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TO: Katie Elmore, Minnesota Legislative Reference Library

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

DATE: January 1, 2017

RE: University of Minnesota mandated report: Human Subjects Research Standards – January 2017

Enclosed are two copies of the mandated report Human Subjects Research Standards – January 2017, pursuant to 2015 Minnesota Law Chapter 69 Article 3 Section 26.

This report can also be found online: http://government-relations.umn.edu/state/legislative-materials

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 Michelle Fischbach, Senate Higher Education Finance and Policy Chair
Representative Bud Nornes, House Higher Education & Career Readiness Policy and Finance Chair
Senator Greg Clausen, Senate Higher Education Finance and Policy Ranking Minority Member
Representative Gene Pelowski, House Higher Education & Career Readiness Policy and Finance Ranking Minority Member

UNIVERSITY OF MINNESOTA

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December 23, 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 eighteenth 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 January 1, includes a narrative summary of what has been accomplished since the last report and in addition provides information at the bottom of report about where more details can be found.

This January report signifies the arrival of our December 31 implementation end date and because of this this will be our last formal report. We look forward to sharing the continued advancements and evolution of our human research protection program upon your request.

SUMMARY

As we have and continue to report to the Board of Regents Audit and Compliance Committee, this university is dedicated to meeting, upholding, and exceeding the highest ethical standards in research practices involving human participants. We have reached the end of our implementation period and with the exception of our new electronic IRB system, nearly all of the 63 recommendations (see table and progress card below) from our external review will be implemented by 12/31/16. It is important to note that the University added recommendations for changes to our human research protection program and those enhanced or exceeded what the external review panel proposed. Many faculty and staff have put in considerable time and effort into advancing human research protections and they have had significant accomplishments thus far and it will require continuous attention and focus from the University's research community. This is a challenging and vexing lift for the University and our work continues as we maintain and build upon these changes in our day to day operations.

All the final reports from each work area are approved and available on our implementation website. Most recently we finalized and approved the monitoring and accountability reports. Our oversight committees continue to meet including the Fairview University Research and Oversight Committee (FUROC) which recently met on 12/21/16. In January we will report our progress to both

the Community Oversight Board on 01/12/17 and the University's faculty research compliance advisory committee later in the month.

We believe we have and will continue to make great advancements in our human research protection program. For complete implementation details including final work team reports, please visit http://research.umn.edu/advancehrp/implementation.html.

Advancing Human Research Protections
Table: External Review Recommendation Summary

R#	External Review Report Section	Page Reference	External Review Recommendation	Completion Status	Additional Commentary
1.	Leadership Initiative	20	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.	Complete	UMN adopted these Core Commitments to represent shared responsibility to protect research participants, uphold the highest ethical standards and improve practices at every step. UMN also launched a communication effort to recognize IRB member service, including recognition of those who have served, those that have continued to serve, and those new to this role.
2.	Leadership Initiative	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.	Complete	Two mechanisms have been established: Community Oversight Board (COB) and the Fairview University Research Oversight Committee (FUROC)
3.	Leadership Initiative	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.	Complete	Adoption of the Core Commitments was made by UMN departments/units. References to the Core Commitments can be visibly seen on UMN department websites and office spaces.

R#	External Review Report Section	Page Reference	External Review Recommendation	Completion Status	Additional Commentary
					Enhancements were made to research participant resources including revisions to the HRPP research participant webpage and development of a research participant brochure, participant contact card, and legally authorized representative brochure. This work continues with a plan of integrating participant resources with additional UMN department websites including Study Finder. The HRPP announced the anticipated release of new software for IRB submissions in March 2017. The system's acronym, ETHOS, stems from the University's mission to cultivate a culture of research ethics—to protect research participants, uphold the highest ethical standards, and improve our practice at every step. This launch is part of the larger initiative to adopt new and enhanced approaches to the review of human research, including the adoption of the HRPP Toolkit.

R#	External Review Report Section	Page Reference	External Review Recommendation	Completion Status	Additional Commentary
4.	Leadership Initiative	21	Incorporate the University's stated commitment to, and plans for strengthening, research ethics and research participant protections in future strategic planning.	Complete	To continue University's mission and commitment, the Human Research Protection Program committee was formed, representing stakeholders across human research protections. The HRPP committee will provide a coordinated approach for effective planning, implementation, and monitoring of the HRPP's mission. This includes the following objectives: ● Establish methods to promote transparency and collaboration across the HRPP ● Identify, evaluate, and prioritize HRPP gaps ● Review and make recommendations to university leadership regarding the university's mission to protect participants, uphold ethical standards, and improve HRPP practices ● Share accountability for and evaluate the overall performance of the HRPP
5.	Leadership	21	Require all departments engaged in	Complete	AdvancingHRP developed a

R#	External Review Report Section	Page Reference	External Review Recommendation	Completion Status	Additional Commentary
	Initiative		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.		communicators toolkit to provide access to digital and print assets related to the Core Commitments for use by units and departments.
6.	IRB Membership	27	Implement guidelines regarding IRB meeting attendance in order to ensure that a larger, more critical mass of members are present at each meeting.	Complete	Eight IRB panels of eight members per panel have been established. Each panel meets every other week. To meet performance standards and be eligible for compensation, members must attend a minimum of 22 (of 26) meetings each year.
7.	IRB Membership	27	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.	Complete	Biomedical IRB membership has increased from 37 to 67 members and representation is based, in approximate proportion to the volume of submissions received from each department/division. Quarterly evaluation of this alignment is underway.
8.	IRB Membership	27	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.	Complete	A compensation plan has been implemented for IRB members and chairs.
9.	IRB Review	30	Revise the format of the convened IRB	Complete	The format of IRB meeting minutes

R#	External Review Report Section	Page Reference	External Review Recommendation	Completion Status	Additional Commentary
	Process		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		has been revised to align with the Huron Toolkit. The format aligns with regulatory criteria and has been reviewed by the Association of Accreditation for Human Research Protection Programs - most recently in October, 2016.
10.	IRB Review Process	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	Complete	A training plan has been implemented to calibrate staff determinations for level of review and to identify actions that do not warrant convened IRB review. This training plan is part of the larger implementation of the Huron Toolkit and includes both group training sessions as well as individual mentoring.
11.	IRB Review Process	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.	Complete	A cap has been placed on the number of items that may be placed on a committee agenda. No more than 20 items can be placed on an agenda. With 8 panels, and a recalibration of items that go to full committee, the agenda size for meetings is 8-12 items. A process is in place to evaluate compliance with agenda development.
12.	IRB Review Process	31	Consider making arrangements for the University's IRB staff to attend IRB	Complete	IRB staff conducted a visit to Penn State in July, 2015. An IRB chair

R#	External Review Report Section	Page Reference	External Review Recommendation	Completion Status	Additional Commentary
			meetings at peer institutions so as to better assess best practices and to determine ways in which the University's IRB can be improved.		from Harvard served as a chair for one of the new IRB panels for several months in 2016. Mayo's IRB chair lead the spring 2015 implementation team and shared their best practices.
13.	IRB as an Investigative Body	34	Reconsider the reliance on IRB membership to staff ICs 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.	Complete	In July, 2016, a new administrative policy "For-Cause Investigations Related to Research Compliance Concerns" was implemented under the direction of the Research Compliance Office. The Research Compliance Office has assumed the role of looking into incidents of noncompliance defined by policy.
14.	IRB as an Investigative Body	34	More rigorously make use of other internal resources (such as the PAR Monitoring Program discussed in section 3.3.3 below) and external resources to supplement the work of the ICs.	Complete	Clarity about the Post Approval Review (PAR) quality assurance program and the Clinical and Translational Science Institute (CTSI) clinical trial monitoring program - in substance and projected volume - is now available for the Research Compliance Office (RCO) and the Institutional Official (IO).

R#	External Review Report Section	Page Reference	External Review Recommendation	Completion Status	Additional Commentary
15.	IRB as an Investigative Body	34	Evaluate the mechanisms through which IC findings and any corrective action required are disseminated, particularly with regard to follow-through with complainants.	Complete	Information from PAR quality assurance reviews and the CTSI clinical trial monitoring program will be regularly shared with the Research Compliance Office and the IO.
16.	Education and Training	39	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	Complete	An evaluation was included in the Education and Training Final Report. The Education Advisory Group will take in consideration the recommendations included in the final report and analysis.
17.	Education and Training	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	Complete	Additional opportunities for advanced training were offered including but not limited to workshops on expanded access, local laws and human research, capacity to consent with the MacCAT-CR and UBACC tools. The HRPP offered advanced sessions sponsored by multiple professional research ethics organizations including Public Responsibility in Medicine and Research, Association for the Accreditation of Human Research Protection Programs, and Quorum

R#	External Review Report Section	Page Reference	External Review Recommendation	Completion Status	Additional Commentary
					IRB Review.
18.	Education and Training	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	Complete	The HRPP implemented policy HRP-110 which requires the completion of a newly developed online course, Assessing Capacity to Consent to Research, for those obtaining consent in studies involving persons potentially with diminished, fluctuating, or absent capacity to consent.
19.	Education and Training	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	Complete	A collaboration exists between the Post Approval Review (PAR) program and HRPP’s Education and Outreach to identify training needs for investigators and staff based on compliance gaps. This includes: ● A mechanism for ensuring compliance with identified training requirements through Corrective Action and Prevention Plans; ● Forwarding of monthly reports of QA/QI activities by the PAR program to the HRPP team; and ● Weekly management team meetings that includes

R#	External Review Report Section	Page Reference	External Review Recommendation	Completion Status	Additional Commentary
					dialogue and updates regarding compliance activities of the PAR program.
20.	Education and Training	40	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	Complete	The HRPP launched in September 2015 a research community newsletter that is sent to over 10,000 researchers, student researchers, advisors, coordinators, and representatives of research administration and leadership. The HRPP has found this avenue most effective for communicating policies, procedures, and other regulatory information based on the review of feedback from the research community and reporting and analytics. The HRPP and IRB websites underwent significant revision to ensure easy access to policies, procedures, and guidance related to the protection of human subjects in research.
21.	Education and Training	40	Create expectations for the involvement of research departments and centers in the development of educational programs tailored to the nature and	Complete	The Human Research Education Advisory Group was launched to address recommendations from the Education and Training final report

R#	External Review Report Section	Page Reference	External Review Recommendation	Completion Status	Additional Commentary
			context of their research activities		and to consider other education-related recommendations from across the University.
22.	Education and Training	40	Consider ways to involve the University's Center for Bioethics in the educational programs focusing on human subjects research	Complete	The Education Advisory Group includes a representative from the Center for Bioethics. In addition, representation from the Center for Bioethics has been included in the development process of the online course, Assessing Capacity to Consent to Research, and a hybrid course on the topic of informed consent.
23.	Education and Training	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	Complete	HRPP's Education and Outreach included targeted efforts to engage communities in the development of research participant facing educational resources.
24.	Education and Training	40	Upgrade and professionalize education in, among other subjects, the responsible conduct of research and research ethics	Complete	HRPP efforts to enhance and professionalize human research education include the launch of an online course, Assessing Capacity to Consent to Research. The HRPP now requires all new IRB members and staff to complete the Public Responsibility in Medicine and Research, Ethical Research Oversight Course (E-ROC).

R#	External Review Report Section	Page Reference	External Review Recommendation	Completion Status	Additional Commentary
					Additional considerations for human research education will be considered by the Education Advisory Group.
25.	Scientific Review	45	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	Complete	Revised policy, implemented March, 2016, removes evaluation of study merit by the department from the list of acceptable methods for scientific assessment.
26.	Scientific Review	45	Carefully consider whether a robust review at the department level is feasible for each department, taking into considerable the size of the department, reporting relationships, and the volume of research	Complete	Revised policy, implemented March, 2016, removes evaluation of study merit by the department from the list of acceptable methods for scientific assessment.
27.	Scientific Review	45	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.	Complete	Revised policy, implemented March, 2016, removes evaluation of study merit by the department from the list of acceptable methods for scientific assessment.
28.	Scientific Review	47	Revise the HRPP policy on scientific review and related guidance on the	Complete	In the adoption of the HRPP Toolkit, HRP-SOP-050 includes a

R#	External Review Report Section	Page Reference	External Review Recommendation	Completion Status	Additional Commentary
			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.		process for identifying whether scientific reviewers have a conflict of interest prior to the review of research. The process includes procedures for re-assigning the review to a reviewer that does not have a conflict of interest.
29.	Scientific Review	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.	Complete	The template was not revised due to the elimination of departmental review. However, the HRPP adopted feedback in the development of HRP-SOP-050. This SOP establishes a process for identifying scientific reviewers with conflicts of interest. In addition, the process includes a re-assignment of the review to a reviewer that does not have a conflict of interest.
30.	Scientific Review	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.	Complete	Revised policy, implemented March, 2016, removes evaluation of study merit by the department from the list of acceptable methods for scientific assessment.
31.	Scientific Review	49	Develop a mechanism for systematically incorporating scientific reviews into the IRB	Complete	HRPP Toolkit SOPS 040, 041 and 043 require scientific review checks

R#	External Review Report Section	Page Reference	External Review Recommendation	Completion Status	Additional Commentary
			review process to ensure that scientific concerns impacting the criteria for IRB approval are sufficiently addressed.		and documentation of convened IRB acceptance of scientific review. IRB Minutes template includes requirement for the convened IRB to systematically consider the acceptability of scientific review for each new research proposal. In addition, the criteria for IRB approval worksheet (HRP 314) is used as a guide for IRB reviewers when assessing research.
32.	Scientific Review	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.	Complete	Toolkit SOP 043 prompts for minutes to include any substantive concerns raised about scientific assessment.
33.	Monitoring	54	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	Complete	Expansion of quality assurance activities is underway in the HRPP. All PAR investigator quality assurance activities that involve research conducted at Fairview are reported to Fairview.

R#	External Review Report Section	Page Reference	External Review Recommendation	Completion Status	Additional Commentary
			process.		
34.	Monitoring	54	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.	Complete	A decision was made to implement a plan that involves communication to institutional leaders. These leaders would cascade communication, when appropriate, to department heads.
35.	Monitoring	54	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.	Complete	A comprehensive reporting plan has been developed - some aspects under the monitoring plan and some under the broader accountability metrics plan.
36.	Monitoring	54	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.	Complete	The Research Compliance Office - created under the Advancing Human Research Protection implementation plan, while reporting to the OVPR, is positioned to receive and follow up on information or complaints about alleged deficiencies in IRB review processes/functioning.
37.	Monitoring	54	In the context of ongoing concerns about problems related to subject	Complete	A comprehensive plan for live

R#	External Review Report Section	Page Reference	External Review Recommendation	Completion Status	Additional Commentary
			recruitment and consent in psychiatric studies, PAR should include live consent monitoring of such studies in its repertoire of subject safeguards.		consent monitoring has been developed. This plan will offer an additional option to the IRB as the consent process for each study is reviewed. When live consent monitoring is stipulated by the IRB, PAR will carry out this work.
38.	Monitoring	54	Separate reporting chains for IRB review and Post-Approval Review should be considered.	Complete	Staff conducting IRB review and staff conducting both investigator and IRB quality assurance review continue to report to the HRPP Executive Director. Physically, most PAR staff are now located in an office separated from the IRB staff. Information about PAR procedures will be taken off the IRB website and moved to the HRPP website to help clarify and make distinct the separation of functions. Robust reporting - under the monitoring plan and accountability metrics will create transparency in appropriate communication of all findings.
39.	Engagement of Research Participants	58	Establish accessible and reliable electronic and non-electronic channels (in addition to existing complaint mechanisms) for facilitating sustained communication among research	Complete	As part of the Advancing Human Research Protections initiative, the Engaging Research Participants Work group recommended the consolidation of phone numbers for

R#	External Review Report Section	Page Reference	External Review Recommendation	Completion Status	Additional Commentary
			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.		research participants to call with questions and concerns to reduce confusion. Previously there were two numbers (Fairview Research Administration and the Research Participants' Advocate line) listed in the informed consent form. Informed consent forms have been revised to include only one number, the Research Participants' Advocate line. The new text aligns with the recently released research participant contact cards.
40.	Engagement of Research Participants	58	Develop mechanisms to regularly solicit, evaluate, and respond to research participant feedback.	Complete	The HRPP has refined mechanisms for soliciting research participant feedback with the consolidation of participant hotlines. In addition, the HRPP is in the process of finalizing procedures for the administration of a participant survey (See recommendation 41).
41.	Engagement of Research Participants	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. For example, the HRPP might afford research participants an	Complete	The Engaging Research Participants Workgroup developed a draft research participant survey as part of its final report. The HRPP has begun work to finalize the survey in collaboration with the Office of Measurement Services to finalize the survey and develop a plan for

R#	External Review Report Section	Page Reference	External Review Recommendation	Completion Status	Additional Commentary
			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.		administration, maintenance, and monitoring.
42.	Engagement of Research Participants	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	Complete	Significant efforts were made to include community members on relevant committees and educational programs. This includes soliciting input and collaboration in the development of educational offerings. In addition, the Community Oversight Board (COB) was developed in order to

R#	External Review Report Section	Page Reference	External Review Recommendation	Completion Status	Additional Commentary
			priorities and areas of community concern.		solicit feedback on community priorities and concerns.
43.	Engagement of Research Participants	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.	Complete	A systematic approach was considered by the Engaging Research Participants work group. In the ERP Final Report, a recommendation was made to develop recognition efforts at the study, department, or organizational level, as appropriate. Many of which already exist.
44.	Capacity to Consent	65	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.	Complete	Toolkit documents HRP-110 Capacity to Consent has been created to prompt and guide consideration of the methods used for assessing capacity to consent.
45.	Capacity to Consent	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.	Complete	Toolkit checklist HRP-417 Cognitively Impaired Adults has been created and implemented to prompt and guide the IRB's substantive assessment of protocols.
46.	Capacity to Consent	65	Revised policies on legally effective informed consent should: a. provide the means for verifying decision-making capacity and voluntariness in all	Complete	Toolkit SOP HRP-090 Informed Consent Process for Research has been created and implemented to address this feedback.

R#	External Review Report Section	Page Reference	External Review Recommendation	Completion Status	Additional Commentary
			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.		
47.	Capacity to Consent	66	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.	Complete	HRP-110 Capacity to Consent Policy and HRP-417 Cognitively Impaired Adults have been created and implemented to prompt and guide the IRB to evaluate protocols and to promote the use of strategies to support or enhance subject decision-making.
48.	Vulnerability to Coercion	68	Develop standards that protect against real or perceived coercion in psychiatric treatment settings in which individuals may fear involuntary court proceedings.	Complete	By IRB policy and MN State Law (2016), patients on a 72-hour hold cannot be recruited for research during the hold period. HRP-111 Research Involving Adults Under Court Jurisdiction has been created to codify U of M standards.
49.	Vulnerability to Coercion	68	Encourage and support the use of independent consent monitors, particularly in those cases where the treating physician is also the	Complete	HRP-417 Checklist Cognitively Impaired Adults and HRP-333 Vulnerable Populations were created and implemented to guide

R#	External Review Report Section	Page Reference	External Review Recommendation	Completion Status	Additional Commentary
			investigator, so as to minimize the possibility for undue influence or coercion.		IRB review on this topic.
50.	Longitudinal Assessment of Capacity	69	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.	Complete	HRP-110 requires investigators to provide plans about steps that will be taken if capacity to consent diminishes over the course of study participation.
51.	Longitudinal Assessment of Capacity	69	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.	Complete	HRP-417 Checklist Cognitively Impaired Adults has been created and implemented to guide the IRB review of protocols involving adults with potentially fluctuating decision-making capacity.
52.	Legally Authorized Representatives	71	Policies and procedures related to the use of LARs must be comprehensively re-assessed in accordance with the foregoing observations and conclusions.	Complete	An additional enhancement includes the development of a LAR-facing brochure which the IRB may require use of for research studies.
53.	Legally Authorized Representatives	71	The OVPR and HRPP leadership should consider consultation with OHRP or DHHS on this topic.	Complete	HRPP leadership benchmarked institutional policies, state law, and engaged stakeholders regarding LAR requirements.
54.	Use of Surrogate Consent	73	The HRPP should develop effective strategies to educate research personnel on the legal use of surrogate decision-	Complete	Barbara Shiels, Senior Associate General Counsel and legal liaison to the Institutional Review Board,

R#	External Review Report Section	Page Reference	External Review Recommendation	Completion Status	Additional Commentary
			makers when considering the involvement of research participants with limited decision making capacity.		facilitated a workshop, Human Research and the Law, on November 10, 2016. She explored the difference between capacity and competency to consent and provided guidance on the University's position on engaging legally authorized representatives in human research. In addition, mandated reporting requirements for human research were shared.
55.	Use of Surrogate Consent	73	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.	Complete	The HRPP developed standard operating procedures for the review of research involving legally authorized representatives (HRP-013).
56.	Use of Surrogate Consent	73	IRB policies should require: a. A process for informing prospective LARs about their responsibilities; b. Maximization of assent, with consideration of the use of an assent form in appropriate circumstances; c. A verification of the lack of dissent when assent is not possible; d. A plan for re-consent if a subject regains capacity; and e. A plan for monitoring subjects who are likely to have fluctuating capacity, including the steps to be	Complete	The HRPP is in the process of finalizing a LAR brochure which includes important information for LARs on making decisions for others to participate in research. The IRB may require the use of this brochure in certain research studies. The brochure will be finalized in December 2016 and released in January 2017.

R#	External Review Report Section	Page Reference	External Review Recommendation	Completion Status	Additional Commentary
			taken if capacity diminishes.		
57.	Department of Psychiatry	84	IRB membership, expertise and training should more effectively address risk evaluation and management for psychiatric research.	Complete	Psychiatry expertise is reflected in IRB membership to approximate the volume of research submitted to the IRB by the department.
58.	Department of Psychiatry	84	Best practices regarding consent and capacity to consent should be introduced and made routine.	Complete	List all of the toolkit documents available to the entire community - including psychiatry. The Department endorsed using GCP for all clinical trials. CTSI will assume management of interventional drug and device trials in the Department of Psychiatry.
59.	Department of Psychiatry	84	Fairview staff should be involved in protocol review, in gatekeeping functions, and in research monitoring.	Complete	Implementation of FUROC and enhanced collaboration with Fairview Research Administration in the review of recruitment processes for research involving Fairview employees, patients, and/or records. 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.
60.	Department of	84	[The investigators] as the focus of	Complete	If the investigators of concern

R#	External Review Report Section	Page Reference	External Review Recommendation	Completion Status	Additional Commentary
	Psychiatry		ongoing concern and criticism, should receive supervision, coaching in leadership, and advanced training in human subjects protections.		return to the University to conduct research, a Corrective Action Plan must be completed which includes participation in the Professionalism and Integrity in Research Program sponsored by Washington University in St. Louis, NIH, and CITI. One of the investigtors has retired and has been replaced by a new department head. Dr. Sophia Vinogradav joined the University in August of this year.
61.	Institutional Culture	89	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.	Complete	The University developed two additional groups to sustain the mission of AdvancingHRP in the shared responsibility for human research protections—the Human Research Protection Program Committee and the Education Advisory Group. In addition the implementation of FUROC and enhanced collaboration with Fairview Research Administration in the review of recruitment processes for research involving Fairview employees, patients, and/or records. See accountability chart presented to the Legislature March 2016.

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					http://www.research.umn.edu/advancehrp/documents/OrgChart.pdf
62.	Institutional Culture	90	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.	Complete	Developed a campaign that builds awareness of the University's principles, policies and processes that uphold ethical research practices. This effort is founded on a set of core commitments—developed and adopted by University leadership, faculty and staff— that identifies our shared responsibilities and reinforces our collective commitment to meeting the highest ethical standards in the planning and conduct of research. Along with the core commitments, messages, posters and digital signs will be posted on our websites and shared throughout the University to ensure that that our core values are visible everywhere research takes place.
63.	Institutional Culture	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.	Complete	The University launched an annual Research Ethics Day which includes discussions and workshops on various topics related to human research protections.

AdvancingHRP Implementation Progress Report **December 31, 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 (***expected completion Spring 2017***)
			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	√	Miles	Implement tool to assess capacity

Participants Who Have Impaired or Fluctuating Capacity to Consent	√		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)

√ = Work Team Completed and Transitioned to Operations
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