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: October 1, 2015

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

Enclosed are two copies of the mandated report Human Subjects Research Standards – October 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: September 25, 2015

RE: Report to Legislature

Included for your review and approval is the fourth 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 October 1, includes a narrative summary of what has been accomplished since the last report along with the full progress dashboard.

SUMMARY

Each team submitted an approved work plan on schedule and all have begun recruiting other stakeholders to participate in the implementation. The commitment to this work seen with the Implementation Team continues to be evident, showing that the University community at large is dedicated to driving excellence in this area.

A major area for improvement identified in the external review was size and expertise of our IRB. In response, we have developed four medical IRB rosters that more closely align expertise with submission type. The four medical rosters will focus on the following specialties: Vulnerable Subjects; Pediatric Studies: Hematology, Oncology, BMT, and Department of Medicine; Adult Studies: Hematology, Oncology, BMT, Cardiology, and CMRR; and Pharmacy, Genetics, Surgery, Public Health and Broad Medical Sciences. Each medical roster will have 13 members and a majority must be present during each review, including at least one member whose primary concerns are in nonscientific areas. Reevaluation of this structure and expertise will be evaluated twice yearly to ensure appropriate workload and allocation of resources. Department heads and senior leaders will be engaged in recruiting members to serve on these rosters as well as promoting the value of service on the IRB.

Secondly, language has been drafted for a change to the individual conflict of interest policy to clarify that investigators on human participant studies will disclose financial interest from the first dollar and may not receive any personal income from the industry sponsor during the time of the study. Those policy changes are currently being consulted with faculty governance and other stakeholders.

Planning is well underway for a national conference on December 2, 2015 entitled “Research with Human Participants: The National Debates”. This conference will include University faculty and leadership, national experts in bioethics, and representatives from industry. This is a recommendation from the implementation team’s final report chapter three, “Cultivating a Culture of Ethics”, both in terms of hosting a conversation about this important topic as well as comparing ourselves to our peers.

As we submit this report, several teams are meeting the first of our deadlines and next month we will provide a summary of that completed work. Those teams include: IRB Membership and For Cause Investigation, as well as establishment of FUROC, the Community Oversight Board and a Research Compliance Office.

Finally, each month we also publish a blog update to accompany submission of this report for those who sign up for regular updates and we 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

October 2015 Progress Report

Work plan Section	Status	Lead	Scope
IRB Membership	○	Billings, Biros	Recruit membership
			Form new committees; restructure biomedical; target membership to accurately reflect protocol submission
			Set compensation structure and policy for medical and nonmedical IRBs
FUROC	√	Herman	U establish committee jointly with Fairview
For Cause Investigations	○	Webb	Establish Research Compliance Office (RCO)
		Waldemar	Transition For Cause Investigations to RCO; establish more robust procedures specific to complainant and SAE reporting
Community Oversight Board	○	Herman	Establish board structure and guidelines
			Finalize membership; appoint chair
			Invite members
External Advisor	√	Herman	Hire external advisor (external review panel member); 2015 AAHRPP Accreditation
Scientific Review of Studies	○	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	○	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	○	Dykhuis	Implement new eIRB technology
			Implement IRB forms and procedures
			Add new FTEs
			Complete 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
	○	Dykuis	Implement LAR policy changes
	√		Implement 72-hour hold policy
Department of Psychiatry	○	Paller	Transition to 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 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