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: August 1, 2016

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

Enclosed are two copies of the mandated report Human Subjects Research Standards – August 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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July 18, 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 fourteenth 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 August 1, includes a narrative summary of what has been accomplished since the last report along with the full progress dashboard.

SUMMARY

This month marks a huge milestone for the AdvancingHRP teams and their final objectives. The following teams submitted their final reports to Vice President for Research Brian Herman for review and approval:
- Cultivating a Culture of Ethics
- IRB Protocol Review Process
- Monitoring of Studies
- Human Research Participants Who Have Impaired or Fluctuating Capacity to Consent
- Department of Psychiatry
- Engaging Research Participants
- Education and Training of Investigators
- Accountability Metrics
- Conflict of Interest

These reports are now being consulted with key oversight bodies and stakeholders and this process will occur throughout the months of July and August. Key groups reviewing the reports include the Fairview Research Oversight Committee (FUROC), Community Oversight Board (COB), Research Compliance Advisory Committee and external advisor, Dr. David Strauss. Full reports will be made available upon completion of the review process, but the key recommendations from each of the teams is described below:

- The Cultivating a Culture of Ethics work team wrapped up their work launching a University-wide Ethics Campaign and setting a March 7, 2017 date for the next Research Ethics Day conference that includes an afternoon of local faculty forums. The group also laid the ground work for customizing and administering a survey tool which appears to be the only validated instrument in the U.S. for assessing the perceived climate of research integrity. This tool called the Survey of Organizational Research Climate (SOuRCe) will launch Fall 2016 and will allow us to benchmark climate assessment data against some of our peers.
- The IRB Protocol Review Process team completed their work on implementing the external review panel's four primary recommendations. They also simultaneously took on the challenge of implementing a new eIRB technology and corresponding enhanced business toolkit that is expected to be fully implemented by March 2017.
- An expanded and risk based HRPP monitoring system is described in the Monitoring of Studies team's final report. This integrated monitoring system includes coordinated efforts between Post Approval Review, CTSI Clinical Trial Monitoring, and the Research Compliance office. Resources have been allocated and implementation of this expanded model is well underway.
- New policies, assessment instrument and procedures are the key outcomes described in the Human Research Participants Who Have Impaired or Fluctuating Capacity to Consent final report. Communication to and education of the research community around these changes is underway and the Decision Making Capacity Consent Assessment Pilot has been initiated.
- The Department of Psychiatry throughout the AdvancingHRP implementation has been a key focus and their final report describes significant improvement s and change where they have gone above and beyond what was expected of them. The Department's culture has already begun to shift under new leadership, and the faculty is looking forward to the new permanent department head starting this summer, Dr. Sophia Vinogradov.
- The Engaging Research Participants work group submitted 10 recommendations including a research participant experience survey, contact card (attached), and a Community Liaison position description that will be staffed using existing resources in HRPP and be the principle liaison with the Community Oversight Board. The participant contact card is now available for use. Information on how to order and use the card is available on the IRB's informed consent Tools and Resources page.
- The Education and Training of Investigators final report includes six primary recommendations including results from an evaluation conducted of current human research participant training. The recommendations range from establishing a transparent education infrastructure to specifying Advanced training for investigators conducting research with vulnerable individuals and those with diminished capacity to consent.

- An accountability metrics structure has been drafted and described in that final report. Those metrics will be further evaluated and refined as operational responsibilities are fully transitioned and the integration of the AdvancingHRP implementation work is complete.
- The Conflict of Interest final report includes the final policy revisions and consultation summary. This revised policy has been endorsed and voted on by the Faculty Senate. It now awaits the results of the faculty union vote, which will likely be sometime Fall 2016 or later.

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 http://research.umn.edu/advancehrp/implementation.html or contact me with any questions.

Attachment

Research Participant Contact Information Card Template

FRONT

UNIVERSITY OF MINNESOTA_____

For questions about **research appointments**,
research study, **research results**, or other
concerns,
call the study team at:

_____

You will receive a response within 1 business day.

BACK

To share feedback **privately** about your research
experience, call the Research Participants'
Advocate Line at:
612-625-1650
Or go to www.irb.umn.edu/report.html

You will receive a response within 1 business day.
UMN Research Participants' Bill of Rights:
www.irb.umn.edu/xxxxxxx

AdvancingHRP Implementation

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 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	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 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	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	√	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	O	Ingbar, Schacker	Integrate and coordinate human research protection training
			Curriculum development
			Training delivery
Accountability Metrics	O	Waldemar	Track and report accountability metrics
Conflict of Interest	√	Durfee	Implement updated COI policy (complete pending faculty unionization vote)

√ = Completed
O = 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