

## UNIVERSITY OF MINNESOTA

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TO: Reed Polakowski, Minnesota Legislative Reference Library

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

DATE: August 1, 2015

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

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

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

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

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

# UNIVERSITY OF MINNESOTA

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July 27, 2015

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

FROM: Brian Herman, Vice President for Research

SUBJECT: August report to the Legislature



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

## SUMMARY

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

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

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

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

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

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

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

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

enclosure

# Advance HRP Implementation

August 2015 Progress Report

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

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

√= Completed

○= In Progress

□= Not Started

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