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: December 1, 2015

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

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

RE: Report to Legislature

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

SUMMARY

Last month teams again made significant progress in implementing the recommendations of the external review panel. As previously mentioned, we have asked David Strauss of that panel to provide guidance and feedback of our work. He is highly engaged and has reviewed all the final plans submitted to date. He has provided in general very positive feedback indicating that the changes will offer us a level of accountability that other institutions do not currently have. He also offered additional tangible suggestions and observations.

The University's National conference on "Research with Human Participants" is highly anticipated and registration is full. Many faculty and leaders, as well as patient advocates, policy makers, and national scholars, are engaged in the program and will be in attendance. The conference is intended to educate as well as continue a national conversation about best practices in ethics and research.

We have also taken major steps in improving education for researchers. Dr. Steve Miles has developed a new course entitled "Standards for Research with Human Participants" which will be offered spring semester. It includes 15 distinct modules addressing separate aspects of standards and regulations related to this research that can be taken individually or as a course, and for credit or for CME and CNE credit. This will provide easily accessible and necessary training for researchers, faculty and staff involved in human participant research.

The HRPP program has hired an education and outreach specialist, trained in bioethics and research ethics and with experience in senior IRB management. She will be responsibility for initial and ongoing training for IRB members and the development and delivery of training for researchers on human

research protections. She has already created an education structure for new IRB members, expanded communications on educational issues, and developed and launched a training tracker to document IRB and HRPP training. This work will help us understand the access to and effectiveness of our training opportunities and identify any gaps that need to be addressed.

Finally, the 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. In October there was extensive consultation with faculty governance. That work will continue with a goal of action in the University Senate next March.

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

DECEMBER 2015 Progress Report

Work plan Section	Status	Lead	Scope
IRB Membership	O	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	O	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	O	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