UNIVERSITY OF MINNESOTA

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TO: Reed Polakowski, Minnesota Legislative Reference Library

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

DATE: November 1, 2015

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

Enclosed are two copies of the mandated report Human Subjects Research Standards – November 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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MEMORANDUM

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

FROM: Brian Herman, Vice President for Research

DATE: October 26, 2015

RE: Report to Legislature

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

SUMMARY

Last month five of our work teams submitted final reports, resulting in significant progress in implementation. As previously reported, we have engaged an external advisor, David Strauss, a member of the original external review team, to work with the University on implementation. He is currently reviewing the final reports submitted to date.

The Research Compliance Office structure and operations became effective on October 2, 2015. The Research Compliance Office will take responsibility for conducting for-cause investigations for financial compliance on sponsored projects, as well as for-cause investigations related to human participants, animal subjects, and institutional biosafety issues. The intent of this change is to separate for-cause investigations from the IRB.

Paul Mattessich, executive director of Amherst H. Wilder Foundation, has agreed to serve as the inaugural chair of the Community Oversight Board. A Board of Regents resolution (3/27/15) called for a Community Oversight Board (COB) to be established to ensure that the U of M is using best practices in the protection of research participants. Dr. Mattessich is determining membership for this board, which will include University of Minnesota Professor Jean Wyman and me as ex officio members. The purpose of this board is to help build and foster trust and mutual understanding of research values, culture, and research participant protection, including the development of communication strategies for use within and outside the U of M.

The IRB membership final report includes key outcomes such as establishing four medical IRB rosters and requiring additional expertise. Each medical roster will have 13 members including at least one non-scientific member. Members will be required to attend 65 percent of meetings, and a majority must be present for each review. The Medical School is currently recruiting members for these panels.

In response to a request from President Kaler and a Board of Regents resolution (03/27/15), the University has engaged Compass Point Research to conduct a routine review of 100 randomly selected active studies to identify additional strengths and areas for improvement in our research. Researchers involved were notified October 22 and 23 and the review began the week of October 26, 2015. Findings will be presented to University leadership in writing.

As always, this month we will publish a blog update to accompany submission of this report for those who sign up for regular updates and continue to monitor emails at advancehrp@umn.edu for any additional feedback.

The attached dashboard shows the full scope of work and this month's updated status of each item. For complete details, please visit research.umn.edu/advancehrp or contact me with any questions.

Advance HRP Implementation

November 2015 Progress Report

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

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

√= Completed

O= In Progress

☐ Not Started

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