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TO: Katie Elmore, Minnesota Legislative Reference Library

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

DATE: November 1, 2016

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

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

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October 25, 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 sixteenth 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 November 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

Human Research Education Advisory Group

The AdvancingHRP final report recommendations and the Association for the Accreditation for Human Research Protection Programs (AAHRPP) call for collaboration and coordination in the development, delivery, and evaluation of human research protection training. To fulfill this commitment, a Human Research Education Advisory Group (EAG) is being formed to pull together key stakeholders responsible for education and training functions at the University. Invitations were sent to these individuals in October. The EAG will begin meeting in November and start 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.

IRB Renew Project – new electronic submission and review system

Progress on the IRB Renew project continues on the three main fronts: (1) HRPP- Human Research Protection Program Toolkit implementation; (2) Institutional Review Board (IRB) staff and committee mentoring; and (3) Click IRB software implementation. The HRPP Toolkit implementation is divided into 6 phases. Toolkit documents in phases 1 and 2 are already

implemented and include basic worksheets, checklists and Capacity to Consent policies and SOPs. Phase 3 Toolkit documents will be rolled out by the end of October 2016 and include various SOPs, worksheets, and other tools focused on protocol pre-review, non-committee review, and IRB committee management and review. The remaining documents in phases 4-6 will be rolled out November 2016 through the Click IRB go-live in spring 2017. The research community will be kept informed of the rollout progress and will be offered training opportunities. The Click IRB software implementation is still on track for a spring 2017 rollout.

HRPP Organization and Structural enhancements

The HRPP office has completed the hiring and restructuring process for eleven IRB analyst positions within the office. These individuals conduct pre-review on all submissions received by the office, route those submissions for the appropriate level of review, and, when appropriate, conduct non-Committee Review. In addition, IRB analysts manage the workload and administrative functions of the IRB panels.

Concerning the Institutional Review Board (IRB) panels, we have been dramatically increasing the number of members and range of expertise on our IRB. All eight medical IRB panels have been established and each panel has held at least three convened IRB meetings. We now have 75 members with expertise in critical areas of research, including more focused attention to psychiatric research. The IRB, made up primarily of U of M faculty, is responsible for reviewing human participant research protocols and making determinations for approval, further review or study continuation. IRB members, recruited and selected from our research community, are highly regarded by their peers and have deep scientific and technical knowledgeable in their respective fields.

Serving on the IRB requires a significant time commitment and an ability to make critical decisions that impact research studies, study personnel and participants. We are truly fortunate to have this dedicated group of individuals willing to devote their time and energy to this important work.

Research Ethics and Integrity Climate Survey

In order to gain a better understanding of the existing climate for research ethics and integrity at the University of Minnesota, members of our research community were asked in October to participate in an important survey. The Survey of Organizational Research Climate (SOuRCe) was developed and is administered by the University of Illinois. This externally-validated instrument assesses the environment for responsible research practices from the perspective of individuals directly engaged in research activities at our institution. The results from the survey are expected back by the end of the calendar year and will be shared with University leadership, AdvancingHRP oversight committees, and the community surveyed.

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 — November 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