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

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

FROM: Brian Herman, Vice President for Research

DATE: June 24, 2016

RE: Report to Legislature

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

SUMMARY

One of the recommendations we received from the external review of the University of Minnesota’s human participant research program is that we should “publicize unequivocal statements” about our commitment to “create and nurture a culture of ethics in research” and that “we must animate these values to life by investing in their visibility and adoption at all levels of the University’s research enterprise.”

In response to this, the Cultivating a Culture of Ethics work team has developed a campaign to build awareness of the University’s principles, policies and processes that uphold ethical research practices. This effort is built around a set of core commitments1—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, we are launching a Research Ethics campaign, including messages, posters and digital signs to be posted on our websites and shared throughout the University to ensure that our core values are visible everywhere research takes place. I will be sending a broad communications to a University-wide audiences sharing these core commitments and announcing the campaign, which begins in June 2016 and continues throughout the coming academic year.

1 Core Commitments and Research Ethics Campaign http://research.umn.edu/advancehrp/researchethics.html
The Engaging Research Participants work group held its final meeting on June 15, 2016. The group has a final report entitled “Design for Implementing Recommendations from the Engaging Research Participants work group,” that outlines 10 recommendations to develop a system to foster the co-creation and evaluation of knowledge about research conduct. One of the final recommendations includes a contact card, which should be regularly provided as a small wallet-sized card to all participants, Legally Authorized Representatives and family members. Ideally, the card will be provided to all people approached for consent. The recommendations also include a research participant experience survey, and recommends outsourcing the implementation and administration of the survey to an objective third party. The survey should be administered bi-annually with summary of results and trends provided to the Post Approval Review/HRPP, the Community Oversight Board (COB), the Fairview University Research Oversight Committee (FUROC), and eventually to a newly formed Human Research Participants Education Committee. The complete list of the 10 recommendations was submitted to VP Herman on June 23, 2016.

The Institutional Review Board (IRB) has continued their work to update the biomedical panel structure. Trainings are underway (June and July) for the implementation and adoption of Huron Consulting’s IRB Toolkit. Meetings for the first four new panels are scheduled and will including additional member training. In order to provide timely and meaningful reviews for investigators, the IRB has created an “overflow” panel of legacy IRB members to manage the number of submissions as the new panels begin. The IRB has also identified ad hoc consultants in multiple disciplines to ensure that the appropriate expertise is available.

Clinical and Translational Science Institute (CTSI) is working to develop new training on informed consent and good clinical practices. This training is being jointly developed and in consultation with the Center for Bioethics and the IRB, and will be piloted in Psychiatry by the end of summer or early fall.

The FUROC (Fairview University Research Oversight Committee) met in June and continues to discuss improved communication and partnership between researchers and nursing staff. The committee is also reviewing new policies and reports that result from the implementation work and will take responsibility, through Fairview Research Services, for a climate assessment in the behavioral health unit.

Vice President Herman held a meeting for all work team leads on June 22 to share updates and assess progress. All teams are on track to meet the June 30th deadline for final reports, with the exception of final passage of the new Conflict of Interest policy which is delayed due to faculty union negotiations.

As always, this month we will publish a blog update to accompany submission of this report for those who sign up for regular updates and continue to monitor emails at advancehrp@umn.edu for any additional feedback.

The attached dashboard shows the full scope of work and this month’s updated status of each item. For complete details, please visit http://research.umn.edu/advancehrp/implementation.html or contact me with any questions.
<table>
<thead>
<tr>
<th>Work plan Section</th>
<th>Status</th>
<th>Lead</th>
<th>Scope</th>
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<tbody>
<tr>
<td>IRB Membership</td>
<td>√</td>
<td>Billings, Biros</td>
<td>Recruit membership</td>
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<td>Form new committees; restructure biomedical; target membership to accurately reflect protocol submission</td>
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<td>Set compensation structure and policy for medical and nonmedical IRBs</td>
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<td>FUROC</td>
<td>√</td>
<td>Herman</td>
<td>Establish Research Compliance Office (RCO)</td>
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<td>For Cause Investigations</td>
<td>√</td>
<td>Webb, Waldemar</td>
<td>Transition For Cause Investigations to RCO; establish more robust procedures specific to complainant and adverse event reporting</td>
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<tr>
<td>Community Oversight Board</td>
<td>√</td>
<td>Herman</td>
<td>Establish board structure and guidelines</td>
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<td>Finalize membership; appoint chair</td>
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<td>Invite members; convene first meeting</td>
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<tr>
<td>External Advisor</td>
<td>√</td>
<td>Herman</td>
<td>Hire external advisor (external review panel member); 2015 AAHRPP Accreditation; Compass Point compliance review</td>
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<tr>
<td>Scientific Review of Studies</td>
<td>√</td>
<td>Billings, Biros</td>
<td>Eliminate department reviews and move to Human Research Protection Program (HRPP) office.</td>
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<td>Define a new IRB process and policy in consultation with other required scientific reviews</td>
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<tr>
<td>Cultivating a Culture of Ethics</td>
<td>√</td>
<td>Aronson, Zentner, Wolf</td>
<td>Create language explaining the University’s commitment to research participant protection</td>
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<td>Clear statements on key websites</td>
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<td>Host a campus conversation or other forum on human research participant protection</td>
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<td>Regular benchmark our program against our peers</td>
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<td>Implement Huron Toolkit IRB forms and procedures</td>
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<td>Add new FTEs</td>
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<td>Complete benchmarking visits</td>
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<tr>
<td>Monitoring of Studies</td>
<td>⬜</td>
<td>Dykhuis</td>
<td>New post-approval review FTEs</td>
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<td>Reengineer post approval review function; Includes work with Compass Point to further refine methodology.</td>
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<td>Human Research Participants Who Have Impaired or Fluctuating Capacity to Consent</td>
<td>⬜</td>
<td>Miles</td>
<td>Implement tool to assess capacity</td>
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<td>Train and communicate change to researchers</td>
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<td>⬜</td>
<td>Dykhuis</td>
<td>Implement LAR policy changes</td>
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<td>Implement 72-hour hold policy</td>
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<td>Department of Psychiatry</td>
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<td>Paller</td>
<td>Transition to Clinical &amp; Translational Science Institute (CTSI) management of trials</td>
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<tr>
<td>Engaging Research Participants</td>
<td>Eder</td>
<td>Engage consultant for climate assessment plan. Enhance culture of inclusion and mutual trust.</td>
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<td>Create a research participant satisfaction survey and a plan to collect and analyze data</td>
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<td>Revise IRB forms to include a section expressing appreciation and a plan for sharing research results</td>
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<td>Create and publicize mechanisms for participants and families to provide confidential feedback and report concerns, develop a small handout</td>
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<td>Create and publicize procedures for handling concerns and for notifying reporter when they have been handled</td>
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<td>Create position of Community Liaison officer</td>
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<td>Create link to Community Oversight Board</td>
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<td>Education and Training of Investigators</td>
<td>Ingbar, Schacker</td>
<td>Integrate and coordinate human research protection training</td>
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<td>Education and Training of Investigators</td>
<td>Ingbar, Schacker</td>
<td>Curriculum development</td>
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<td>Ingbar, Schacker</td>
<td>Training delivery</td>
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<td>Waldemar</td>
<td>Track and report accountability metrics</td>
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<td>Conflict of Interest</td>
<td>Durfee</td>
<td>Implement updated COI policy</td>
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| ✓    | Completed |
| ○    | 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](http://research.umn.edu/advancehrp/implementation.html)