UNIVERSITY OF MINNESOTA

Government and Community Relations
Office of the President

3 Morrill Hall
100 Church Street SE
Minneapolis, MN 55455

Office: 612-626-9234
Fax: 612-624-2800
govrelations.umn.edu
Email: govrelations@umn.edu

TO: Katie Elmore, Minnesota Legislative Reference Library

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

DATE: December 1, 2016

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

Enclosed are two copies of the mandated report Human Subjects Research Standards – December 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

Office of the Vice President for Research *420 Johnston Hall*
101Pleasant Street S.E
Minneapolis, MN 55455-0421
612-625-3394
Fax: 612-626-2800

November 22, 2016

TO: **Regent Johnson, Chair**
Regent Brod, Chair, Audit Committee

FROM: **Brian Herman, Vice President for Research**

Included for your review and approval is the seventeenth report to the Legislature on implementation of the work plan to improve research with human participants at the University of Minnesota, institutionally referred to as AdvancingHRP. The report, due to the Legislature on December 1, includes a narrative summary of what has been accomplished since the last report and in addition provides information at the bottom of the summary about where more detail can be found. Our institution has been working hard to strengthen its human research protection program to ensure that the welfare of research participants is our highest priority.

SUMMARY

IRB Metrics

The University of Minnesota Human Research Protection Program (HRPP) has developed baseline metrics related to IRB activities. These metrics are an important element of tracking and monitoring IRB performance and implementing quality improvement initiatives.

Many program improvements currently are underway, including expansion of the biomedical IRB, adoption of the HRPP Toolkit, and implementation of an electronic IRB submission system. The metrics provided will be used as a way to measure progress toward our goal of enhancing the HRPP program and improving the IRB experience for researchers. See http://www.research.umn.edu/irb/metrics.html for full details.

Revision to Informed Consent Templates

As part of the Advancing Human Research Protections initiative, the Engaging Research Participants Work group recommended the consolidation of phone numbers for research participants to call with questions and concerns to reduce confusion. Previously there were two numbers (Fairview Research Administration and the Research Participants' Advocate line) listed in the informed consent form. Informed consent forms have been revised to include only one

number, the Research Participants' Advocate line. The new text aligns with the recently released research participant contact cards.

IRB Expansion and Restructuring Message To Research Community

On November 18th, President Kaler along with VPs Herman and Jackson jointly sent a communication to those actively involved with human research participant studies re-introducing them to the newly reconstituted IRB. Their message emphasized the dramatic increase in the number of members and the range of expertise represented. The IRB now includes more than 80 members with expertise in critical areas of research, including psychiatry, pediatrics, and oncology. IRB members, most of whom are faculty, make a significant time commitment and bear a heavy responsibility: to be an independent voice with a focused goal of ensuring high quality research while protecting the rights and welfare of research participants.

The University is truly fortunate to have this dedicated group of individuals willing to devote their time and energy to this important work, and the University stands ready to provide additional resources for their success and the advancement of our broader research mission.

Human Research Education Advisory Group

A Human Research Education Advisory Group (EAG) began meeting in November and started addressing recommendations primarily from the Education and Training final report. Where there are other related educations recommendations from the other work teams, they will be reviewed and considered for inclusion as well.

As a reminder, the timeline for implementation is July 2015 – December 2016. We will continue to report back on our progress throughout this timeline and 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.

For complete implementation details, please visit http://research.umn.edu/advancehrp/implementation.html or contact me with any questions.

Attachment

ATTACHMENT

AdvancingHRP Implementation Progress Report — December 2016

Work plan Section	Status	Lead	Broad 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	○	Dykhuis	Implement new IRB technology – IRB Renew (Spring 2017 expected completion)
			Implement Huron Toolkit IRB forms and procedures
	√		Add new FTEs
			Complete benchmarking visits
Monitoring of Studies	○	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	√	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 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 (complete pending faculty unionization vote)

√ = 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