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: July 1, 2016

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

Enclosed are two copies of the mandated report Human Subjects Research Standards – July 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: June 24, 2016

RE: Report to Legislature

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

SUMMARY

One of the recommendations we received from the external review of the University of Minnesota's human participant research program is that we should "publicize unequivocal statements" about our commitment to "create and nurture a culture of ethics in research" and that "we must animate these values to life by investing in their visibility and adoption at all levels of the University's research enterprise."

In response to this, the Cultivating a Culture of Ethics work team has developed a campaign to build awareness of the University's principles, policies and processes that uphold ethical research practices. This effort is built around a set of core commitments[1]—developed and adopted by University leadership, faculty and staff— that identifies our shared responsibilities and reinforces our collective commitment to meeting the highest ethical standards in the planning and conduct of research.

Along with the core commitments, we are launching a Research Ethics campaign, including messages, posters and digital signs to be posted on our websites and shared throughout the University to ensure that that our core values are visible everywhere research takes place. I will be sending a broad communications to a University-wide audiences sharing these core commitments and announcing the campaign, which begins in June 2016 and continues throughout the coming academic year.

[1] Core Commitments and Research Ethics Campaign http://research.umn.edu/advancehrp/researchethics.html

The Engaging Research Participants work group held its final meeting on June 15, 2016. The group has a final report entitled "Design for Implementing Recommendations from the Engaging Research Participants work group," that outlines 10 recommendations to develop a system to foster the co-creation and evaluation of knowledge about research conduct. One of the final recommendations includes a contact card, which should be regularly provided as a small wallet-sized card to all participants, Legally Authorized Representatives and family members. Ideally, the card will be provided to all people approached for consent. The recommendations also include a research participant experience survey, and recommends outsourcing the implementation and administration of the survey to an objective third party. The survey should be administered bi-annually with summary of results and trends provided to the Post Approval Review/HRPP, the Community Oversight Board (COB), the Fairview University Research Oversight Committee (FUROC), and eventually to a newly formed Human Research Participants Education Committee. The complete list of the 10 recommendations was submitted to VP Herman on June 23, 2016.

The Institutional Review Board (IRB) has continued their work to update the biomedical panel structure. Trainings are underway (June and July) for the implementation and adoption of Huron Consulting's IRB Toolkit. Meetings for the first four new panels are scheduled and will including additional member training. In order to provide timely and meaningful reviews for investigators, the IRB has created an "overflow" panel of legacy IRB members to manage the number of submissions as the new panels begin. The IRB has also identified ad hoc consultants in multiple disciplines to ensure that the appropriate expertise is available.

Clinical and Translational Science Institute (CTSI) is working to develop new training on informed consent and good clinical practices. This training is being jointly developed and in consultation with the Center for Bioethics and the IRB, and will be piloted in Psychiatry by the end of summer or early fall.

The FUROC (Fairview University Research Oversight Committee) met in June and continues to discuss improved communication and partnership between researchers and nursing staff. The committee is also reviewing new policies and reports that result from the implementation work and will take responsibility, through Fairview Research Services, for a climate assessment in the behavioral health unit.

Vice President Herman held a meeting for all work team leads on June 22 to share updates and assess progress. All teams are on track to meet the June 30th deadline for final reports, with the exception of final passage of the new Conflict of Interest policy which is delayed due to faculty union negotiations.

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.

AdvancingHRP Implementation

July 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	√	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