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TO: Reed Polakowski, Minnesota Legislative Reference Library

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

DATE: May 1, 2016

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

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

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

FROM: Brian Herman, Vice President for Research

DATE: April 26, 2016

RE: Report to Legislature

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

The implementation teams are on track to deliver their final implementation reports by June 30, 2016 (See attached Progress Summary and Recommendations). Beyond that date, these activities will require the remainder of 12-18 month original timeline to finalize operational transitions (from work teams), map changes over to the eIRB system implementation, roll out educational programming and evaluating outcomes. We want to make sure that what we have implemented works effectively and efficiently within the larger institutional structures.

SUMMARY

On March 30 and 31 Dr. David Strauss was on campus reviewing progress with each of our work teams. His schedule included time with leadership of the IRB, the new Community Oversight Board, the Office of the Legislative Auditor, members of the Board of Regents, and Vice Presidents Jackson and Herman. Prior to his visit he consulted with Dr. Carl Elliot and Nicki Gjere. Post-visit he spoke with Dr. Steven Miles and with two members of the Psychiatry faculty. We expect his report and recommendations soon.

Also this month Dean/VP Jackson announced the hire of a new head of the Department of Psychiatry. Dr. Sophia Vinogradav will join the University in August of this year. She is currently a professor and Vice Chair of the Department of Psychiatry at UCSF. Dr. Vinogradav is an internally renowned schizophrenia researcher focused on cognitive training exercises, as well as an accomplished clinician and innovative leader. She is already engaged with the department and has begun meeting with interested stakeholders.

The Department of Psychiatry continues their progress with transferring clinical trial management to CTSI. The department has also implemented several policy changes with regards to psychiatry research. They have endorsed using the Good Clinical Practices (GCP) for all studies, even those protocols where it is not required. They have created, with health system partners, a checklist for trials involving Fairview patients that will ensure clinical staff involvement and collaboration. On April 20, the faculty also approved the Department of Psychiatry Dual Role Consenting Policy which states clearly that when a study investigator is also the treating clinician of a potential study participant, he/she should not be involved in the consenting process, that another study team member will answer questions about the study, and that the potential participant will be given the option to discuss treatment options with another clinician not involved in the study.

The Medical IRB panel structure has been revised, based on member feedback and recommendations from consultants. The structure will now include eight panels (an increase from four) which will include eight members from a variety of disciplines and meet every other week. Three orientation meetings were held in April for new and current IRB members who will serve under the new panel structure. In addition, members received training in ethical and regulatory issues in human participant research, as well as the committee review process.

In addition, the Office of the Legislative Auditor continues to meet with key stakeholders as part of an implementation follow-up review. The OLA has met with all the work area leads, several faculty members and leaders from the IRB, the Department of Psychiatry, Fairview Health Services and the CTSI. This review has also required a significant amount of implementation team effort in information gathering, responding to inquiries and scheduling. 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. In addition, attached is a more detailed progress summary. This document will continue to be updated weekly. For complete details, please visit research.umn.edu/advancehrp or contact me with any questions.

ATTACHMENT

AdvanceHRP Implementation **ATTACHMENT**

http://research.umn.edu/advancehrp/index.html

Progress Summary & Recommendations Alignment Table (v26April2016)

Work Plan Section	Lead(s)	Percent Complete*	Work Scope (Responsible Officer)	External Review Panel Recommendation	Completed Deliverables (Progress Reporting to BOR and Legislature including date reported)
IRB Membership	Billings, Biros	**80%**	Recruit membership, form new committees. Set compensation structure & policy **(VPs Herman and Jackson)**	- Implement guidelines regarding IRB meeting attendance in order to ensure that a larger, more critical mass of members are present at each meeting. - Broaden the membership of the Medical IRB to ensure that it includes individuals with expertise reflecting the nature and volume of the University's research. - Consider providing compensation, or alternate incentives (e.g., released teaching time, reduction of other responsibilities, consideration during promotion, etc.) to foster and support qualified faculty participation on an IRB. (page 27)	**Final Report Submitted and Posted on Website** -September 2015 Developed four medical IRB rosters that more closely align expertise with submission type. -September 2015 Proposed a minimum IRB meeting attendance requirement of 65%. Each medical roster will have 13 members including at least one non-scientific member. A majority must be present for each review. -January 2016 Further developed a compensation plan that conforms to federal guidance and incorporates the recommendations of the implementation team. -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. -Orientation meetings for all IRB members will begin in April 2016. New members meeting scientific reviewer qualifications will be engaged in scientific review beginning in April. -March 2016 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. -April 2016 Unanticipated challenges have been identified during preliminary implementation of the work plan recommendations related to IRB membership. In collaboration with experts from Huron Consulting Group, an alternative plan that meets the spirit of recommendations as noted in the work plan is currently underway. The HRPP office continues to monitor IRB membership and engage other groups, including the Community Oversight Board, to assist with recruiting a more diverse member base reflective of the community of research participants.
FUROC	Herman	**100%**	Establish committee	-Fairview staff should be involved in protocol review, in gatekeeping	-August 2015 Fairview University Research Oversight Committee (FUROC)

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			(VP Herman) Committee leadership **(VP Jackson and Thomas/Fairview CMO)**	functions, and in research monitoring. (page 84)	chairs charged and membership finalized. First meeting September 2015. -February 2016 FUROC reconstituted to include Beth Thomas, DO, Chief Medical Officer of Fairview, and Debra Cathcart, Chief Nursing Executive for M Health. At February's meeting the group agreed to meet bimonthly and focused on communication with the OVPR/IRB and increased collaboration between clinical and research staff as priorities. Between meetings a small group agreed to develop possible policies and practices to discuss further. The next meeting is scheduled for April 2016.
For Cause Investigations	Webb	**90%**	Establish Research Compliance Office **(VP Herman)**	N/A	**September 2015 Final Report Submitted and Posted on Website** Research Compliance Office (RCO) structure and operations became effective 10/2/15. The Research Compliance Office now has responsibility for conducting *For-Cause Investigations* (see below)
	Waldemar	**90%**	Transition For Cause Investigations **(VP Herman)**	- 3.2.8 Reconsider the reliance on IRB membership to staff ICs [investigative committees] looking into incidents of noncompliance; a. Consider whether one or more non-IRB individuals might also be appointed to the ICs; b. If the University will continue to draw only from IRB membership to formulate these panels, expand the IRB membership to ensure sufficient expertise to meet this charge, a. recommendation that was independently made in the foregoing section. - 3.2.9 More rigorously make use of other internal resources (such as the PAR Monitoring Program discussed in section 3.3.3) and external resources to supplement the work of the ICs. - 3.2.10 Evaluate the mechanisms through which IC findings and any corrective action required are disseminated, particularly with regard to follow-through with complainants. (page 34)	**September 2015 Final Report Submitted and Posted on Website** Deliverables related to plans 3.2.8 and 3.2.9 have been completed. Some deliverables related to 3.2.10 remain to be completed and they involve the revision of procedures about the actual investigation and the processes for dissemination of findings and management of any related corrective action requirements. The revised policy and procedures are in process.
Community Oversight Board	Herman	**100%**	Establish board structure and finalize membership **(VP Herman)**	N/A	October 2015 Appointed Paul Mattessich as chair of the newly established Community Oversight Board. Membership has been invited, accepted and first meeting held. -The COB had its inaugural meeting on February 8. The first meeting included

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					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 2016. -March 2016 The COB met with Dr. David Strauss.
External Advisor	Herman	**100%**	Hire external advisor: external review panel member **(VP Herman)**	N/A	-August 2015 Engaged Dr. David Strauss, member of the external review panel, to work with the University on implementation rollout. -External advisor Dr. David Strauss has reviewed and provided feedback on the following implementation work products: For cause investigations, the Research Compliance Office, updates to the IRB review process, changes to scientific review, Compass Point Research review and the consultant report on the Department of Psychiatry. -Dr. David Strauss, was on campus March 30 and 31 to review progress with each of our work areas. Dr. Strauss also met with faculty and University senior leaders. We expect a report from him summarizing his visit. Dr. Strauss will continue his engagement with the University through June and will provide a final report.
Scientific Review of Studies	Billings, Biros	**100%**	Change policy-eliminate dept. review, define HRPP process **(VP Herman)**	- Carefully consider the impact on the IRB's overall ability to conduct an appropriate risk-benefit analysis when the evaluation of study merit is delegated to the department. (page 47) - Carefully consider whether a robust review at the department level is feasible for each department, taking into consideration the size of the department, reporting relationships, and the volume of research. (page 47) - If the University chooses to maintain a department-based process for scientific review: a. Ensure the applicable policies delineate departmental and IRB responsibilities regarding the assessment of study design; b. Develop guidelines for careful scientific review and ensure that the de minimis requirements are adhered to when department-level scientific review is used. (page 47)	**December 2015 Final report submitted.** -The policy on scientific review of study protocols was revised and posted in March 2016. 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 2016.

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				- Revise the HRPP policy on scientific review and related guidance on the IRB's website to state that individuals with a conflict of interest or conflict of commitment may not serve as a scientific reviewer. Conflict of interest should be operationally defined in these documents. (page 47) - Revise the template titled "Departmental Scientific Assessment Form" (used pursuant to Method 3) to ensure that this form includes a statement defining potential conflicts of interest and affirming that individuals with such a conflict of interest may not serve as a scientific reviewer. (page 47) - Consider whether additional protections are needed to ensure that scientific reviews of research proposed by senior faculty are not reviewed by subordinates. Given these concerns, the University should determine whether department-based review is feasible for individual departments. (page 47) - Develop a mechanism for systematically incorporating scientific reviews into the IRB review process to ensure that scientific concerns impacting the criteria for IRB approval are sufficiently addressed. (page 49) - Require that the IRB meeting minutes specifically document the IRB's review of the scientific assessment documents and any substantive concerns raised in the course of this review. (page 49)	
Cultivating A Culture of Ethics	Aronson, Wolf, Zentner	**50%**	Communications: Commitment Statement, Culture: campus conversations, education Hierarchy of accountability **(VPs Herman and Jackson)**	- Publicize unequivocal statements on the administration's intention to create and nurture a culture of ethics in research; the OVPR must then animate these values to life by investing in their visibility and adoption at all levels of the University's research enterprise. (page 20) - Convene a task force that would include research participants, research ethicists, educators, researchers, and HRPP/IRB staff to consider ways in which ethics and ethics education on the topics of research participant protections will be integrated into practice. (page 20) - Explore ways in which an acknowledgement of the primacy of research participant protections and ethical research could be integrated into relevant University publications, materials, and web pages. (page 20) - Incorporate the University's stated commitment to, and plans for	Dec. 2, 2015 University hosted conference entitled "Research with human participants: The National Debates". Large national audience including external experts participated. Videos available online. September 2015 To address the "two task force" recommendation, the implementation team designed a structure where this would be a shared responsibility between the Community Oversight Board and FUROC. December 2, 2015 Building on the momentum and success of the University's conference, Research with Human Participants: The National Debates, conference organizers are now making plans to hold an annual half-day conference on research ethics. The Consortium on Law and Values, which

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				strengthening, research ethics and research participant protections in future strategic planning. (page 21) - Require all departments engaged in clinical research to acknowledge this refocusing of University research priorities and craft statements reflecting their own commitment to excellence and accountability in human subjects protections. (page 21) --Consider efforts to engage the local community of patients and prospective subjects with programs on the ethics of research and the University's HRPP (page 40) - Define a hierarchy of accountability for human research ethics and thereby expand oversight responsibilities beyond the IRB. Department chairs should be expected to review and approve the submission of IRB protocols, be engaged in follow-up compliance activities, develop department-specific educational programs, and share ultimate responsibility for human subjects protections within their departments. (page 89) - Rework institutional messaging in policies and procedure to include unequivocal statements on the administration's intention to create and nurture a culture of ethics, and adopt communication strategies to bring these core values to life by investing in their visibility and adoption at all levels of the University community and beyond (page 90) - Establish both formal and informal means of stimulating a university-wide conversation about the manner in which this newly endorsed culture of ethics can be most effectively realized. (page 90)	hosted the initial conference, will lead the planning efforts for a spring 2017 conference as well. Dec. 11, 2015 Vice President for Research incorporated a stated commitment to ethical culture into the research strategic plan and presented during annual report to the Board of Regents. In addition, the 2015 University Accountability report (pg. 80) includes a similar ethics statement about meeting, upholding and exceeding the highest ethical standards in research practices involving human subjects. February 2015 The Cultivating a Culture of Ethics leadership team has drafted a University 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 increasing awareness about our value system as well as University policies and procedures. The key stakeholder groups include department heads, clinical department faculty, faculty governance, and an open call for comments using the AdvancingHRP website. March 2015 Began work on developing a messaging campaign that communicates the University core commitments to a culture of ethics (above) and offers a way for people to voice concerns and find more information. -December 2015 Through conversations with national experts, an evaluation tool called the Survey of Organizational Research Climate (SOuRCe) was identified. This survey instrument is described at http://ethicscenter.csl.illinois.edu/sorc/. To our knowledge it is the only validated instrument in the U.S. for assessing the perceived climate of research integrity. To guide UMN customization and administration of the SOuRCe, an

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					Advisory Committee has been assembled and will include collaboration of Brian Martinson, PhD, a co-developer of the SOuRCe. **OTHER AREAS CONTRIBUTING WORK** - Hierarchy of accountability for human research ethics: an accountability org chart was created for the March 2016 legislative hearings and will serve as the basis for this hierarchy. [AdvancingHRP Communications] - HRPP is working with OVPR communications on website upgrade to include a "one-stop" concept. This work will be done in partnership with the AdvancingHRP communications team and the IRBRenew project implementation. [HRPP and OVPR Website Redesign]
IRB Protocol Review Process	Dykhuis	**80%**	eIRB, new forms & procedures, new FTEs, benchmarking visits **(VP Herman)**	- Revise the format of the convened IRB meeting minutes to include a meaningful summary of the study, any controverted issues that are discussed, their resolution, and documentation to support the IRB's rationale for requesting modifications to the study. (page 30) - Consider whether certain actions may not warrant convened IRB review and therefore may not require discussion at the convened IRB meeting, freeing up time for the discussion of more complex and challenging protocols. (page 30) - Consider developing a system for evaluating the appropriate number of action items per convened meeting agenda with consideration of the expertise of those present and the planned length of the agendas. (page 30) - Consider making arrangements for the University's IRB staff to attend IRB meetings at peer institutions so as to better assess best practices and to determine ways in which the University's IRB can be improved. (page 31)	-IRB staff conducted benchmarking visit in July 2015 visit to Penn State. -August 2015 Enhanced the pre-review process to more appropriately utilize non-meeting IRB review (referred to in regulations as "Expedited Review") for applicable submissions. -August 2015 Established meeting agenda "caps" on number of items reviewed - September 2015 Revised IRB minutes and meeting management. More closely aligned practices for documenting controverted issues with regulatory requirements & accreditation standards by revising the meeting minutes template to enhance and facilitate IRB deliberations. September 2015 -Doubled total number of IRB continuing review meetings and increased number of medical meetings. -January 2016 Hired reliance agreement position into HRPP operations. -December 2015 The HRPP continues to make progress on implementing an electronic system to manage documents and processes for the IRB (IRB Renew). The first phase of this project officially launched on January 4 and is anticipated to last six weeks. During this phase, the IRB Renew Project team members will work closely with Huron Consulting and a small number of institutional stakeholders to gather and document the requirements of the U's

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					IRB and HRPP. The second phase of the project launched on March 28, 2016. This phase will consist of customization and implementation of the Huron Toolkit, redefining organizational structure and augmentation of staffing resources and training/mentoring of IRB staff and members on the effective utilization of new SOPs, checklists, worksheets and training guides. The third and final phase, which will run concurrently with implementation of the toolkit, will be configuration and the launch of the online submission system. -HRPP hired an expert consultant who is attending IRB committee meetings to provide consultative support for the committee. -The HRPP enhanced the continuing review meeting documentation procedures which includes a revised IRB review worksheet.
Monitoring of Studies	Dykhuis	**50%**	New FTEs, reengineer PAR function + external advisor **(VP Herman)**	- Efforts to expand monitoring conducted through the PAR program and/or via the application of its methods to other HRPP monitoring efforts should be considered. Specific emphasis should be placed on increasing PAR monitoring efforts for research conducted at Fairview with an active dialogue with the Fairview staff so that they can be actively engaged in the process. - PAR should track and measure IRB follow-through on its findings and recommendations and report these to research leadership including department chairs and the Dean of the Medical School. - PAR should regularly share summary reports of its findings with department chairs and other institutional leaders charged with research oversight responsibilities to ensure that key areas of investigator and programmatic noncompliance can be readily identified and addressed. - Deficiencies in IRB review processes/functioning should also be addressed through existing reporting and supervisory hierarchies, and not be addressed solely within the more limited authority of the IRB and Office of the Vice President of Research. - In the context of ongoing concerns about problems related to subject recruitment and consent in psychiatric studies, PAR should include live	-Two new monitoring staff hired in HRPP to address expanded monitoring. -Development of new tools is underway to use during the performance of live consent monitoring. In addition, creation of tools to facilitate engagement of research participants during the assessment of informed consent and development of tools to enhance understanding of informed consent is underway. The PAR team is also evaluating use of existing, validated survey tools that could be deployed following informed consent of participants to assess the quality and effectiveness of informed consent. - PAR staff are preparing for collaboration with work plan leads related accountability metrics and reporting. Effort is being spent compiling data for monthly reports of quality improvement and quality assurance initiatives, including assessment of IRB review process/functioning, that will facilitate development of more transparent reporting mechanisms with key stakeholders as recommended by the external review panel and as detailed in the work plan. - Enhanced methodology for monitoring. Engagement of an external clinical and translational research management and consulting firm (Compass Point Research) submitted a final report in March 2016 that included PAR

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				consent monitoring of such studies in its repertoire of subject safeguards. - Separate reporting chains for IRB review and Post-Approval Review should be considered. (page 54)	methodology recommendations.
Human Research Participants Who Have Impaired or Fluctuating Capacity to Consent	Miles, Dykhuis	**50%**	Implement tool to assess capacity. Train and communicate researchers **(VP Herman)**	- Policies, guidance, application and review forms, and the IRB review process itself, should be redrafted and/or restructured for clarity and consistency to ensure that they will be appropriately used to prompt consideration of the methods used for assessing capacity to consent. (page 65) - The IRB should ensure that its review includes a substantive assessment of the scope and appropriateness of protocol-specific procedures that address the capacity to consent in light of the subject population being approached. (page 65) - Revised policies on legally effective informed consent should: a. provide the means for verifying decision-making capacity and voluntariness in all protocols as preconditions for all human subjects research; b. reject the standard that presumes capability by establishing a test of "substantial evidence otherwise" for adults with impairments. (page 65) - The IRB must provide adequate review and oversight of its policies to ensure that they: a. align subject screening or other protections with the degree of risk involved in a study or the level of risk of impairment in a targeted or enrolled population; b. promote the use of strategies to support or enhance subject decision-making, including the advance selection of a surrogate decision-maker by a subject who may later lose decision making capacity. (page 66) -Develop standards that protect against real or perceived coercion in psychiatric treatment settings in which individuals may fear involuntary court proceedings. - Encourage and support the use of independent consent monitors, particularly in those cases where the treating physician is also the investigator, so as to minimize the possibility for undue influence or coercion.	September 2015 IRB Policies Amended: IRB Policy 501: Vulnerable Populations IRB Policy 506: Adults Lacking Capacity and/or Adults with Diminished Capacity to Consent Held Informed Consent training session designed for research coordinators in March 2016. Recording of "Informed Consent: Enhancing Participant Understanding" is available on the IRB training page http://mediasite.ahc.umn.edu/Mediasite/Catalog/catalogs/ovpr-hrpp A new course is being offered spring semester 2016 at the University of Minnesota. This fifteen week lecture series, Standards for Research with Human Participants, is offered through the Center for Bioethics and is taught by Steven Miles, M.D., professor in the Department of Medicine and Maas Family Endowed Chair in Bioethics in the Center for Bioethics.

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				(page 68) - IRB policies should more clearly require that protocols involving adults with potentially limited decision-making capacity include a plan for monitoring subjects who are likely to have fluctuating capacity, including the steps to be taken if capacity diminishes over the course of study participation. - IRB policies should more clearly require that protocols involving adults with potentially limited decision-making capacity specify the plan for re-consent when a subject regains capacity. (page 69)	
	Dykhuis	**50%**	LAR policy changes 72-hour hold policy **(VP Herman)**	- Policies and procedures related to the use of LARs must be comprehensively re-assessed in accordance with the foregoing observations and conclusions. - The OVPR and HRPP leadership should consider consultation with OHRP or DHHS on this topic. (page 71)	December 2015 HRPP hired an expert IRB consultant to facilitate revision of LAR policies. -The HRPP is evaluating interest in establishing a community wide workgroup to gain consensus on the definition and interpretation of the Minnesota statute regarding the role of the legally authorized representative in research. -The HRPP is evaluating validated capacity (to consent) assessment tools. -The post approval review team is developing draft tools to perform consent monitoring activities including a brochure for use with LARs to facilitate the informed consent process.
		50%		-The HRPP should develop effective strategies to educate research personnel on the legal use of surrogate decision-makers when considering the involvement of research participants with limited decision making capacity. -The IRB's review of protocols proposing the use of surrogate decision-makers be rigorous and in keeping with applicable laws and best practices, as well as with University policies. (page 73)	-September 2015. Implemented no recruitment of individuals/patients on 72-hour hold. Changes documents in revisions to Appendix I and HRPP Policies 501 and 506 related to the 72-hour hold policy were released in April.
Dept. of Psychiatry	Paller	**70%**	Clinical & Translational Science Institute (CTSI) management of trials.	- IRB membership, expertise and training should more effectively address risk evaluation and management for psychiatric research. - Best practices regarding consent and capacity to consent should be	- Dec 2015 IRB website http://www.research.umn.edu/irb/ updated so that departments or academic instructors may request basic or advanced training tailored to individual needs and meet the greater goal supporting culture

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			Engage consultant for climate assessment plan. Enhance culture of inclusion and mutual trust. **(VP Jackson)**	introduced and made routine. - Fairview staff should be involved in protocol review, in gatekeeping functions, and in research monitoring. - [The investigators] as the focus of ongoing concern and criticism, should receive supervision, coaching in leadership, and advanced training in human subjects protections. (page 84)	change. - The Implementation Team work plan included a recommendation that the Clinical Translational Science Institute (CTSI) assume management of interventional drug and device trials in the Department of Psychiatry. CTSI contracted with Clinical Research and Compliance Consulting in response to that charge, and the consultant's final report and CTSI management plan were shared with the Board of Regents Audit and Compliance Committee on February 11. -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. - With CTSI, the Department of Psychiatry has begun the changeover to OnCore Clinical Trials management system. - The Department endorsed using GCP for all clinical trials. CTSI is continuing their progress with the Department of Psychiatry's investigators to implement the required GCP. There is a full time CTSI staff working with psychiatry investigators. - The Department has worked with Fairview to **adopt a new checklist** to ensure more and better interactions between research and clinical staff from the study design through implementation. This had been adopted by both the Department and Fairview. - Of the two investigators identified in the external panel review, one has retired from the University and one is no longer engaged in clinical research. To reengage in research, the investigator is aware that he must complete the required training and literature review. To date he has participated in the OVPR summit and has engaged in departmental discussions regarding

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					interactions with clinical staff, consent processes and conflicts of interest.
Engaging Research Participants	Eder	**70%**	-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	- Establish accessible and reliable electronic and non-electronic channels (in addition to existing complaint mechanisms) for facilitating sustained communication among research participants, their family members and other advocates (within the permissible bounds of the Health Insurance Portability and Accountability Act (HIPAA)), researchers, research team members, and HRPP/IRB administration. - Develop mechanisms to regularly solicit, evaluate, and respond to research participant feedback. (page 58) - Partner with researchers to incorporate mechanisms for soliciting feedback regarding the research participant experience so that it can be secured contemporaneously with the individual's agreement to participate in research;10 For example, the HRPP might afford research participants an opportunity to complete a research participant satisfaction survey at the end of study participation, or add an option to the University's template consent form asking subjects if they would agree to be contacted by the HRPP about their experiences as a research participant. Contact information for individuals who agree to this option could then be shared with HRPP officials and, post-participation, these individuals could be surveyed about their experiences. Data from these evaluations could be used to assess the research participant experience more broadly and would afford the HRPP a road map for developing programmatic changes that are directly responsive to the expressed needs of the research participant community. (page 58) - Include members of the research participant community on relevant research related committees, task forces, and/or educational programs as another means by which researchers, research staff, research administrators, and University leadership can form relationships with them and thus more directly solicit their input on community priorities and areas of community	-The Engaging Research Participants work area gathered research participant surveys from other Clinical and Translational Science Award (CTSA) institutions across the country and is crafting a survey to assess research participants' experiences (Jan – March); two drafts of the survey have been reviewed by the work group (March – April). Expectation is to have a final version in late May or early June. - The group is drafting recommendations for research dissemination to participants and the public that reflect community preferences. - The group has developed recommendations related to the informed consent process, particularly emphasizing consent as an ongoing or continuous process. The recommendations will be complete in early May. - 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. A final version of the card will be available in early May. - The group drafted a Community Liaison Officer (CLO) position description and anticipates posting the position in April. A final version of the job description has been shared with University leadership in April with the expectation of its posting in the next month. Key responsibilities of the CLO will be supporting the Community Oversight Board, implementing the research participant survey, and compiling information to report on the University-community relations around research.

Work Plan Section	Lead(s)	Percent Complete*	Work Scope (Responsible Officer)	External Review Panel Recommendation	Completed Deliverables (Progress Reporting to BOR and Legislature including date reported)
			(VP Herman)	concern. (page 59) - Consider systematic approaches to express appreciation for subject participation, develop mechanisms to share research findings, and where appropriate, individual research results with subjects as a method of demonstrating partnership, showing respect and building trust. (page 59)	
Education and Training of Investigators	Ingbar, Schacker	**75%**	Integrate and coordinate human research protection training: curriculum development, training delivery **(VP Herman)**	-Conduct an evaluation of the resources of the HRPP specifically dedicated to the education and training of the research community to ensure that appropriate resources are in place to offer basic and advanced training opportunities in human subjects' protections (page 39) -Create opportunities for advanced training in human subjects protections for all individuals involved in human subjects protections including investigators, IRB members and staff, research personnel, and clinical staff on units that conduct research (page 39) -Evaluate whether additional mandatory training requirements, comparable to the new mandatory training for sponsor-investigators, should be implemented. Careful attention should be given to areas of research that are considered to be "high-risk," including those involving vulnerable populations such as individuals with the potential for limited decision-making capacity (page 39) -Institute a more substantive requirement for advanced level training for investigators and research teams when a determination has been made by the IRB of serious or continuing noncompliance, and develop a mechanism for ensuring compliance with this requirement (page 39) -Evaluate the mechanisms through which HRPP policies and procedures are communicated to the broader University research community in order to ensure that all its members are knowledgeable about and have ready access to the policies and procedures related to human subjects research (page 40)	Dec. 2015 CTSI hires consultant to perform human research protection education and training gap analysis and curriculum design plan based on national CTSA consortium information. March 2016: Draft summary of existing UMN resources and Education & Training gap analysis with recommendations completed. April 2016 - Education & Training gap analysis with recommendations accepted by work group, meeting with Drs. Herman and Jackson to present a comprehensive plan on April 20 and includes need for longer time horizon (18 rather than 12 months) to develop analysis, recommendations and plan for implementation. Implementation will commence based on results of that meeting. <u>OTHER AREAS CONTRIBUTING WORK</u> Sept. 2015 HRPP program education and outreach specialist hired and has created an education structure for new IRB members, expanded communication and education issues, and launched a training tracker to document HRPP and IRB training. Dec. 2015 - Center for Bioethics releases fifteen week lecture series spring semester entitled, "Standards for Research with Human Participants".

AdvanceHRP Implementation **ATTACHMENT**

http://research.umn.edu/advancehrp/index.html

Progress Summary & Recommendations Alignment Table (v26April2016)

Work Plan Section	Lead(s)	Percent Complete*	Work Scope (Responsible Officer)	External Review Panel Recommendation	Completed Deliverables (Progress Reporting to BOR and Legislature including date reported)
				-Create expectations for the involvement of research departments and centers in the development of educational programs tailored to the nature and context of their research activities (page 40) -Consider ways to involve the University's Center for Bioethics in the educational programs focusing on human subjects research (page 40) -Consider efforts to engage the local community of patients and prospective subjects with programs on the ethics of research and the University's HRPP -Upgrade and professionalize education in, among other subjects, the responsible conduct of research and research ethics. (page 40)	Dec. 2015 IRB Website http://www.research.umn.edu/irb/ now includes advanced training opportunity, tailored training and new IRB Newsletter designed to deliver timely updates about policy, procedure and training opportunities. **Center for Bioethics: Standards for Research with Human Participants** Spring Semester, Jan 19 - May 6, 2016
Accountability Metrics	Waldemar	**60%**	RCO track and report accountability metrics. Create reporting mechanism to Community Oversight Board and FUROC. **(VP Herman)**	N/A	- Portfolio of identified items being finalized. Metrics team has been identified. Meetings with stakeholders and data analysts are being scheduled. Data collection slated to commence July 1 while work continues on data presentation, level of detail, infrastructure requirements (queries, tables, access, etc.).
Conflict of Interest	Durfee	**80%**	Revise COI policy **(Chief of Staff/Office of Inst. Compliance Director)**	N/A	-Revisions to the Conflict of Interest policy are now in the final stages of consultation and review. Policy will be discussed, and possibly voted on, at the May University Senate meeting. Even if voted upon by the Senate, the new policy will not be put into place until after the faculty union vote, which will likely be sometime this Fall. Once passed, the University will be one of only three institutions (including UCSF and Mayo) to have a policy requiring no personal income from a company while working as a PI on a study funded by the same company.
Other: BOR	Herman		Suspended enrollment of psychiatric	N/A	-Hired Quorum IRB to review 15 psychiatric studies suspended and 3 psychiatric studies not yet approved by IRB.

Progress Summary & Recommendations Alignment Table (v26April2016)

Work Plan Section	Lead(s)	Percent Complete*	Work Scope (Responsible Officer)	External Review Panel Recommendation	Completed Deliverables (Progress Reporting to BOR and Legislature including date reported)
or Senior Leadership Assigned			2015 AAHRPP Accreditation, interventional drug studies outsourced, engage external consultant to review protocols **(VPs Herman and Jackson)**		-All new Psychiatry interventional drug trial applications continue to be outsourced to Quorum *IRB*. - June 2015 AAHRPP reaccreditation site visit and follow-up draft comments. Sept. 2015 Final site visit report and pending accreditation status received. Quarterly improvement plans required through Aug. 2016. -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. -One outcome of the Senate hearing is a new Advancing HRP implementation organizational chart to help clarify the new processes and accountability lines. -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.

***Percent Complete = percent complete of external review panel recommendations. Work scope could include additional items described in the Implementation Team's Final Report that go beyond the external review panel recommendations.**

Advance HRP Implementation

MAY 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. Enhance culture of inclusion and mutual trust.
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 human research protection 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