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: April 1, 2016

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

Enclosed are two copies of the mandated report Human Subjects Research Standards – April 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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TO: Regent Johnson, Chair
Regent Brod, Chair, Audit Committee

FROM: Brian Herman, Vice President for Research

DATE: March 24, 2016

RE: Report to the Legislature

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

SUMMARY

This month President Eric Kaler, Vice President Brian Herman, and Dean/VP Brooks Jackson provided updates on the Advancing Human Research Protections implementation work to both the Senate Higher Education Committee and the House Higher Education Committee. Both sessions were productive discussions that highlighted both progress and continued need to makes changes, communicate transparently, and rebuild trust with the community. One outcome of the Senate hearing is a new Advancing HRP implementation organizational chart to help clarify the new processes and accountability lines (attached is the version distributed at the meeting). We intend to maintain this chart on our AdvancingHRP website.

An external consulting firm, Compass Point Research, submitted a final report of its independent review of close to 100 IRB protocols for active studies. Compass Point looked at how these studies were complying with federal and University of Minnesota IRB institutional requirements and good clinical practice. Adherence to the principles of good clinical practices (GCPs), including adequate human participant protection, is universally recognized as a critical requirement to the conduct of research involving human participants. Consistent with the recommendations of the external review panel that examined human participant research at the University of Minnesota last year, the studies were chosen carefully from those posing the highest potential risk to human participants.

Overall, the report indicates that the U of M does not have a systemic issue with the conduct of clinical research. According to statistics maintained by the Food and Drug Administration, the University performs well compared to national norms in terms of frequencies of clinical investigator deficiencies.

The report did identify two areas with higher incidence of non-compliance among U of M investigators when compared to the FDA's national norms: consent issues and IRB communication. In addition to recommending additional education and training for investigators, the report provided several recommendations for post-approval review and monitoring of studies to help minimize and address compliance issues as they arise. We are working to implement those recommendations.

The Engaging Research Participant work group has met monthly to develop the components of a system to foster shared understanding of research and research participation among researchers, participants, families and the broader community. The work group is engaged with community groups to more clearly understand public preferences for reporting results and providing information about research at the University. The group is working with Human Research Protection Program (HRPP) office to design and implement a participant contact card for study staff to give to participants and families, drafting a participant feedback survey, working on an information dissemination strategy that reflects community preferences, and developing recommendations to help researchers continually assess participant understanding throughout a study. This group anticipates finalizing its work in May.

The Department of Psychiatry and the Clinical Translational Science Institute (CTSI) are moving forward on implementing the management plan of clinical trials finalized in January. The management plan describes how the CTSI will assume management of interventional drug and device trials in the Department of Psychiatry. The CTSI has posted positions for a new Clinical Research Manager and a Regulatory Specialist, as well as two additional clinical trial monitors. CTSI is continuing its progress with the Department of Psychiatry's investigators to implement the required GCPs. The Department of Psychiatry has also begun the changeover to OnCore Clinical Trials management system and has adopted a new checklist to ensure more and better interactions between research and clinical staff from the study design through implementation.

The policy on scientific review of study protocols was revised and posted in March. IRB application forms were revised and communications were sent to researchers to indicate that departmental review is no longer accepted. Current and new IRB members will begin to conduct scientific assessments of research protocols in April.

Progress continues on IRB membership. Orientation meetings for all IRB members will begin in April. As noted above, the new members meeting scientific reviewer qualifications will be engaged in scientific review beginning in April. The HRPP office conducted outreach activities with community organizations, such as a Parent Advisory Board, the National Alliance for Mental Illness (NAMI), and the Ombudsman for Mental Health and Developmental Disorders for recruiting members of the community. Significant progress was made on committee membership

mapping and panel definition during March. Remaining expertise gaps will be filled during April.

Our external advisor to the implementation, Dr. David Strauss, was on campus March 30 and 31 to review progress with each of our work teams. Dr. Strauss also met with faculty and University senior leaders. We expect a report from him summarizing his visit. That summary will be shared with you in a future report. Dr. Strauss will continue his engagement with the University through June and will provide a final report at that time.

In addition, the Office of the Legislative Auditor is meeting with key stakeholders on campus to do a follow-up review. The OLA is focused on consent, recruiting and participation of vulnerable participants, conflict of interest, communication with family and friends of study participants, appropriate delegation of study tasks, IRB review, documentation of adverse events and communication between researchers and the IRB. We expect a report from Auditor Nobles in May.

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.

Attachment

Advance HRP Implementation

APRIL 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 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	O	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	O	Paller	Transition to Clinical & Translational Science Institute (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

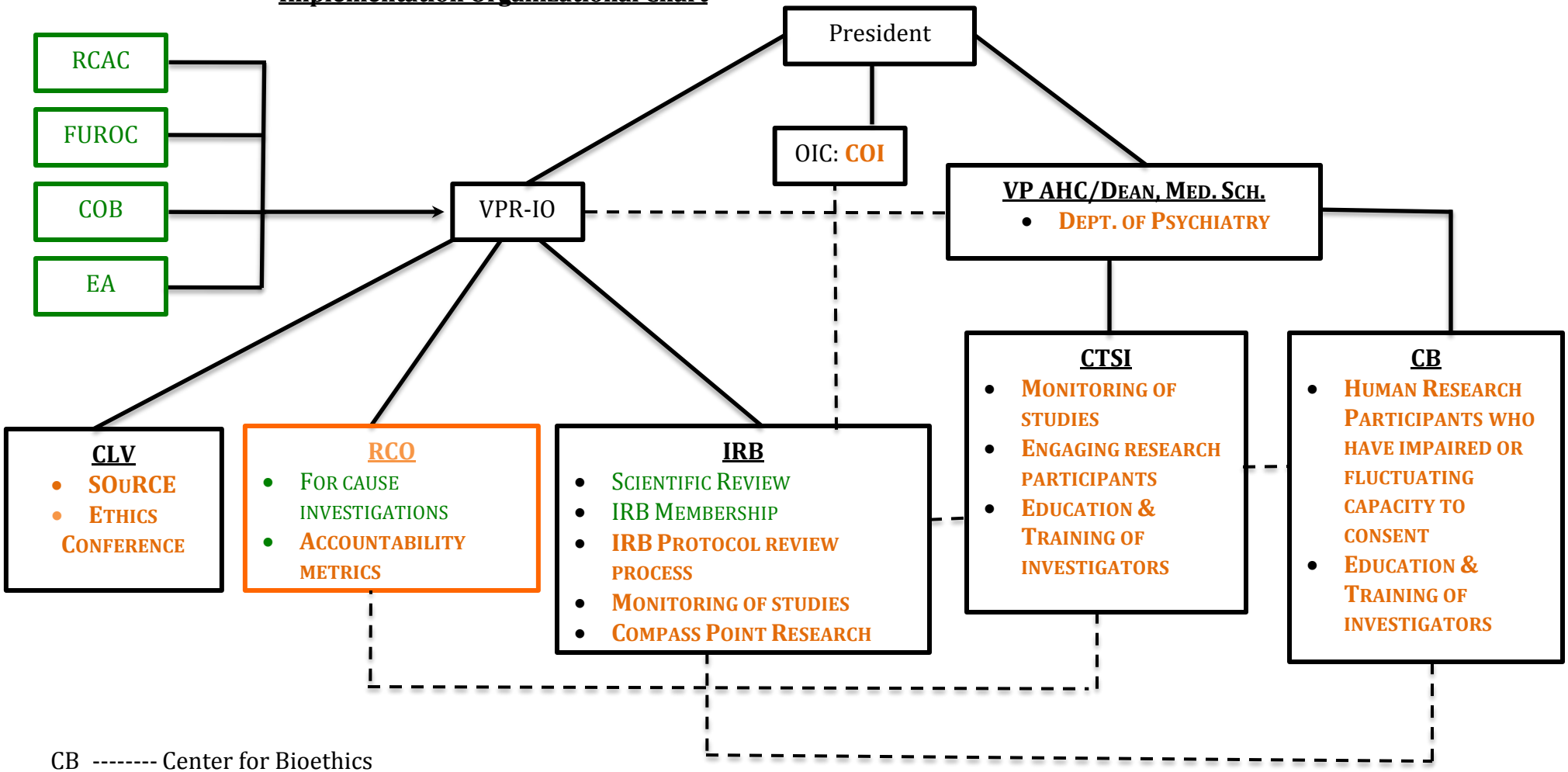
√ = Completed

O = In Progress/some items completed

☐ = 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

Advancing Human Research Protections
Implementation Organizational Chart



CB -------- Center for Bioethics
CLV ------- Consortium on Law and Values
COB ------ Community Oversight Board
CTSI ------ Clinical Translational Science Institute
EA -------- External Adviser
FUROC --- Fairview University Research Oversight Committee
IRB ------- Institutional Review Board
OIC:COI -- Office of Institutional Compliance: Conflict of Interest
RCAC ----- Research Compliance Advisory Committee
RCO ------ Research Compliance Office
VP AHC--- Vice President Academic Health Center
VPR-IO --- Vice President Research – Institutional Official

CHANGE IN PROGRESS
CHANGE COMPLETE
ESTABLISHED PRE-IMPLEMENTATION