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: June 1, 2016

RE: University of Minnesota mandated report: Human Subjects Research Standards – June 2016

Enclosed are two copies of the mandated report Human Subjects Research Standards – June 2016, 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: May 25, 2016

RE: Report to Legislature

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

SUMMARY

The Office of the Legislative Auditor (OLA) released their report on May 19, 2016 and the OLA, VP Brian Herman and VP Brooks Jackson testified in front of the Senate Higher Education Committee on the same day. The report indicated that the University, while engaged in a complex process, is making good progress. The Auditor is encouraged by the work and the commitment of the faculty and staff involved in the process. It was noted that the work is on time and on target based on the timeline requested by President Kaler.

The Engaging Research Participant work group is drafting the work area's final report that adopts a systems approach, identifying expectations of researchers in engaging participants and the public as well as evaluating participant and public responses related to research. Work group recommendations focus on the informed consent process and documents and the ongoing engagement of research participants. The work group is in the process of finalizing participant contact cards for study coordinators to give to participants and their family members at each visit, and a participant feedback survey that will provide real time feedback and trends about participant's experience in research studies to University leadership, the Community Oversight Board (COB) and the public. Feedback from participants and the public, primarily through the survey, will also help inform education and training for investigators and their study teams. The work group is also finalizing recommendations about the dissemination of research results to participants and the broader public.

The Community Oversight Board (COB) held its second quarterly meeting on May 12, 2016. Key agenda items included the Compass Point Report, the Department of Psychiatry Assessment Report and CTSI Management Plan and the composition of the board.

We continue to make progress on our IRB function. IRB member assignments for four of the eight biomedical panels have been finalized and will start in July. Additional orientation meetings and training sessions were held during the month of May, and new positions have been posted to support the increase in panels.

Regarding participants with impaired or fluctuating capacity to consent, revised policies, standard operating procedures, an education and training proposal and an investigator guide are under review. These were developed in consultation with the Center for Bioethics and our external advisor.

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 http://research.umn.edu/advancehrp/implementation.html or contact me with any questions.

Advance HRP Implementation

June 2016 Progress Report

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

			Engage consultant for climate assessment plan. Enhance culture of inclusion and mutual trust.
Engaging Research Participants	○	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	○	Ingbar, Schacker	Integrate and coordinate human research protection training
			Curriculum development
			Training delivery
Accountability Metrics	○	Waldemar	Track and report accountability metrics
Conflict of Interest	○	Durfee	Implement updated COI policy

√ = Completed
○ = In Progress/some items completed
☐ = Not Started

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