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: January 1, 2016

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

Enclosed are two copies of the mandated report Human Subjects Research Standards – January 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: December 23, 2015

RE: Report to Legislature

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

SUMMARY

In December, the Scientific Review team completed their work. The Implementation Team Work Plan recommended eliminating departmental scientific review and creating a process within the Human Research Protection Program (HRPP) office in order to address real or perceived conflict. The team has submitted a final report to change policies to ensure the elimination of departmental scientific review, engagement of additional expertise by scientific members of the IRB, and changes to the HRPP managed scientific review process. The team also recommends a change to the minutes and process of an IRB review in order to include documentation of their findings regarding the acceptability of the scientific assessment.

As previously reported, on December 2nd, 2015, the University of Minnesota hosted a national conference on research with human participants. We were overwhelmed by both the high quality of the discussions and the level of interest in the topic – 300 people attended in person, and nearly 1300 viewed the simultaneous webcast. Videos of all sessions are now posted at z.umn.edu/humanresearchvideos where researchers and the public can view, share, and use them in educational or professional activities.

The HRPP office continues to make progress on implementing an electronic IRB. The eIRB is an important technology enhancement that will help speed up review for researchers, add review capacity, and ensure proper documentation. The first phase of the IRB Renew Project implementation will officially launch January 4th. During this phase, UMN project team members will work closely with our vendor, Huron Consulting, and key institutional stakeholders to gather and document the unique requirements of the University of Minnesota's IRB and HRPP to inform the launch of an online IRB submission, review and communication tool. The first phase is anticipated to last six weeks.

The second phase of the eIRB project will consist of customization and implementation of the Huron Toolkit, a suite of IRB forms, policies, worksheets and review guides, and the third and final phase will be the launch of Click, the online system. More information about phases 2 and 3, including the anticipated timeline for each, will be provided at the conclusion of phase 1.

Progress continues with the University's faculty education and training. The University's Clinical and Translational Science Institute (CTSI) has hired a staff member to conduct a gap analysis and curriculum design plan for human participation research training and education at the University. This work will be a collaborative effort between many key research offices including the IRB and Center for Bioethics.

The Conflict of Interest team continues to work on the revisions to the Conflict of Interest policy to disclose and manage any real or perceived conflict when partnership with industry. The work team is focused on consultation with clinical faculty to fully understand the issues and impact. That work will continue with a goal of action in the University Senate March 2016.

Finally, new tools are being developed to communicate timely human research protection updates and important information to the University's research community. A monthly newsletter, "Research news from the IRB," is sent to more than 10,000 investigators, advisors, and correspondents on active IRB studies. Another monthly newsletter is sent to the IRB membership and staff. In addition, a series of educational workshops are being offered to interested members of the research community and public. Additionally, the IRB website has been updated so that departments and/or academic instructors may request basic or advanced training tailored to the unique needs of investigators. Education and communication will both play a key role in informing our community of important changes in policies and practice, and will play a role in driving culture change.

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

JANUARY 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 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; Compass Point compliance review.
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	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