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: February 1, 2016

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

Enclosed are two copies of the mandated report Human Subjects Research Standards – February 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: January 26, 2016

RE: Advancing HRP: Report to Legislature

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

SUMMARY

This month the chair of the newly formed Community Oversight Board, Paul Mattessich, and Vice President for Research, Brian Herman, successfully recruited membership for the Board. The Board is diverse with members representing health care providers, patient advocates, the state, the University and the non-profit community. The roster (attached) ensures a thoughtful and impactful board to advise the Vice President for Research and Human Research Protection Program (HRPP) on best practices for research participant protections. The Board will assess its membership and add additional members if needed to represent additional constituencies. The first meeting of this board is currently being scheduled for February.

The Fairview University Research Oversight Committee has been recently reconstituted to include Beth Thomas, DO, Chief Medical Officer of Fairview, and Debra Cathcart, Chief Nursing Executive for M Health. This committee's work had been delayed due to staff changes at Fairview Health Services. The next meeting is scheduled for early February.

The faculty committee that planned the Dec. 2 research ethics conference reconvened in January to consider next steps. The committee's enthusiastic recommendations were reviewed and endorsed by Vice President for Research, Brian Herman and they are as follows: The U should build on the momentum created by the Dec. 2 conference and offer a first-rate, half-day conference each year on research ethics. Committing to this series on research ethics publicly demonstrates an ongoing U commitment. The Consortium on Law and Values is poised to again lead this half-day national conference with the goal of its becoming an anticipated event and valued tradition. If the conference is held in the morning, departments and other units would be strongly encouraged to create afternoon workshops, in-service training, or other events on research ethics. This will bring research ethics concepts "home" to individual units and key groups of U employees (e.g., study coordinators) for local adoption.

The implementation team continues to work on the revisions to the Conflict of Interest policy to disclose and manage any real or perceived conflict when partnerships with industry exist. The leads have met with several faculty groups as well as department chairs in the Medical School to understand the impact of policy changes. When passed, the University will be one of only three institutions (including UCSF and Mayo) to have a policy requiring no personal income from a company while working as a PI on a study funded by the same company. The current plan is for this policy to be discussed by the University Senate in March and voted on in April.

The HRPP continues to make progress on implementing an electronic system to manage documents and processes for the IRB. The first phase of this project officially launched on January 4 and is anticipated to last six weeks. During this phase, the IRB Renew Project team members will work closely with Huron Consulting and a small number of institutional stakeholders to gather and document the requirements of the U's IRB and HRPP. The second phase will consist of customization and implementation of the Huron Toolkit and the third and final phase will be the launch of the online submission system.

It is anticipated that the Reliance Agreement Administrator position in the human research protection program office will be filled in February 2016. This role of this position is to oversee the submission process of University of Minnesota studies that qualify for review by an external IRB due to a condition of membership in a consortium, requirement of a federal award, or similar arrangement, to ensure institutional requirements have been met for specific studies.

As always, this month we will publish a blog update to accompany submission of this report for those who sign up for regular updates. We will 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.

Attachments

Advancing Human Research Protections
Community Oversight Board Roster
February 2016

First Name	Last Name	Title/Organization
Susan	Abderholden	Executive Director, NAMI Minnesota
Nancy	Dillon	Psychiatric Mental Health Advanced Practice Nurse, Educator/Consultant in Private Practice
JoAnne	Disch	Professor ad Honorem, U of M School of Nursing
Nancy	Feldman	Former CEO and President, UCare
Trixie	Girtz Golberg	President and CEO, Lifetrack
Dick	King	Professor Emeritus, University of Minnesota Medical School
Paul	Mattessich (Chair)	Executive Director, Wilder Research
Judge Jay	Quam	Hennepin County Judge, Fourth Judicial District
Sharon	Sayles Belton	VP of Community Relations and Government Affairs, Thompson Reuters; Former Mayor of Minneapolis
Darrell	Thompson	Executive Director, Bolder Options
Sally	Trippel	Mayo Clinic (Emeritus)
Stella	Whitney West	CEO, NorthPoint Health and Wellness Center
Bruce	Wolff	Mayo Clinic (Emeritus)
Jean	Wyman	Professor, UMN School of Nursing

Advance HRP Implementation

FEBRUARY 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 – IRB Renew
			Implement Huron Toolkit 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 COI 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