent to FY 2014

The annual review of fees and services is based on a look-back for the prior fiscal year. The Audit Committee should note that in early FY 2015 (subsequent to the fiscal year covered by this annual review) Deloitte was awarded large contracts in the amount of $2,762,000 for other audit and non-audit engagements. Because these are FY 2015 audit engagements, they do not appear in the amounts being reported on the accompanying schedule. They will be reported to the Audit Committee next year, during the review of FY 2015 audit fees and services, and it is expected that the total fees paid to Deloitte for FY 2015 will be significantly higher than FY 2014 due to the timing of those two engagements. It should also be noted that the Audit Committee discussed the matter of consulting engagements awarded to our external audit firm at the December, 2014 Audit Committee meeting.

UNIVERSITY OF MINNESOTA
BOARD OF REGENTS AUDIT COMMITTEE
MAY 7, 2015
Schedule I - Fees Paid To Deloitte & Touche, LLP
FY 2014 Engagements

	FY 2014 Engagements			*Total FY 2013*
Annual Institutional Audit and AUP Engagements	*Contract Amount*	*Billed Amount*	*Over/(Under) Budget*	*(prior year)*
University Financial Statement Audit	$ 385,000	$ 365,633	$ (19,367)	$ 359,832
RUMINCO Financial Statement Audit	23,000	23,000		21,000
Compliance Audit (OMB A-133 and MOHE)	115,000	113,311	(1,689)	110,317
NCAA Agreed-Upon-Procedures	15,100	15,100		15,976
Total Fees for Institutional Engagements	**$ 538,100**	**$ 517,044**	**$ (21,056)**	**$ 507,125**
Other Audit, Audit Related, and Non-audit Fees				
Audit of Department of Concerts and Lectures	7,600	7,886	$ 286	7,702
Audit of Weisman Art Museum	7,600	7,874	274	7,702
Student Organization Agreed-Upon Procedures	77,000	77,417	417	82,037
Consent procedures related to Bond Offerings	8,000	8,000	0	16,800
Schulze Diabetes Center Agreed-Upon Procedures				5,000
Enterprise Asset Management Analysis				283,200
UMN Position Profile analysis	40,000	40,000	0	35,000
Biomedical Health Informatics Initiative				1,569,381
Total Other Audit, Audit Related, and Non-Audit Fees *(1)*	**$ 140,200**	**$ 141,177**	**$ 977**	**$ 2,006,822**
Total Fees	**$ 678,300**	**$ 658,221**	**$ (20,079)**	**$ 2,513,947**

(1) In FY 2015, Deloitte was awarded contracts in the amount of $2,762,000 for other audit and non-audit engagements. As of April, 2015 $1,762,521 had been billed on those engagements. See "Note on Deloitte Engagements Subsequent to FY 2014" 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 2014. These services were:

- Bradley P. Mickelson, CPA was engaged by the Tweed Museum of Art to perform a yearly report on the Tweed budgets for FY 2014, to be included in an application for Minnesota State Arts Board Grant funds. This contract was previously reported to the Audit Committee

- BWK Rogers, PC was engaged by the College of Education and Human Development to perform an audit of the Business and Financial Acumen grant as required by the sponsor, Minnesota Department of Employment and Economic Development.

- Licari Larsen & Co Ltd was engaged by KUMD, the Duluth campus radio station, to perform attest services in FY 2014 in conjunction with the receipt of federal funds from the Corporation for Public Broadcasting. This contract was previously reported to the Audit Committee.

- McGladrey, LLP was engaged by the Office of Technology Commercialization to evaluate whether the sales subject to royalty and the royalties paid by Boehringer Ingelheim Vetmedica, Inc. were in accordance with license agreements. This contract was previously reported to the Audit Committee.

- PriceWaterhouseCoopers, LLP was engaged by the University to provide consulting services related to the implementation of the ESUP Oracle Identity Manager (OIM) solution. 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 COMMITTEE
MAY 7, 2015

Schedule II - Report of Fees Paid To Audit Firms for FY 2014 Engagements (through March, 2015)

	FY 2014 Engagements			*FY 2013*
Audit Firm	***Audit Fees***	***Non-Audit Fees***	***Total Fees***	***Total Fees Paid***
Bradley P. Mickelson, CPA	$ 1,900		$ 1,900	$ 1915
BWK Rogers, PC	4,000		4,000	
Deloitte & Touche, LLP	618,221	$ 40,000	658,221	2,513,947
Licari Larsen & Co., LTD		5,200	5,200	5,200
McGladrey, LLP		97,296	97,296	104,891
PriceWaterhouseCoopers, LLP		789,386	789,386	762,394
Total Fees Paid	**$ 624,121**	**$ 931,882**	**$ 1,556,003**	**$ 3,388,347**

BOARD OF REGENTS
DOCKET ITEM SUMMARY

Audit **May 7, 2015**

Agenda Item: External Audit Plan

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

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

Presenters: Michael Volna, Associate Vice President
Tom Roos, 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 2015 financial and compliance audits. Members from the Deloitte engagement team will provide the Audit Committee with an overview of the audit plan, including the firm's assessment of audit risks, testing approach, and timelines for the FY 2015 audits.

Tom Roos, Deloitte's new lead engagement partner to the University of Minnesota, will be introduced to the Audit Committee.

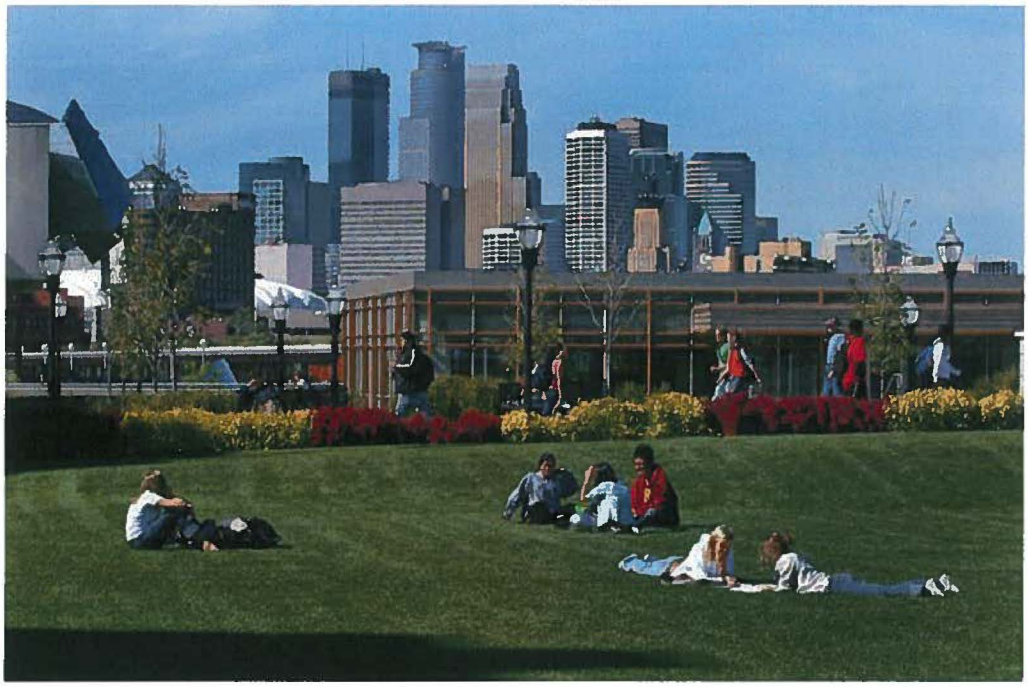
Background Information

This report assists the Audit 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

2015 Audit service plan



Deloitte.

Deloitte & Touche LLP
50 South Sixth Street
Suite 2800
Minneapolis, MN 55402-1538
USA

Tel: +1 612 397 4000
Fax: +1 612 397 4450
www.deloitte.com

May 7, 2015

The Board of Regents Audit Committee
University of Minnesota
1300 South Second Street
Minneapolis, MN 55455
USA

Dear Members of the Board of Regents:

We are pleased to present Deloitte & Touche LLP's fiscal 2015 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 Committee of the Board of Regents (the "Audit 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 Tom Roos, lead client service partner, at +1 612 397 4566 if we can be of assistance in any way.

Yours truly,

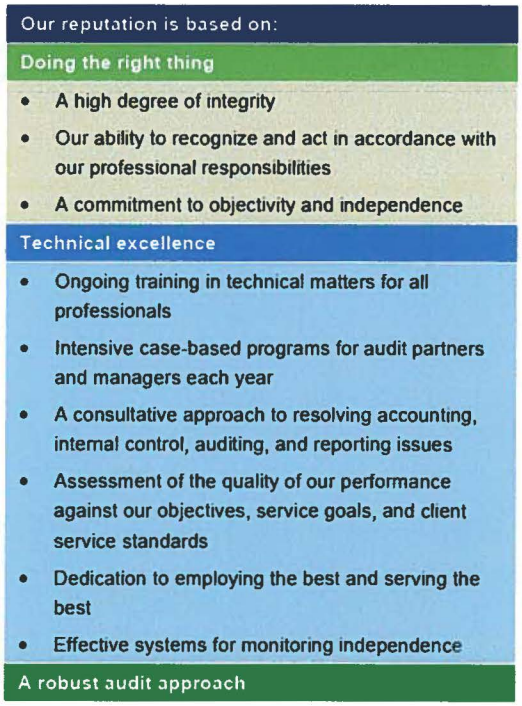
cc: Management of the University of Minnesota

Contents

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 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.



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 2014 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 2015 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 Tom Roos, lead client service partner. Tom is responsible for all services provided to the University and will be supported by a team that includes Jeff Cotton, advisory partner, and Chris Terhark, engagement quality control review partner.

Significant risk areas

Based on our risk-based audit approach and the updated fiscal 2015 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.

The number of inspection comments we received from the PCAOB declined by more than 50 percent during our most recent inspections (2012 and 2013) as compared to 2011. Additionally, in October 2013, the PCAOB communicated to us its determination that the remedial actions we took in response to Part II of our 2009 and 2010 inspection reports addressed the quality control criticisms in those reports to the board's satisfaction (in contrast, portions from 2007 and 2008 were publicly released, as efforts made several years ago in response to those reports were not satisfactory to the PCAOB). These determinations close the inspection cycles for 2009 and 2010 and are further evidence of the substantial progress we have made towards the achievement of our audit quality objectives.

> 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.

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 Tom Roos, lead client service partner. Tom is responsible for all services provided to the University. Tom has extensive experience serving the University, dating back to 1996. Tom 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 Tom for any needs that arise throughout the year.

Jeff Cotton, advisory partner, will work closely with Tom and will serve as a resource to management, the Audit Committee, and our team. In addition to providing advice, insights, and perspectives based on his extensive experience, Jeff 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 Tom's primary consultation resource. When a matter requires review at a higher level, Tom 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 2015 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
- 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, 2015, 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)
- Weisman Art Museum (a unit of the University of Minnesota)
- Department of Concerts and Lectures (Northrop Auditorium) (a unit of the University of Minnesota)

Compliance reports

- Federal Award Programs (Office of Management and Budget Circular A-133)
  - 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 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.
- Plan tests of controls.
- 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:** • Tailored procedures for the University • Direct linkage between identified risks of material misstatement, controls that respond those risks, and substantive testing • Focus on risks of material misstatement and the elimination of testing that offers little additional audit assurance • A risk-based sampling methodology that enables us to perform appropriate audit procedures • 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 Tom 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 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. Tom will guide the upfront planning and execution of the audit, using his deep understanding of your organization, your industry, and the professional literature to drive quality throughout the process. He 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. Tom will guide the engagement team in identifying risks of material misstatement by considering what could go wrong in significant account balances and disclosures. He 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. He will continuously challenge the procedures performed to deliver an effective audit.

Under the leadership of Tom, 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 Committee and management, Tom 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 Committee. We will consult with management and the Audit 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 operating effectiveness 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 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 audit status updates as well as at Audit 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

- Helps us identify opportunities for the University's management to consider refining its assessment of risks and related controls
- Provides insights on industry matters, business issues, and risks that may affect the University

Quality

- Focuses our specialists by identifying and addressing areas of significant risk
- Facilitates the identification of more effective audit methods

Efficiency

- 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 Committee and management of any significant changes.

Execute the audit plan

The performance of the audit plan includes evaluating the design and testing the operating effectiveness of controls and performing substantive audit procedures.

Testing 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 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 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 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 GAAP.

Perform subsequent-events review and obtain management representations

Our subsequent-events review will cover the period from June 30, 2015, 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 Committee prior to report issuance.

Continuous communication and coordination

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

Our coordination plan features:

- Onsite supervision of fieldwork by our international partners
- Regular status meetings conducted by Tom 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, Tom 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.

Tom is responsible for the resolution of all technical matters. Tom has deep experience in dealing with technical matters and has often worked with Deloitte's National Office and has led emerging technical industry matters within the firm. Because issue resolution is an art, not a science, deciding which issues require additional consultation is a key part of Tom's role. When a complex technical matter arises, Tom 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 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. Tom 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 Tom, he will have timely access to Deloitte's most knowledgeable specialists on those occasions when he believes he 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 Tom'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 company'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
Journal Entry Data Analysis Routines (JEDAR)	Exploratory data analysis (JEDAR) used to profile journal entry populations, with the objective of identifying journal entries of interest with respect to management override of controls	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 Connect	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 2015 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 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 Committee and management.

Soon after completing the year-end audit, Tom 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.

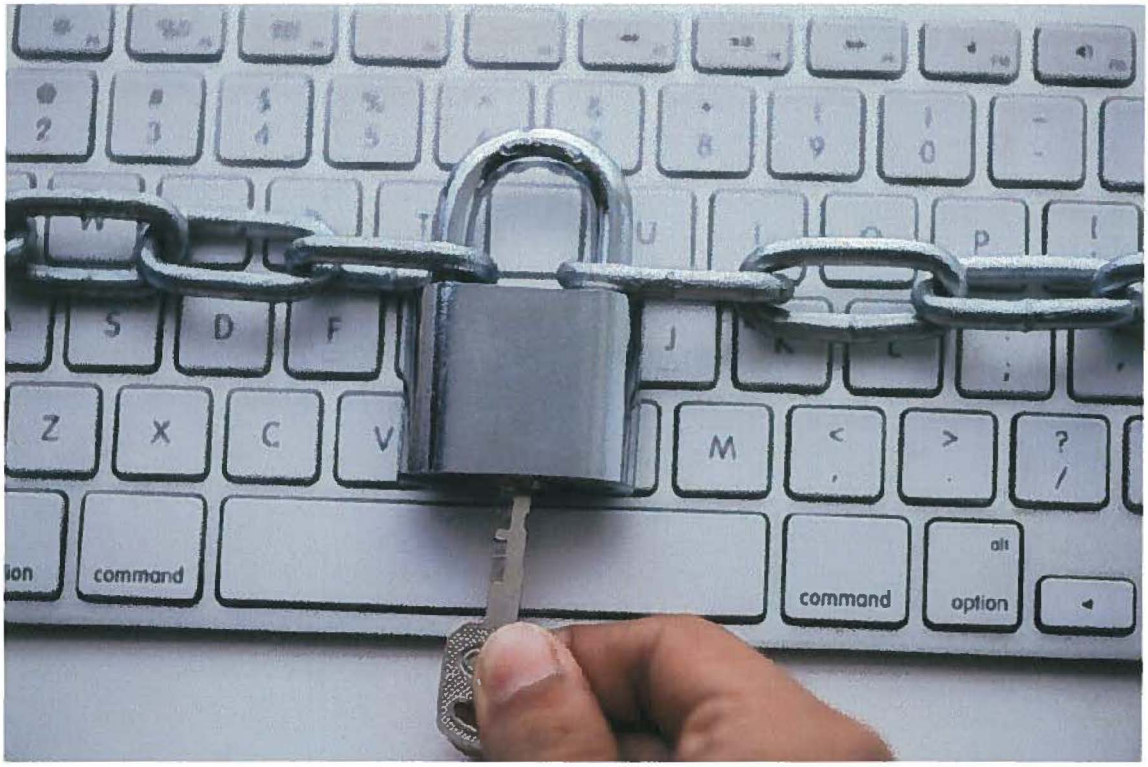
The initial risk assessment will be revisited throughout the audit process. Our monitoring activities are performed in conjunction with our interim review procedures and in our frequent interactions with management. Our team will respond to changes in our risk assessment and implement appropriate audit 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 Committee and management of significant changes to our risk assessment or audit scope as we perform our work.

Areas of audit focus for 2015

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 **Investments (significant risk)**	• Fair value of investments, particularly those that are not readily marketable	• Evaluate management's methodology and process for valuing alternative investments • Test the design and implementation of controls surrounding alternative investments • Review support for the valuation of alternative investments for potential impairment • Confirm alternative investment balances with the fund manager and the record-keeper • Obtain and examine the underlying agreements related to alternative investments • Obtain and review the most recent audited financial statements for the alternative investments • Perform substantive analytical detail procedures to test the fair value measurements from the date of the most recent audited financial statements to June 30, 2015 • Obtain and review the most recent unaudited financial statements for the alternative investments • Consult with Deloitte professionals with specialized knowledge of auditing alternative investments in designing our audit plan and reviewing the results of our audit • Perform audit procedures surrounding the disclosures included in the consolidated financial statements
Long-term debt	• Default by counterparties on SWAP agreements • Existence of debt covenant violations	• Obtain an understanding of all SWAP agreements • Review management's analysis and conclusion on accounting for SWAP agreements • Assess the financial condition of the SWAP counterparties • Confirm long-term debt • Assess compliance with debt covenants
Student, tuition and fees — net **Federal grants and contracts** **Auxiliary enterprises — net**	• Risk of overstatement of student tuition and fees, and other revenues (through premature revenue recognition or recording fictitious revenues) • 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 • 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 • 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 (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 • Obtain an understanding of the business rationale of significant 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 • Test areas of critical management judgment and estimates • Hold discussions regarding the risk of fraud and management override with members of management and the Audit 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 • Assess the system implementation, including that all information was appropriately transferred to the system



Our client service team

Consolidated financial statement audit

Tom Roos—Lead client service partner
Jeff Cotton—Advisory partner
Chris Terhark—Engagement quality control review director
Amy Kroll—Enterprise Risk Services principal
Judi Dockendorf—Audit senior manager
Matt Koktan—Audit manager
TBD—Audit manager (Investments)

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
Matt Koktan—Audit manager

RUMINCO Ltd

Muhammad Khan—Audit partner
Chris Steele—Audit manager

Financial statement audits (Weisman and Northrop)

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

Tom Roos

Partner

Relevant experience

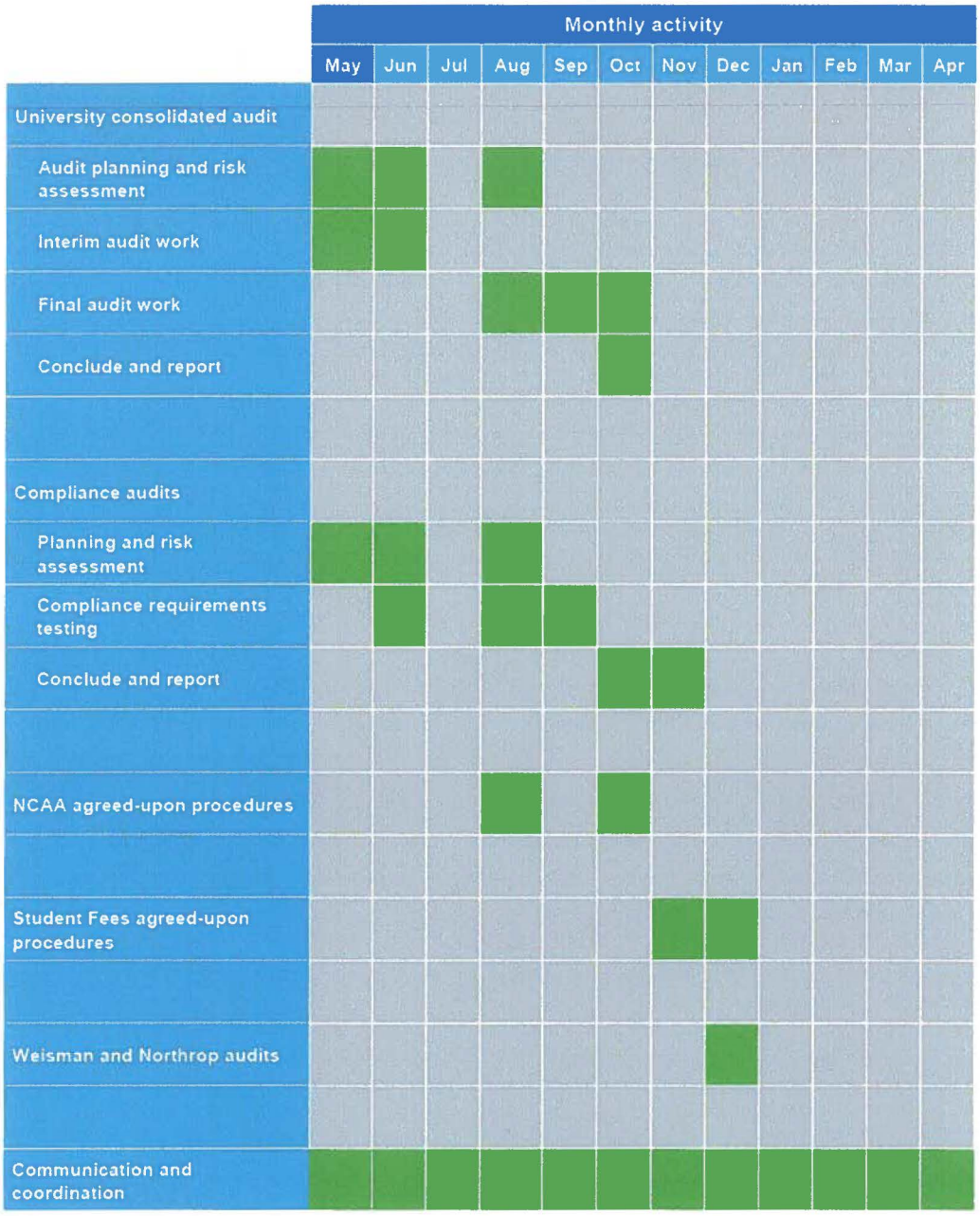
Tom is a partner in our Minneapolis office and has more than 19 years of professional experience, with a focus on serving insurance clients and some of the firm's largest and most complex clients. Tom has worked closely with Deloitte & Touche's national office and industry leaders on emerging technical accounting and reporting matters, and is uniquely qualified to drive accounting matters on his engagements. Tom's has been an industry and technical resource for other Deloitte engagement teams—including his role in our Firm's Health Plan and Insurance industry professional practice and as a health sector partner. Tom also has significant governmental accounting experience, including A-133 audits and audits of internal controls and has over 10 years of auditing experience with the University of Minnesota. Tom has a proven track record of excellence in client service and delivers the firm on each of his engagements.

Tom is also the Central Region United States India (USI) Leader. In this role, Tom works with firm leadership to ensure audit engagements continue to be conducted in an effective and efficient manner. In this role Tom works directly with engagements teams to further deepen USI integration, and provides training and strategy oversight to USI professionals locally.

Tom's clients served include University of Minnesota, Great West Life and Annuity Insurance Company and subsidiaries, UnitedHealth Group and subsidiaries, CUNA Mutual, BCBS of California, Trustmark Companies, Mutual of Omaha, and Capital Safety Group (a KKR portfolio company).

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.



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 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.

Recent accounting and industry matters

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 project is currently under deliberation.

Fair value measurement and application

Final standard (GASB Statement No. 72, Fair Value Measurement and Application) issued in February 2015 and is effective for financial statements for periods beginning after June 15, 2015, and early adoption is permitted. 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 techiques should be consistent with one or more of the following approachs: 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. 72 is applicable for the University for the year ended June 30, 2016.

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

BOARD OF REGENTS
DOCKET ITEM SUMMARY

Audit **May 7, 2015**

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 the following issues:

1. Considerations associated with the recent External Reviews of the University's Human Research Protections Program and the 2004 Café Study;
2. Matters associated with Equal Opportunity and Affirmative Action;
3. Global Programs and Strategy Alliance (GPSA) - New state law requires the reporting of study abroad statistics;
4. HIPAA Security Risk Assessment; and
5. UReport statistics.

Background Information

Under Board of Regents Policy: *Audit Committee Charter,* the Audit Committee is responsible for the oversight of the institutional compliance program. The director last reported to the committee on December 11, 2014.

**REPORT OF THE DIRECTOR, OFFICE OF INSTITUTIONAL COMPLIANCE,
FOR THE AUDIT COMMITTEE OF THE BOARD OF REGENTS
ON THE UNIVERSITY COMPLIANCE PROGRAM
MAY 7, 2015**

INTRODUCTION

This report addresses the following: (1) Considerations Associated With the Recent External Reviews of the University's Human Research Protections Program and the 2004 Café Study; (2) Matters Associated with Equal Opportunity and Affirmative Action; (3) Global Programs and Strategy Alliance (GPSA) - New State Law Requires the Reporting of Study Abroad Statistics; (4) HIPAA Security Risk Assessment; and (5) UReport statistics.

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.

ADDRESSING AND FURTHERING PRESIDENT KALER'S CHARGE TO BECOME A NATIONAL MODEL FOR HUMAN SUBJECTS RESEARCH

On April 8, 2015, President Kaler announced the establishment of an Implementation Team ("the Team") formed for the purpose of advancing the University of Minnesota's Human Subjects Research Protection Program. The President charged the Team with strengthening the University's human subjects research practices, especially those involving people with limited decision making capacity. The President also asked the Team to advance the program to become a national model, meeting the highest standards of ethics and science.

The charge to and efforts undertaken by this Team are extremely important and the Compliance Office is committed to supporting and furthering the recommendations of the Team going forward. This may also be the time for the University to look more broadly across all missions of the institution, and re-evaluate its focus on ethics in the context of all of its core missions. The Code of Conduct ("Code") may be the place to start because it speaks to the values of the institution, guides day to day decision making, and establishes expectations. The University has three codes of conduct – one that applies to the members of the Board of Regents, one that applies to students, and a third that applies to employees. The focus, for the purposes of this report, is on the Code that applies to employees. That Code was adopted in 1996 in response to a request made by the National Institutes of Health to develop a code following a federal investigation into alleged research misconduct at that time. The Code was last revised in 2006.

The Code states the values of the University through the following ten standards intended to advance the mission of the University and its culture:

- Act Ethically and with Integrity
- Be Fair and Respectful to Others
- Manage Responsibly
- Protect and Preserve University Resources
- Promote a Culture of Compliance
- Preserve Academic Freedom and Meet Academic Responsibilities
- Ethically Conduct Teaching and Research
- Avoid Conflicts of Interest and Commitment
- Carefully Manage Public, Private, and Confidential information
- Promote Health and Safety in the Workplace

The Office of Internal Audit conducted a review of the University's Code of Conduct in 2012. Part of that review involved benchmarking the University's Code against sixteen other institutions of higher education. As the December 2012 Audit Report, titled *University of Minnesota – A review of the Employee Code of Conduct Policy* ("Audit Report"), states, when compared to the Codes of other institutions of higher education, the University's Code is one of the most comprehensive and well written. The audit report also notes that the Code of Conduct is communicated to the University community in numerous ways, including through:

- A video viewed by attendees at New Employee Orientation that provides specific examples of how the Code is applied in the day to day activities of the University;
- Financial training course materials;
- The "Education in the Responsible Conduct of Research" curriculum developed and implemented by the Office of the Vice President for Research;
- The Conflict of Interest Program website;
- The Office of Human Resources online "Managers' Toolkit" in a section titled "Onboarding New Employees"; and
- Provisions in certain contracts the University enters into that require strict adherence to the Code.

The audit report notes, however, that there are several opportunities to expand communications regarding the Code and to make it applicable to the roles carried out on a daily basis by both faculty and staff. Some opportunities have already been implemented. Among the options to consider that have not yet been implemented are the following:

- including a question regarding the Code in engagement surveys;
- requiring training of all new employees that would include reference to the Code (currently, participation in New Employee Orientation is voluntary);
- requiring reference to the applicable provisions of the Code in all required post-onboarding training;
- developing an awareness campaign that utilizes a variety of messaging approaches; and
- referencing the Code of Conduct in University communications, to either focus on those activities and achievements that reflect the highest values of the institution and, conversely, to reflect on the missteps that reflect a departure from the University's espoused values.

It may be appropriate for the Compliance Director to convene a group of senior leaders to address these issues and define the course of action going forward.

It may also be appropriate for the same, or another convened committee of University's leaders, to address the current breadth of the UReport system. That scope currently is limited to violations of law and policy. It does not include ethical issues. In this context it is important to note that a significant percentage of the individuals who use this reporting system prefer to report anonymously, likely concerned that there would be negative consequences for them should the individuals to whom they report learn that they lodged a report in the UReport system. Given the President's charge, this may also be the time to determine whether the UReport system ought to be expanded to address ethical issues and provide guidance about how such claims might be evaluated and by whom.

Efforts on some of the Audit Report recommendations are already underway. The Compliance Office is currently coordinating efforts with University Relations to develop an awareness campaign to:

- ensure that all faculty and staff are aware of the University's confidential reporting system (UReport);
- reaffirm the University's commitment to ensure that faculty and staff who submit reports to UReport are protected from retaliation; and
- reaffirm the values articulated in the University's Code of Conduct.

In addition to efforts to communicate the University's values across the institution, the Compliance Office is currently partnering with the Office of Information Technology, as a result of a charge from the Executive

Oversight Compliance Committee to gather information regarding current training offerings throughout the University and determine the infrastructure needed to ensure that all faculty and staff are adequately educated/trained for their respective responsibilities. All such training should also reference the relevant provisions of the Code. This training initiative is also relevant to President Kaler's recent charge.

As a final reflection on these issues, it may be beneficial to determine the scope of the role of the Office of Institutional Compliance. The University's compliance program differs from those implemented by its counterparts at Penn State, Purdue, the University of Illinois, and Ohio State University. Each of these institutions combines compliance and ethics. This distinction is reflected in the names of their offices and the titles of the individuals charged with these combined roles. It has been said that ethics and compliance are the opposite sides of the same coin. State, local, and federal laws and regulations define compliance for us, namely what we must do and what we cannot do. However, "ethics" speak to the core values of the institution.

MATTERS FALLING WITHIN THE SCOPE OF EQUAL OPPORTUNITY AND AFFIRMATIVE ACTION

ALLEGED VIOLATION OF TITLE IX

The Audit Committee of the Board of Regents has previously been advised by the General Counsel of the Title IX investigation initiated by the Department of Education's Office of Civil Rights (OCR) in mid-December 2014. The complaint likely emanates from concerns about the track that is no longer useable for competition by either men or women in track and field athletics. The track has not been competition-worthy for a decade. It is likely the investigation emanates from concerns about the elimination of the practice track facility as part of the Athletes Village project. The scope of the investigation is very broad. OCR has requested that the University provide information in thirty two different categories. Some of the requests are for information dating back to 1972. The breadth is significant as the examples below reflect:

- A list of all teams in the intercollegiate athletic program, the athletic conference in which each team is a member, the division level at which each team competes, and the number of participants of each sex who were/are on each team.
- A copy of any intercollegiate athletic gender equity studies conducted at the university since 1972. Also provide a copy of all reports prepared since 1972 by any University component, such as the Office of the President, the Board of Trustees, the Athletic Department, the Student Government Association, or an intercollegiate athletic committee, that discuss actual or possible growth and/or contraction of the men's or the women's intercollegiate athletic program; or actual or contemplated changes in division level or conference affiliation for any sport.
- A copy of all written requests and a summary of all verbal requests made to the University since 1972, if any, by any individual or group to expand the men's or the women' intercollegiate athletes program through the addition of new sports or teams or through the expansion of existing teams, a description of the University's response to each request and the rationale for each response.

As of the date of this report, the matter remains pending. We expect that OCR reviewers will be on campus in early May and again in early June.

NEW REQUIREMENTS UNDER THE CLERY AND THE VIOLENCE AGAINST WOMEN ACTS

The Department of Education issued regulations on October 10, 2014, to implement the changes made to the Clery Act as a result passage of the Violence Against Women Reauthorization Act of 2013. The deadline for achieving full compliance with the new regulations is July 1, 2015. The investigation of all sexual assaults will be centralized in the Office of Equal Opportunity and Affirmative Action (EOAA) which will coordinate efforts with the University of Minnesota Police Department as appropriate, and will coordinate efforts with the Office for Student Conduct and Academic Integrity when students are involved.

Given the changes in the law, new training is also required. The University has purchased a new training curriculum to meet this need. In addition, the Office of the General Counsel has convened a work group with

representation from all campuses, Student Conduct and Academic Integrity, Residential Life, EOAA, the Office of Human Resources, the Office for Student Affairs, the Aurora Center, the University of Minnesota Police Department, and the Office of Institutional Compliance for the purpose of ensuring that each campus becomes compliant with all of the new requirements.

GLOBAL PROGRAMS AND STRATEGY ALLIANCE (GPSA)

NEW STATE LAW REQUIRES STUDY ABROAD PROGRAMS TO SUBMIT HEALTH AND SAFETY STATISTICS TO THE MINNESOTA OFFICE OF HIGHER EDUCATION

In 2014, the Minnesota Legislature passed legislation requiring postsecondary institutions to report on the health and safety of study abroad participants and directing the Minnesota Office of Higher Education (OHE) to determine the appropriate state regulation of postsecondary study abroad programs. According to the Institute of International Education, nearly 300,000 American students studied abroad during the 2012-13 academic year.

The law passed by the Minnesota Legislature requires Minnesota Postsecondary institutions to report:

- accidents or illnesses that occurred during program participation and required hospitalization;
- deaths of program participants that occurred during program participation as a result of program participation; and
- whether institutions' study abroad programs comply with health and safety standards set by the Forum on Education Abroad or a similar agency.

The first reporting period covers the timeframe August 1, 2014 to July 31, 2015, with the submission of data due to the state required by November 1, 2015. OHE anticipates that the data will be made publicly available by January 1, 2016. Staff of the University's Office of Global Programs and Strategy Alliance has taken a leadership role in responding to this issue, not only on behalf of the University, but by also coordinating efforts with other State of Minnesota institutions of higher education.

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) SECURITY RISK ASSESSMENT

The Director's December 2014 report addressed the requirement imposed by the Office for Civil Rights (OCR) within the Department of Health and Human Services to conduct periodic risk assessments and that the University had selected Deloitte & Touche LLP (Deloitte) to conduct a risk assessment last fall.

The risk assessment covered the following eighteen University components:

- School of Dentistry and Dental Clinics
- University's Health Plan
- Boynton Health Services & Related Health Plans
- University of Minnesota Duluth Health Services
- Community-University Health Care Center
- Julia M. Davis Speech Language Hearing Center
- Medical Schools (Twin Cities and Duluth campus)
- School of Nursing and Faculty Practices
- College of Pharmacy and Faculty Practices
- Academic Health Centers and Institutes
- Academic Health Center Administrative Shared Services
- Academic Health Center Information Systems
- Internal Audit
- Office of the General Counsel
- Office of Institutional Compliance
- Office of Information Technology – Information Security
- Office of Measurement Services
- Athletic Training

On March 23, 2015, Deloitte presented the results of the HIPAA Security Risk Assessment. For the purposes of the risk assessment, Deloitte established an assessment framework built upon the requirements of the HIPAA Security Rule and augmented with relevant industry standards. Observations and recommendations were made in the following thirteen security categories:

- Access and Authorization
- Workstation Security
- Security Training and Awareness
- Information Security Governance, Risk Management and Compliance
- Account Management
- System Audit Logging and Monitoring
- Security Incident Management
- Device and Media Controls
- Data Encryption
- Transmission and Network Security
- Contingency Planning and Disaster Recovery
- Physical Security
- Business Associates/Third-Party Risk Management

Deloitte developed reports for each of the eighteen University components addressing the above categories, and also provided an overall report for the entire University addressing the same. In its communications with University staff upon the completion of its risk assessment, Deloitte representatives recommended that the University consider its recommendations as an approach to minimizing risk associated with data security and HIPAA compliance. Overall recommendations identified in the report for the University focused on developing a more centralized approach to security and risk management, and included (i) enhancing existing security governance, risk management and compliance efforts to ensure they extend to all individual University components; (ii) coordinating University logging, monitoring and threat management activities to ensure all critical applications are covered; (iii) coordinating data protection processes and technology across all University components; and (iv) establishing a coordinated disaster recovery/resilience program across all University components. The Office of Health Information Privacy & Compliance and OIT are coordinating efforts to address the recommendations, and a task force is being convened to help drive those efforts.

UREPORT STATISTICS FOR THE PERIOD MAY 1 2014 THROUGH APRIL 15, 2015

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 involved legal or policy violations that involve purely student concerns, except with respect to Medical School students, or issues for which the University is not responsible. 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.

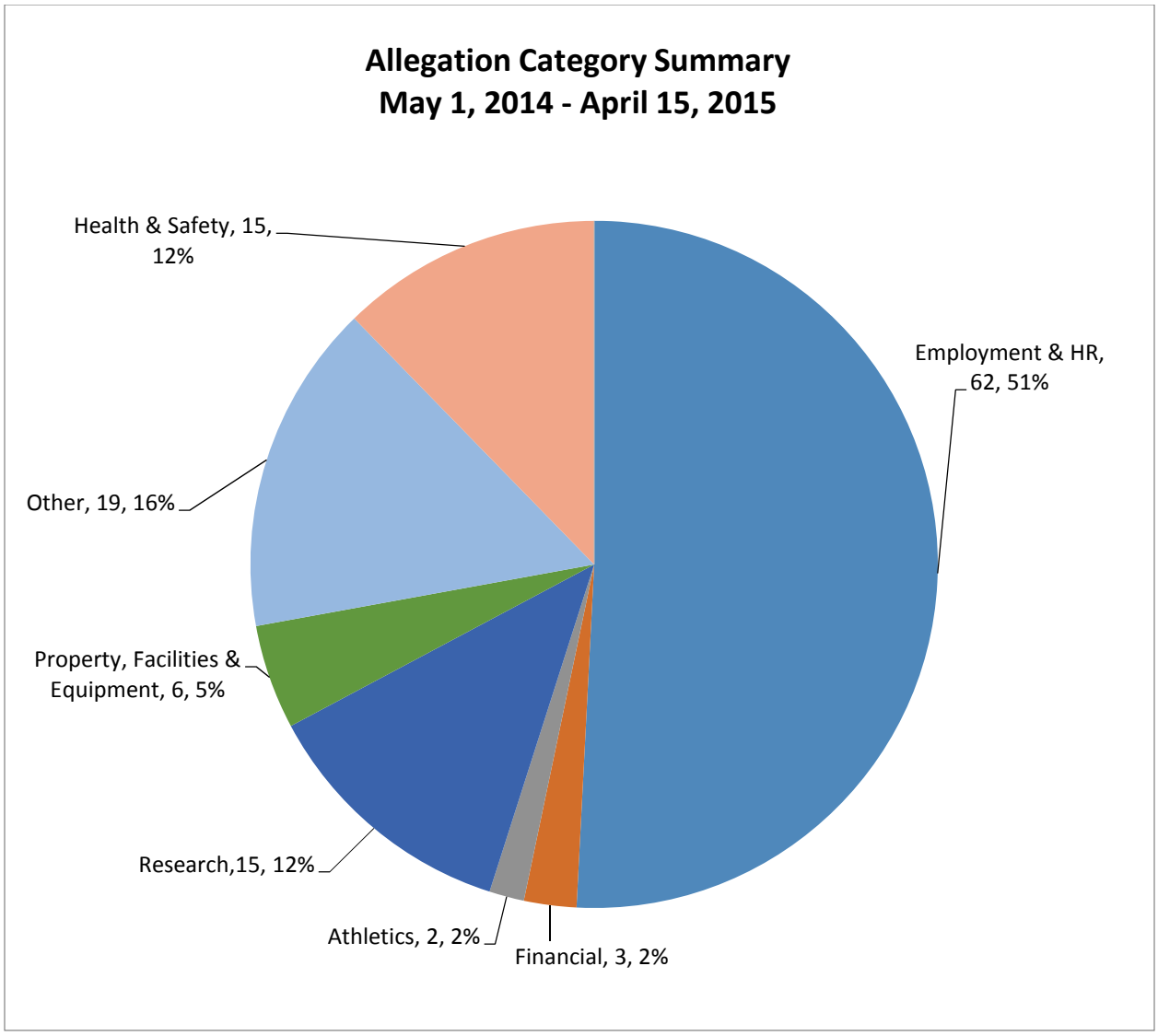
UReport has been in existence at the University since 2005. Since its inception, a total of 1334 reports have been submitted, averaging approximately 130 per year. During the 12 month period, May 1, 2014 through April 15, 123 reports were submitted. Seventy six percent of the reports were anonymous. Eighty four of the reports involved alleged misconduct by faculty and/or staff on the Twin Cities campus. 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

Seventy- -six percent of the reports were received via the internet. Forty three percent of anonymous reporters and fifty-seven percent of non-anonymous reporters checked back to determine the status of the follow up conducted regarding the concerns they have described. The graphs below illustrate these figures.

Issue		Running Total from Launch (August 2005)	May 1, 2014 to April 15, 2015
Total Reports		1334	123
Report Sources:			
	Internet	86%	76%
	Call Center	14%	24%
	Other	<1%	0%
% Anonymous		74%	76%
Reporter “check back rate” for anonymous reports		54%	43%
Reporter “check back rate” for non-anonymous reports		41%	57%
Percentage Substantiated (reflects that an individual was coached, counselled, or disciplined)			35%

At the request of the Medical School, the Office of Institutional Compliance, after consulting with the EOAA Office and the Office of Student Conduct, recently added Medical School students to the scope of individuals who may access this system to raise concerns regarding perceived violations of law or University policy. We anticipate that a substantial percentage of the reports submitted by Medical School students will involve matters that fall within the scope of the Office of Equal Opportunity and Affirmative Action (EOAA). When those circumstances arise, EOAA and Medical School staff will coordinate their respective efforts. During this reporting period, one UReport was submitted by a Medical School Student.


Allegation Category Summary
May 1, 2014 - April 15, 2015
Health & Safety, 15, 12%
Employment & HR, 62, 51%
Other, 19, 16%
Property, Facilities & Equipment, 6, 5%
Research,15, 12%
Athletics, 2, 2%
Financial, 3, 2%

BOARD OF REGENTS
DOCKET ITEM SUMMARY

Audit **May 7, 2015**

Agenda Item: Institutional Review Board Primer

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

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

Presenters: Brian Herman, Vice President for Research
Debra Dykhuis, Executive Director, Human Research Protection Program

Purpose & Key Points

The purpose of this presentation is to provide Regents with a primer on the review and approval process for clinical research that involves human subjects. The presentation will focus specifically on how research projects are reviewed, assessed, approved or not approved. Key points will include:

- Understanding the roles and accountabilities of the investigator;
- The role of the University and the Institutional Review Board (IRB);
- Processes and procedures;
- History of human subjects research and the evolution of protections;
- Involved authorities and resources; and
- The current level of review activity happening at the University.

The presentation will also provide an overview of IRB responsibilities and approval criteria, informed consent procedures, review of research that involves vulnerable subjects, and risk and review levels.

Background Information

The Board of Regents adopted the *Resolution Related to Improving the Conduct of Human Subjects Research* on March 27, 2015 that charged the Audit Committee with ongoing oversight and monitoring of the implementation of recommendations made by the independent external review of current human subject research practices. Further, it directed the Audit Committee to evaluate the implementation plan and receive regular progress reports on the implementation of the recommendations.

Institutional Review Board

The University of Minnesota IRB reviews research projects that involve human subjects to uphold two broad standards: first, that subjects are not placed at undue risk; second, that they give uncoerced, informed consent to their participation. With representation from a wide range of scientific disciplines and from outside the academic community, the IRB gives prompt but individualized attention to the numerous research projects at the university.

By the Numbers

IRB Membership

IRB	Total Members	Faculty Members
Biomedical	41	17
Faculty Social & Behavioral	19	9
Student Social & Behavioral	14	4

Staff

Human Research Protection Program
HRPP has **22 employees** and 3 open positions**.**

2014 IRB Statistics

Items Submitted for Review		Active Protocols		Types of Research	
Total received	**9,959**	**Total number**	**11,707**	Exempt	41%
Expedited	5,739	- Expedited	3,307	Biomedical	32%
Full committee	2,214	- Full committee	1,593	Social behavioral	27%
Exempt	1,231	- Exempt	6,807		

Post-Approval Review

What is Post-Approval Review (PAR)?

- Provides internal oversight on compliance issues associated with the performance of human subjects research conducted at the university. It also provides a mechanism for assuring the quality of human subjects' research by supplementing existing HRPP quality improvement and educational initiatives
- Takes a collaborative review approach with the common goal of protecting human research subjects.
- Is often referred to as "*The eyes and ears of the IRB.*"

What are its primary goals?

- Ensure human subjects are being included in research according to the IRB approved protocol
- Ensure regulatory compliance
- Act as a resource to the research community
- Identify areas for improvement and education

Who is involved?

- PAR staff
- IRB members

- Researchers and researcher staff
- Research subjects

What is reviewed and how?

- Any active IRB study
- Reviews are primarily conducted via site visit, records review and PI self-assessment

What's the typical process and follow-up?

- PI's will be contacted and a visit scheduled
- Staff visit the PI and review study materials (regulatory binder, subject consent forms, relevant source documents)
- Findings/observations are documented in a report to the IRB
- IRB reviews the report and identifies issues requiring PI follow-up
- PAR staff communicate requirements to PI and when non-compliance is identified
- Follow-up includes a variety of mechanisms including
    - Training and education
    - Focus on corrective and preventive measures
    - Abbreviated review periods or additional monitoring visits

Why does PAR exist?

- Referenced in the Common Rule & FDA Regulations
    - *An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.*
- AAHRPP Accreditation Standards
- Terms of the federal-wide assurance

Definitions

Exempt Research
Research activities in which the only involvement of human subjects is in one or more of a set of identified categories are exempt.

Example categories: Research conducted in an educational setting or involving the use of educational tests; research involving the collection of existing data, documents or specimens; taste and food quality evaluation and consumer acceptance studies.

Expedited Review
Research activities that present no more than minimal risk to human subjects and meet certain criteria may be eligible for expedited IRB review.

Example categories: Clinical studies of drugs and medical devices under certain conditions; collection of biological specimens by noninvasive means; research involving materials that have been collected for non-research purposes; research on individual or group characteristics or behavior or research employing survey, interview, oral history or other methods.

Full Committee Review
Research that cannot meet the criteria for exempt or expedited review must be submitted for full committee review.

Criteria for IRB Approval

Adapted from 21 CFR 56.111 (FDA) & 45 CFR 46.111 (DHHS)

1. **Risks to subjects are minimized**

   A. Procedures are consistent with sound research design and do not unnecessarily expose subjects to risk.
   B. Whenever appropriate, procedures are already being performed on subjects for diagnostic or treatment purposes.

2. **Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result**

   A. Consider only those risks and benefits that may result from the research (as opposed to the r/b of therapies that subjects would receive even if not participating in the research).
   B. Do not consider the possible long range effects of applying knowledge gained in research (example: the possible effects on policy) as among those research risks that fall within the purview of its responsibility.

3. **Selection of subjects is equitable**

   A. Take into account the purposes of the research and the setting in which the research will be conducted.
   B. Be aware of the special problems associated with research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

4. **Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with 21 CFR 50 and/or 45 CFR 46.116.**

5. **Informed consent will be appropriately documented, in accordance with 21 CFR 50.27 and/or 45 CFR 46.117.**

6. **Where appropriate, research plans make adequate provisions for monitoring the data collected to ensure the safety of subjects.**

7. **Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain confidentiality of data.**

Additional Requirements Specific to the Criteria for IRB Approval

- When some or all of the subjects, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons, are likely to be vulnerable to coercion or undue influence, confirm additional safeguards have been included in the study to protect the rights and welfare of these subjects. Confirm appropriate expertise is available to assess the adequacy of these safeguards.

- If children are enrolled as subjects in FDA regulated research, that research is compliant with 21 CFR 50, subpart D.

Additional Information & Policies

(The following is not an exhaustive list of all IRB review requirements and/or considerations.)

Upon review of the study, the IRB must:

- Confirm the manner and acceptance of scientific assessment.
- Confirm that the proposed plan for monitoring safety should be commensurate with the nature, size, and complexity of the research as well as the degree of risk involved.
- Determine If research requires compliance with ICH-GCP E6.
- Confirm appropriate expertise is available to ascertain the acceptability of the proposed research.
- Discuss and document the rationale for requiring changes to or disapproving research

Identifying IRB member conflicts of interest:

- A conflict of interest exists for a particular research protocol when an IRB panel member or consultant, or a family member of the IRB panel member or consultant: Is an investigator or other member of the research team conducting the research
- Supervises or is supervised by an investigator on the protocol
- Holds a significant financial interest in the business entity sponsoring the research; and/or
- Holds a business interest in the business entity sponsoring the research and the panel member has
  - a proprietary interest in the research, such as a patent, trademark, copyright, or licensing agreement
  - any other interest the IRB member or consultant believes conflicts with the ability to objectively review the protocol.

Other circumstances that could pose a conflict of interest for a panel member or consultant include, but are not limited to:

- Holding a close personal relationship with an investigator
- Participation in a potentially competing research program or study, and
- Personal biases that may interfere with the exercise of impartial judgment.

Minnesota State Laws that Affect Research

The research community is expected to follow all state or local regulations or laws when conducting research with human subjects. Please see IRB policy 403C for more information regarding the following Minnesota statutes:

- Reporting Requirements (Minnesota Statute 626.556 and 626.557)
- Parental Consent for Minors (Minnesota Statutes 144.341 347, and 524.5- 207)
- Consent by Minors (Minnesota Statute 144.341,342, 343, 344, and 253B.03)
- Consent for Incompetent Adults (Minnesota Statute 524.5-313, 144.291, 13.384)
- Clinical Drug Trials and Inclusion of Persons who are in the process of Commitment (Minnesota

Statute 253B.095 Subdivision 1)

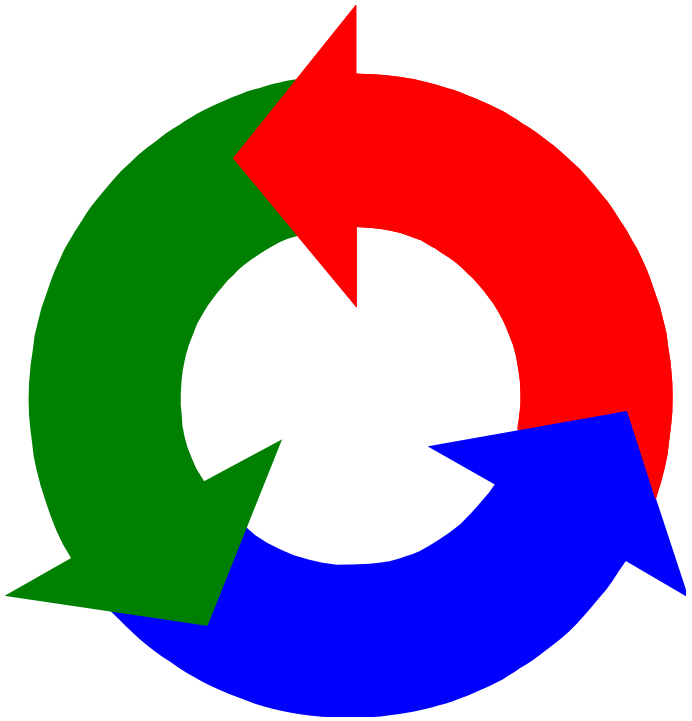
- Labeling of Investigational Drugs (Minnesota Statute 151.212 subdivision 1; Minnesota Rule 6800.3400, subpart 1)
- Disclosure of Health Records for External Research (Minnesota Statute 144. 295)
- Gifts to Researchers (Minnesota Statute 151.461)
- Patients' Bill of Rights (Minnesota Statute 144.651, subdivision 13)
- Minnesota Genetic Privacy Act (Minnesota Statute 13.386)

The Review and Approval Process for Human Subjects Research

Debra Dykhuis, Director
Human Research Protection Program

Human Subjects Protection is a Shared Responsibility

IRB



Investigator/ Researcher

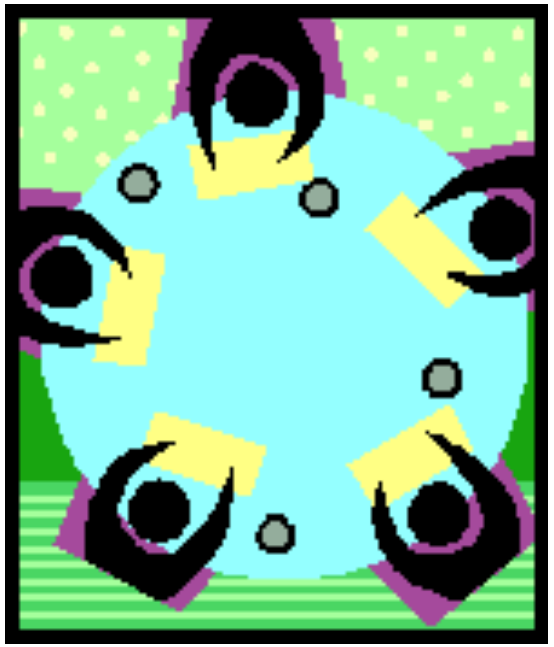
Institution

What does an IRB do with a Protocol?

- Approve, disapprove or modify
- Conduct continuing review
- May observe or perform additional review
- May suspend or terminate approval

Institutional Review Board (IRB)

- Four boards at U of M
- Minimum of five people required at each meeting
  - Technical experts on the types of research under review
  - Non-scientific member
  - Non-affiliated community representatives



Components of Initial Human Subjects Review

- Institutional requirements
- Fairview requirements
- Scientific review
- Researcher education and training
- Conflict of interest management
- Bio safety review
- Regulatory status of investigational products
- Grants and contracts
- Communication with prospective subjects/participants

Federal Regulations and Policy

45 CFR 46 – DHHS Policy for Protection of Human Research Subjects- Subpart A

"The Common Rule" – Federal Policy for Protection of Human Subjects – applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any federal department or agency which makes the policy applicable to such research.

Federal Regulations and Policy

Additional Protections Included in 45 CFR 46:

- **Subpart B -** Additional DHHS protections pertaining to research, development, and related activities involving pregnant women, fetuses and neonates (non-viable and those of uncertain viability)
- **Subpart C -** Additional DHHS protections pertaining to biomedical and behavioral research involving prisoners as subjects
- **Subpart D** - Additional DHHS protections for children involved as subjects in research
- There is no subpart providing additional DHHS protections for vulnerable adults

Federal Regulations and Policy

FDA

U.S. Department of Health and Human Services
Food and Drug Administration

Authority

- Federal Food, Drug, and Cosmetic Act (1962)

Regulations

- IRB: 21 CFR 56
- Informed Consent: 21 CFR 50
- Investigational Drugs: 21 CFR 312
- Investigational Devices: 21 CFR 812

Other Relevant Authorities

- Privacy regulations (HIPAA)
- FERPA and PPRA (education research)
- Applicable state laws pertaining to research, research subjects, records, privacy, etc.
- Institutional policies and codes
- Professional associations and licensure requirements

Belmont Report

- The Belmont Report (1974) summarizes three basic ethical principles relevant to research involving human subjects.
  - Respect for persons
  - Beneficence
  - Justice

IRB Responsibilities 46.109

- Review and approve, require modifications or disapprove all *covered* research
- Require that informed consent is in accordance with regulations
- Require documentation of informed consent or may waive documentation in accordance with regulations
- Notify investigators in writing of decisions
- Conduct continuing review of research no less than once per year

IRB Risk Responsibilities

- Identify risks
- Determine that risks are minimized
- Determine that “risks to subjects are reasonable in relation to anticipated benefits”
- Determine that subjects are adequately informed about “any reasonably foreseeable risks or discomforts”

Criteria for IRB Approval

46.111

- Risks to subjects are minimized
- Risks are reasonable in relation to anticipated benefits
- Selection of subjects is equitable
- Informed consent is sought from each subject
- Informed consent is appropriately documented

When appropriate

- data collection is monitored to ensure subject safety
- privacy and confidentiality of subjects is protected
- additional safeguards are included for vulnerable populations

Criteria for IRB Approval

46.111

BENEFICENCE

Risk/Benefit analysis
Data safety
Experimental design
Qualifications of PI

JUSTICE

Subject selection
Inclusion/exclusion
Recruitment

RESPECT FOR PERSONS

Informed consent
Surrogate consent
Assent

Privacy & Confidentiality
Vulnerable populations

Respect for Persons

- Individuals should be treated as autonomous agents
- The investigator must ensure that the subject has received a full disclosure of the nature of the study, the risks, benefits and alternatives, with an extended opportunity to ask questions.
- Persons with diminished autonomy are entitled to protection
- Persons with diminished autonomy (e.g., prisoners, students, children, etc) should not be coerced to participate in a research

Beneficence

- Maximize possible benefits and minimize possible harms
- The investigator should give forethought to the maximization of benefits and the reduction of risk that might occur from the research

Justice

- Fairness in distribution
- Justice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly
- Equitable selection of participants

Informed Consent

- Consent process should empower subjects to make their own determination about risk
- Risks should be explained in terms to which the subjects can relate - everyday life experiences
- Vulnerable subjects consent especially complicated with little federal regulation
- Main focus of external review panel and OLA reports

Informed Consent Basic Elements

46.116(a)

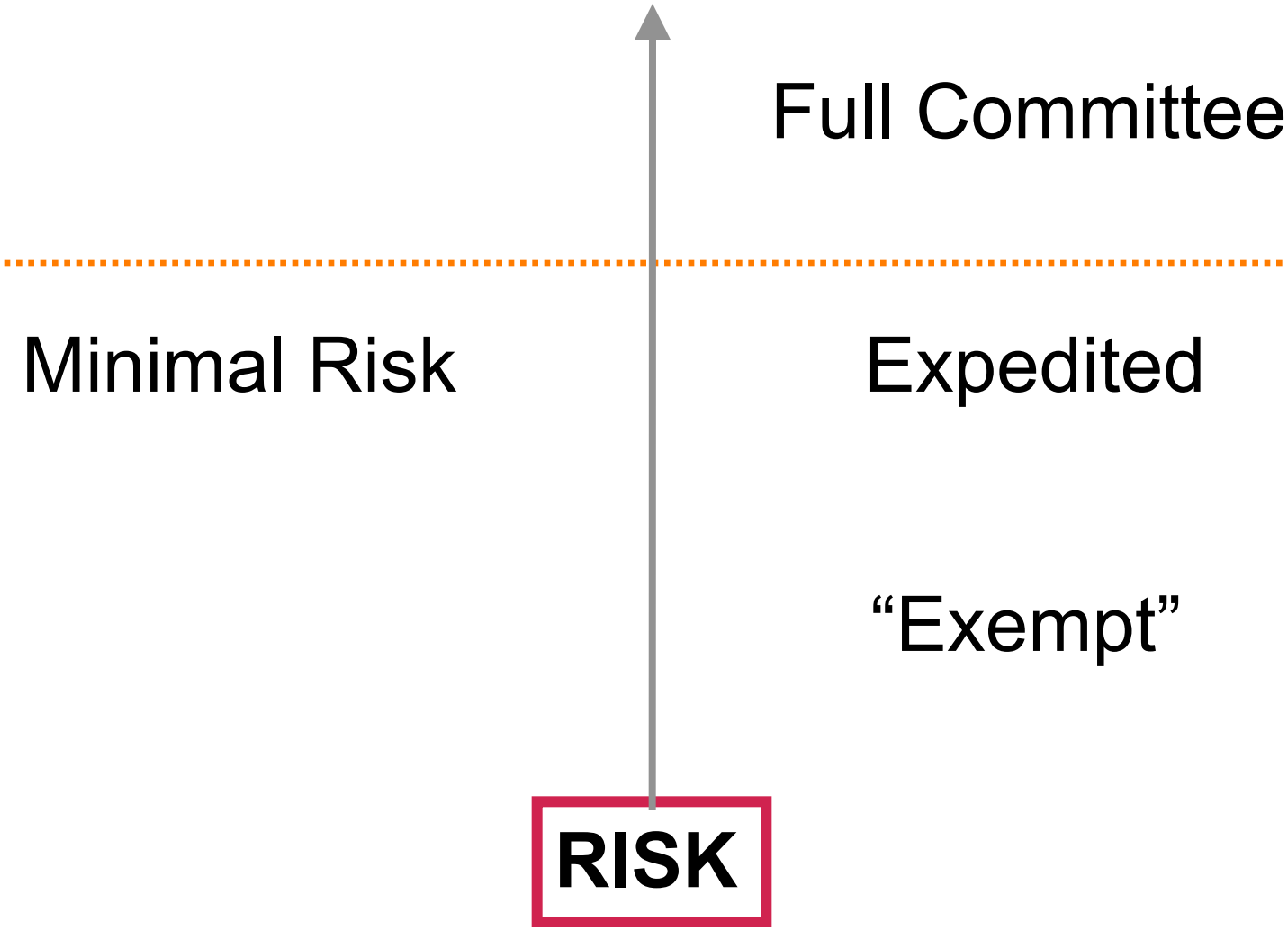
- Research
  - Purpose/Duration
  - Procedures
  - Experimental
- Risks
- Benefits
- Alternatives

- Confidentiality
- Compensation for injury
- Whom to contact
- Right to refuse or withdraw

Informed Consent Additional Elements 46.116(b)

- Currently unforeseeable risks
- Termination of participation
- Additional costs to subjects
- Consequence of withdrawal
- Informing of new findings
- Number of subjects

Level of Risk Determines Level of Review



Vulnerable Populations

- Cognitive vulnerability
- Institutional vulnerability
- Deferential vulnerability
- Medical vulnerability
- Economic vulnerability
- Social vulnerability

Continuing Review

An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, ***but not less than once per year***, and shall have authority to observe or have a third party observe the consent process and the research.

21 CFR 56.109

45 CFR 46.109

Components of Post-Approval Human Subjects Review

- Change in protocol
- Add/remove personnel
- Add/remove funding
- Reportable events
- Continuing/continuous review
  - Post approval monitoring
- Study inactivation

IRB Report Form

UNIVERSITY OF MINNESOTA

Report Form

For the prompt submission of information to the IRB

Submission instructions:

Use this form to report events, including Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSO), which fit the definition of promptly reportable events. See section 1 below for description of events that require prompt reporting. The IRB defines "prompt" to be **within 5 business days** of discovery of the event. See the Reporting Unanticipated Problems webpage for additional guidance

If an event does not meet the criteria outlined below, report it to the IRB in summary form, using a table or spreadsheet, at the time of continuing review. A spreadsheet template is available in the templates section of the IRB forms page

This section for IRB use only

Electronic Submission (preferred):
Submit to: irb@umn.edu
PI must submit request using University of Minnesota e-mail Account.

U.S. Mail Address:
Human Research Protection Program
MMC 820
420 Delaware St. SE
Minneapolis, MN 55455-0392

For more information please visit our website
http://www.research.umn.edu/irb/index.html
Contact our office
Phone: 612-626-5654
Email: irb@umn.edu
Fax: 612-626-6061

IRB Protocol Information

IRB Study Number:	
Principal Investigator:	
Primary Study Title:	
Report Date:	(reference this date on all subsequent submissions including Changes in Protocol related to this event)

Section 1 Reportable Events - Report Type

Events listed below require prompt reporting to the IRB. Indicate the type of information the PI is reporting.

- ☐ Unexpected death of a locally enrolled subject whether considered related to the research or not. Death is considered unexpected if the risk of death is not listed in the consent form or is not listed in the Investigator's Brochure.
- ☐ New or increased risk (For example, publications indicating a new risk, new risk in an investigator brochure, FDA black box warning, new risk identified in a data safety monitoring report, information or change that adversely affects subject safety, or information or change that adversely affects the conduct of the research)
- ☐ Adverse events or safety reports that indicate a potential increase in risk or reduction of benefit (such as those that may prompt a change to the protocol or consent form)
- ☐ Protocol deviation due to the action or inaction of the investigator or research staff
  Those deviations that do NOT affect the scientific soundness of the research plans or the rights, safety or welfare of human subjects can be reported at the time of continuing review.
- ☐ Protocol deviation that harmed a subject or placed subject at risk of harm
- ☐ Protocol deviation made without prior IRB approval to eliminate an immediate hazard to a subject

- ☐ Audit, inspection, or inquiry by a federal agency
- ☐ Written reports of federal agencies (e.g., FDA Form 483)
- ☐ Written reports of study monitors, Data Safety Monitoring Board reports or other sponsor reports (e.g. FDA non-approval letters).
- ☐ Allegation of investigator or study team noncompliance or finding of investigator or study team noncompliance
- ☐ Unauthorized disclosure of confidential information
- ☐ Unresolved subject complaint
- ☐ Suspension or premature termination by the sponsor, investigator, institution or other IRB
- ☐ Incarceration of a subject enrolled in a research study not approved to involve prisoners
  Complete Appendix C "Research including Prisoners" and submit with this report form
- ☐ State medical board or hospital medical staff actions
- ☐ Unanticipated adverse device effect
- ☐ Other information that the PI determines is related to the research and indicates that participants or others might be at increased risk of harm; or that may affect a subject's willingness to continue to participate.

Section 2 Summary of Event/Report

Provide all relevant details of the event.

2.1 Describe the problem/event/report.

Include in the summary the nature and severity of the problem

☐ **This submission includes a report that does not communicate a potential new or increased risk to subjects or others. Go to Section 3 - Attachments. Do not check this box if reporting a protocol deviation or complaint.**

2.2 Date event occurred:

Date event was discovered/report received:

If reporting outside of the required reporting time, explain why the delay occurred and how prompt reporting will be assured in the future.

2.3 Where did this event occur?

☐ **on-site (UMN/Fairview/Gillette PI oversight)** ☐ **off-site (under oversight of PI at another institution/site)**

2.4 Indicate whether this is an initial or follow up report.

☐ **initial**

☐ **follow up - date of initial report:**

IRB Report Form

2.5 Indicate below which criteria of the regulatory definition [45 CFR 46.103(b) (5) and 21 CFR 56.108(b) (1)]of Unanticipated Problem Involving Risks to Subjects or Others (UPIRTSO) are met by this event:

Is the problem/event unanticipated? Unanticipated problems/events are those that are *not* already described as potential risks in the consent form, *not* listed in the Investigator's Brochure or *not* part of an underlying disease.

☐ Yes ☐ No

Is the problem/event at least possibly related to research procedures?

☐ Yes ☐ No

Does the problem/event potentially reflect new or increased risk to subjects or others?

☐ Yes ☐ No

The IRB will make the final determination regarding whether this event meets the regulatory definition of UPIRTSO.

2.6 Describe the likely impact of the event on risk to the study subjects or others?

☐ **No impact**

2.7 What actions, if any, have been taken to address the situation? If none, check the box below.

☐ **None**

2.8 What actions are proposed to be taken?

☐ **Change in protocol**

☐ **Change(s) to the consent form – include updated consent forms (tracked changes and clean versions) with submission**

☐ **Notification to enrolled research subjects, including those who have completed the study**

Describe proposed actions:

☐ **None. Justify below**

Section 3 - List of Attachments

Submit with this report any relevant interim reports or information, including but not limited to: clinical trial monitoring reports, interim safety reports, interim data analyses, or data safety monitoring board reports. Any proposed change in protocol must be documented on a Change in Protocol form and included with this submission. Also include with this submission all proposed notification(s) to subjects, changes to the consent form or changes to any other previously approved study materials.

3.1 What attachments, if any, will be included with this report?

☐ Notification to subjects
☐ Change in Protocol form
☐ Revised consent form (both clean and with changes tracked)
☐ Study monitoring or data safety monitoring board reports
☐ Other(s). List:
☐ No attachments

Original Signature of Principal Investigator

The current PI's signature is required unless submitting via email. Forms sent by email must be emailed from PI's UMN x.500 email account. The Principal Investigator assures the information contained on this form is true and accurate.

Principal Investigator Signature (enter PI UMN x500 if submitting via email)	**Date**

IRB Membership and Compensation

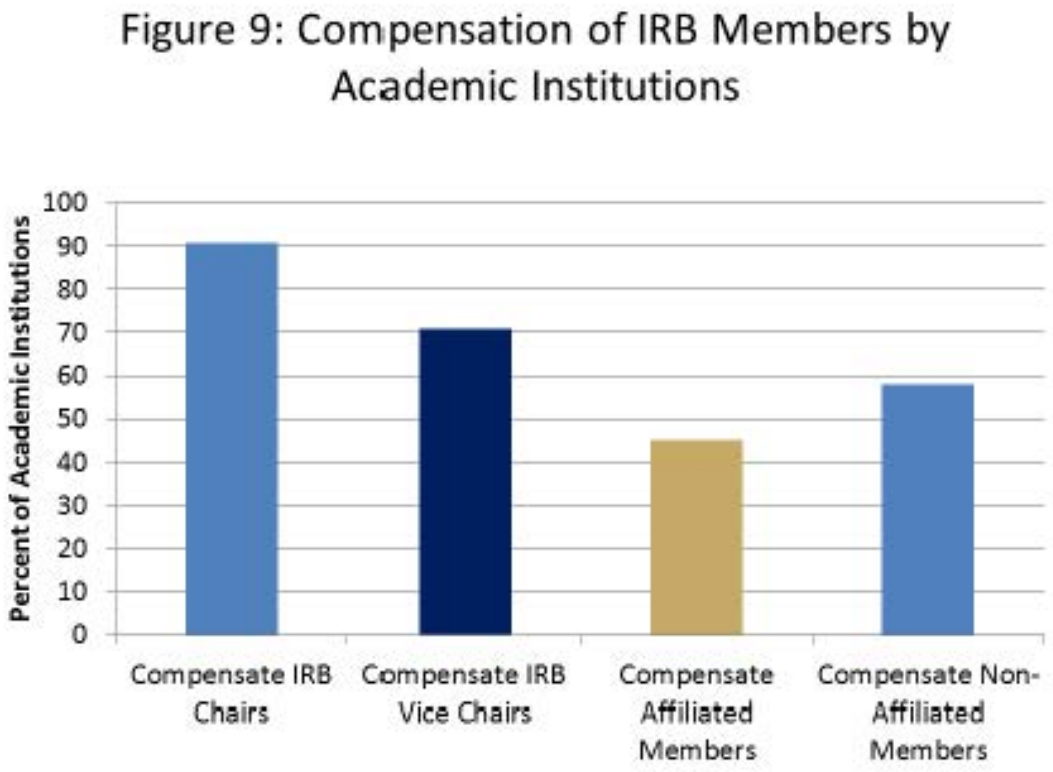


Figure 9: 90.6% of academic institutions Compensate IRB Chairs, 71% Compensate IRB Vice Chairs, 45.2% Compensate Affiliated Members, and 58.1% Compensate Non-Affiliated Members.

IRB Workload and Staffing

Table 1: IRB Staffing and Funding Levels

Protocol Category	Median Number of Staff	Median Number of Protocols	Median Protocols per FTE	Median Dollars Budgeted for IRB
All	14	1821.5	130.1	1,400,000
1-100	-	-	-	-
101-500	3.1	398.0	128.4	$225,000
501-1000	8.5	916.5	107.8	$236,714
1001-2000	11.3	1,453.0	128.6	$1,017,439
2001-4000	22	3056.5	138.9	2,023,199
4000+	30.0	4,943.0	164.8	$3,024,830

University of Minnesota			
Number of protocols	**Number of staff**	**Protocols per FTE**	**Annual budget**
5814 protocols	22 staff members (3 open positions)	264 protocols	$2,182,123

Challenges

- IRB membership and compensation
- IRB workload and staffing
- Scientific assessment
- Identification and management of perceived and real conflicts of interest
- IRB member and staff retention during period of intense scrutiny

Questions & Answers

For more information visit: research.umn.edu/subjects

References

OHRP: http://ohrp.osophs.dhhs.gov/

FDA: http://www.fda.gov/

PRIM&R: http://www.primr.org/

2013 Metrics on HRPP Performance for Academic Institutions: http://aahrpp.org/apply/resources/metrics-on-hrpp-performance

Elizabeth A. Bankert and Robert J. Amdur: Institutional Review Board: Management and Function

Dunn CM, Chadwick G: Protecting Study Volunteers in Research

Levine, RL.: Ethics and Regulation of Human Research, Second Edition

Beauchamp, TL, Childress JF.: Principles of Biomedical Ethics, Fourth Edition

UNIVERSITY OF MINNESOTA

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BOARD OF REGENTS
DOCKET ITEM SUMMARY

Audit **May 7, 2015**

Agenda Item: Information Items

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

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

Presenters: Gail Klatt, Associate Vice President

Purpose & Key Points

To report two engagements with external audit firms to the Board of Regents:

BWK Rogers, PC
The College of Education and Human Development engaged BWK Rogers, PC to provide a closeout audit of a grant as required by the sponsor, the Minnesota Department of Employment and Economic Development. The fees for this engagement are not to exceed $4,000. This engagement does not impair the independence of BWK Rogers, PC as related to an external audit of the University, and was reviewed and approved by the Controller's Office.

Deloitte & Touche, LLP
The Twin Cities campus Office of Student Affairs engaged Deloitte & Touche, LLP (Deloitte) to assist in investigating the books and records of the Graduate and Professional Student Assembly (GAPSA) student group, as it relates to student fees received by GAPSA. The fees for this engagement are not to exceed $30,000. This engagement does not impair the independence of Deloitte as related to the annual external audit of the University, and was reviewed and approved by the Controller's Office.

Background Information

Engagements with external auditors that do not require prior approval by the Board of Regents are reported after the fact to the Audit Committee as information items, in conformance with Board of Regents Policy: *Audit Committee Charter*.