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TO: Reed Polakowski, Minnesota Legislative Reference Library

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

DATE: September 3, 2015

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

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

RE: Report to Legislature

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

SUMMARY

This month we updated two IRB policies (501 – *Vulnerable Populations* and 506 – *Adults Lacking the Capacity and/or Adults with Diminished Capacity to Consent*). These policies and IRB form Appendix were revised to prohibit recruitment of persons temporarily confined under an involuntary medical hold (72 hour emergency hold, 12 hour "intent to leave" period, or 72 hour "intent to leave" period for persons with chemical dependency) into a psychiatric drug, device, or biologic trial. IRB Form Appendix 1 *(Populations with Additional Considerations)* has been amended to restrict any member of the study team from participating in a decision to rescind or discontinue a medical hold before its expiration for a research study. These changes address the external review recommendation to develop standards that protect against real or perceived coercion in psychiatric treatment settings in which individuals may fear involuntary court proceedings. While not specifically referenced in the implementation team report, it was brought to the attention of the team at the end of the process and has been the subject of significant discussion inside and outside the University.

Secondly, we have engaged an external clinical and translational research management and consulting firm (Compass Point Research) to conduct a review of 100 random protocols to further ensure we have addressed issues of human participant protection. These protocols will be reviewed for compliance with institutional requirements, governing regulations, and good clinical practice. This also was not specifically referenced in the work plan but was requested by the President and Board of Regents.

Several recommendations of the external review panel referenced IRB minutes and meeting management. This was also a concern of AAHRPP during their recent accreditation visit. In addition to the improvements reported last month, HRPP staff has made changes to enhance the documentation of items of disagreement among members at meetings and has implemented a revised template to collect required regulatory determinations of the IRB and facilitate deliberation.

Last month we reported the first meeting of the committee working to develop the Fairview University Research Oversight Committee. That committee has been charged and membership formed. Planning is underway for a first meeting this fall.

Finally, to continue to assure transparency and allow for participation and input from those interested, we have updated the website to reflect language changes adopted in the implementation work plan and to provide contact information, opportunities to sign up for progress reporting, and updates on the implementation work.

The attached dashboard shows the full scope of work and this month's updated status of each item. As you can see, all areas are underway and some completed. For complete details, please visit research.umn.edu/advancehrp or contact me with any questions.

Advance HRP Implementation

September 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