UNIVERSITY OF MINNESOTA

Government and Community Relations
Office of the President

3 Morrill Hall
100 Church Street SE
Minneapolis, MN 55455

Office: 612-626-9234
Fax: 612-624-2800
govrelations.umn.edu
Email: govrelations@umn.edu

TO: Reed Polakowski, Minnesota Legislative Reference Library

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

DATE: September 1, 2016

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

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

Office of the Vice President for Research *420 Johnston Hall*
101Pleasant Street S.E
Minneapolis, MN 55455-0421
612-625-3394
Fax: 612-626-2800

August 25, 2016

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

FROM: **Brian Herman, Vice President for Research**

Included for your review and approval is the fourteenth report to the Legislature on implementation of the work plan to improve research with human participants at the University of Minnesota, institutionally referred to as AdvancingHRP. The report, due to the Legislature on September 1, includes a narrative summary of what has been accomplished since the last report along with the full progress dashboard.

SUMMARY

As previously reported, final reports from work teams were submitted to Vice President for Research Brian Herman for review and approval. All final reports have received approval and significant progress continues in adopting and implementing recommendations. Progress in August, 2016 also included the release of policies and supporting documents under Human Research Participants Who Have Impaired or Fluctuating Capacity to Consent.

The external review of the University's human research protection program recommended "building stronger processes for protecting potentially vulnerable subjects" and identified gaps in policies and procedures for "assessing the appropriateness of the methods used to assess capacity to provide informed consent to help ensure that more rigorous methods are used when the degree of subject vulnerability is likely to be greater and when the risks of research are higher." In addition, the external review recommended the IRB revise policies and guidance "to prompt consideration of the methods used for assessing capacity to consent" and to be more engaged in the education on capacity assessment tools and procedures for research involving human research participants who have impaired or fluctuating capacity to consent.

In response to these concerns, the IRB developed new policies and procedures in consultation with the Center for Bioethics, and the AHRP external advisor, David Strauss, to establish requirements for assessing capacity to consent to research and to promote the protection of potentially vulnerable participants. The final drafts were reviewed in July and August by university communities and partners, including the Research Compliance Advisory Committee, the Fairview/University Research Oversight Committee, and the Community Oversight Board.

The new policies, HRP-110: Research Involving Adults with Absent, Diminished, or Fluctuating Capacity to Consent to Participate in Research and HRP-111: Research Involving Adults under Court Jurisdiction as well as the associated standard operating procedures, checklist, and worksheets have been released. These tools will be used by IRB staff and committee reviewers and will be accessible to researchers for reference. Enforcement of policies will begin 60 days after release.

HRP-110 establishes requirements for investigators who plan to enroll adults with absent, diminished, or fluctuating capacity to consent. This includes the requirement that one of the following validated tools be used to assess capacity to consent in research studies:

- MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR) for greater than minimal risk research
- UCSD Brief Assessment of Capacity to Consent (UBACC) for minimal risk research

For studies that do not anticipate enrolling individuals with impaired capacity to consent or where no potential impairment of an individual is evident, assessments can be made without the use of a validated tool, such as using the teach-back method Teach-back is a communication confirmation method used by healthcare providers to confirm whether a patient (or care takers) understands what is being explained to them. If a patient understands, they are able to "teach-back" the information accurately.

HRP-111 establishes conditions under which potential subjects may not be enrolled in any psychiatric drug, device, or biological trial, including adults under a hold, including those subject to a commitment petition and/or temporarily confined involuntarily under 72-hour emergency holds, “intent to leave” periods, or detainment under a Peace Officer/Health Officer Authority.

Policy HRP-403C reflects two changes to Minnesota law effective August 1, 2016. The first change prohibits investigators from enrolling a patient on an involuntary hold (72 hour emergency admission hold, peace officer transport hold, or court apprehend and hold order) into any clinical drug trial. This change extends IRB policy that has, since 2015, prohibited enrolling patients on an involuntary hold from being enrolled in any psychiatry clinical drug, device, or biologic trial. The second change requires investigators in the Department of Psychiatry conducting clinical drug trials to notify the MN Ombudsman for Mental Health and Disabilities within 24 hours of a research participant’s death or serious injury. The Ombudsman has authority to: 1) recommend actions to the University to prevent a recurrence of deaths; 2) receive and investigate complaints from any source related to an individual’s participation in a psychiatric drug trial and recommend actions to the University; and 3) monitor psychiatric drug trials to assure the protection of participants.

Courtney Jarboe, HRPP Education and Outreach Specialist, developed an online, interactive course, *Assessing Capacity to Consent to Research,* to support the education and training needs of the research and IRB community in the adoption of the new policies and procedures. The

course was vetted by university stakeholders including the Center for Bioethics, Department of Psychiatry, and Paul Appelbaum, MD, co-author of the MacArthur Competence Assessment Tool for Clinical Research. The primary focus of the course is the administration of capacity assessment tools in research, including the MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR) and the UCSD Brief Assessment of Capacity to Consent (UBACC). The course recently received approved for accreditation by the University of Minnesota Office of Continuing Professional Development and is certified for 4.0 *AMA PRA Category 1 Credits*™. The course is now open for enrollment. Completing the Registration Request starts the enrollment process.

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.

For complete details, please visit http://research.umn.edu/advancehrp/implementation.html or contact me with any questions.