TO: Reed Polakowski, Minnesota Legislative Reference Library

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

DATE: March 1, 2016

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

Enclosed are two copies of the mandated report Human Subjects Research Standards – March 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
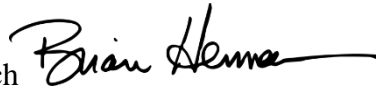
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UNIVERSITY OF MINNESOTA

MEMORANDUM

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

FROM: Brian Herman, Vice President for Research

DATE: February 24, 2016

RE: Report to Legislature

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

SUMMARY

The implementation team work plan's section entitled "Psychiatry" directs the Clinical Translational Science Institute (CTSI) to take over management of clinical trials in the Department of Psychiatry. To assist with managing this transition effectively, CTSI hired a consultant to assess the status of clinical trials in the department early last fall and assist in developing a management plan. The consultant's final report was received in January and made observations similar to previous reports on this topic. To address those observations, the University has increased monitoring of clinical research in the department, including assisting faculty in understanding and using GCP guidelines, and is moving forward on transferring the management of this clinical research to CTSI.

Dr. David Strauss, external advisor to the implementation, has reviewed the recent consultant assessment of Psychiatry, the plan for the Research Compliance Office, updates to the IRB review process, and the changes to scientific review. His participation is extremely valuable in confirming our approach as well as providing additional suggestions and recommendations. Dr. Strauss will be on campus for an in-person visit at the end of March to meet with work area leadership and other interested stakeholders.

The work team on "Promoting a Culture of Ethics in Research" has drafted a Statement of Core Commitments and is currently presenting that language to key stakeholder groups across campus for feedback. The planned use for the statement aligns with the external review panel's recommendations that include engaging the University community in ethics focused conversations and increase awareness about our value system, as well as University policies and procedures. That document is attached.

Early in November, The Association for the Accreditation of Human Research Protection Programs (AAHRPP) received the first status and quarterly improvement plans submitted by the University in response to AAHRPP's final site visit report that included some elements categorized as "standards not met". The second status and quarterly improvement plan reports were submitted in January for the February 1 deadline. The status report included results of monitoring to ensure a valid IND or IDE is in place, as applicable, and the results of monitoring of the IRB minutes to ensure documentation of controverted issues and their resolution on all determinations. The quarterly improvement plans reflect progress made toward meeting all of the standards in the areas of sufficient resources, concerns of research participants, structure and composition of the IRB, training and education activities, and IRB review processes.

In addition to the improvements being made in response to AAHRPP, the Human Research Protection Program (HRPP) has also made progress on enhancements to IRB membership. New and existing IRB members received confirmation notices the last week of February and the HRPP anticipates the rosters for the four medical panels will be complete and new members will begin training in the next few weeks.

Finally, the Engaging Research Participants work area gathered research participant surveys from other Clinical and Translational Science Institutes (CTSAs) across the country, and is crafting a survey to assess research participants' experiences. The group also drafted a Community Liaison Officer (CLO) position description and anticipates posting the position this month. Two key responsibilities of the CLO will be staffing the Community Oversight Board (COB) and implementing the research participant survey.

The COB had its inaugural meeting on February 8. The first meeting included background information and discussion with Vice President Herman, a dialogue with the Chair, Paul Mattessich, on how to begin creating a process to address the COB's charge, and an initial discussion on the composition of the board. The COB plans to meet quarterly, and the next meeting will be scheduled for May. Before the next meeting, the board will assess members' profiles and backgrounds to assess gaps in membership. In addition to the board meetings, members of the COB will meet with David Strauss on March 31.

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.

Advancing Human Research Protection Program
Promoting a Culture of Ethics in Research:
Statement of Core Commitments
DRAFT[1]

The University of Minnesota and each individual investigator has a core duty to keep the well-being of research participants firmly in mind and at the center of University policies and procedures. Individuals who make the gift of consenting to volunteer as research participant trust us to protect their well-being and to respect their freely given, informed consent as they enroll in research. Research participants retain the right to decline to continue participation in a research project for any reason, including as new data, side effects, or unexpected circumstances occur during the course of the study. We bear special responsibilities toward those persons whose capacity to consent to research is impaired or fluctuates during participation in a study. Any action that harms the trust between potential and/or enrolled research participants and researchers affects the entire scientific enterprise.

University leaders and all others who are involved in research with human participants have the responsibility to:

- Ensure that all faculty and staff who oversee and conduct research on human beings have taken ethics training.
- Protect and promote the rights and interests of all research participants, including those who are vulnerable, who may be susceptible to coerced consent, or who lack (or may come to lack) the capacity to consent to or decline continued participation in research.
- Comply with the letter and be committed to the spirit of the laws, regulations, and policies that pertain to the treatment of patients and of participants who are enrolled in research studies.
- Be transparent and accountable in all research activities. Anyone who observes a breach of the ethical rules, laws or regulations that govern the conduct of research involving human participants should be free to report his or her observations without fear of retaliation and with confidence that his or her concerns will be considered and addressed.
- Ensure that individual and institutional conflicts of interest that potentially undermine the well-being of research participants will be effectively managed.
- Sustain a culture of respect and engagement at the U of M that recognizes the importance of integrity in university-based research. Sustaining that commitment requires respect for cultural diversity, understanding the importance of academic freedom and scientific progress, and attention to the societal implications of biomedical research.
- Effectively engage in a dialogue with the broader community that has a stake in benefitting from research involving human participants and an interest in protecting their loved ones who may participate in these studies.

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[1] **Draft 02/08/16** -- Adapted by the Implementation Work Team on Cultivating a Culture of Ethics from *Implementing the Recommendations of the External Review of the University of Minnesota Human Research Protection Program* (Work Plan), page 15. Intended for incorporation into strategic plans, websites, and as a discussion prompt for departments and research units.

Advance HRP Implementation MARCH 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	⭕	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 HRPP training
			Curriculum development
			Training delivery
Accountability Metrics	⭕	Waldemar	Track and report accountability metrics
Conflict of Interest	⭕	Durfee	Implement updated COI policy

√ = Completed
⭕ = 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