TO: Reed Polakowski, Minnesota Legislative Reference Library

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

DATE: December 1, 2015


Enclosed are two copies of the mandated report Human Subjects Research Standards – December 2015, 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: November 25, 2015

RE: Report to Legislature

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

SUMMARY

Last month teams again made significant progress in implementing the recommendations of the external review panel. As previously mentioned, we have asked David Strauss of that panel to provide guidance and feedback of our work. He is highly engaged and has reviewed all the final plans submitted to date. He has provided in general very positive feedback indicating that the changes will offer us a level of accountability that other institutions do not currently have. He also offered additional tangible suggestions and observations.

The University’s National conference on “Research with Human Participants” is highly anticipated and registration is full. Many faculty and leaders, as well as patient advocates, policy makers, and national scholars, are engaged in the program and will be in attendance. The conference is intended to educate as well as continue a national conversation about best practices in ethics and research.

We have also taken major steps in improving education for researchers. Dr. Steve Miles has developed a new course entitled “Standards for Research with Human Participants” which will be offered spring semester. It includes 15 distinct modules addressing separate aspects of standards and regulations related to this research that can be taken individually or as a course, and for credit or for CME and CNE credit. This will provide easily accessible and necessary training for researchers, faculty and staff involved in human participant research.

The HRPP program has hired an education and outreach specialist, trained in bioethics and research ethics and with experience in senior IRB management. She will be responsibility for initial and ongoing training for IRB members and the development and delivery of training for researchers on human
research protections. She has already created an education structure for new IRB members, expanded communications on educational issues, and developed and launched a training tracker to document IRB and HRPP training. This work will help us understand the access to and effectiveness of our training opportunities and identify any gaps that need to be addressed.

Finally, the team continues to work on the revisions to the Conflict of Interest policy to disclose and manage any real or perceived conflict when partnership with industry. In October there was extensive consultation with faculty governance. That work will continue with a goal of action in the University Senate next March.

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

The attached dashboard shows the full scope of work and this month’s updated status of each item. For complete details, please visit research.umn.edu/advancehrp or contact me with any questions.
<table>
<thead>
<tr>
<th>Work plan Section</th>
<th>Status</th>
<th>Lead</th>
<th>Scope</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB Membership</td>
<td></td>
<td>Billings, Biros</td>
<td>Recruit membership; Form new committees; restructure biomedical; target membership to accurately reflect protocol submission; Set compensation structure and policy for medical and nonmedical IRBs</td>
</tr>
<tr>
<td>FUROC</td>
<td>✓</td>
<td>Herman</td>
<td>U establish committee jointly with Fairview</td>
</tr>
<tr>
<td>For Cause Investigations</td>
<td>✓</td>
<td>Webb</td>
<td>Establish Research Compliance Office (RCO); Transition For Cause Investigations to RCO; establish more robust procedures specific to complainant and SAE reporting</td>
</tr>
<tr>
<td>Community Oversight Board</td>
<td></td>
<td>Herman</td>
<td>Establish board structure and guidelines; Finalize membership; appoint chair; Invite members</td>
</tr>
<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>
</tr>
<tr>
<td>Scientific Review of Studies</td>
<td></td>
<td>Billings, Biros</td>
<td>Eliminate department reviews; Define a new IRB process and policy in consultation with other required reviews e.g. CTSI</td>
</tr>
<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; Clear statements on HRPP, IRB, OVPR and AHC websites; Host a campus conversation or other forum on human research participant protection; Regular benchmark our program against our peers</td>
</tr>
<tr>
<td>IRB Protocol Review Process</td>
<td></td>
<td>Dykhuis</td>
<td>Implement new eIRB technology; Implement IRB forms and procedures; Add new FTEs; Complete benchmarking visits</td>
</tr>
<tr>
<td>Monitoring of Studies</td>
<td></td>
<td>Dykhuis</td>
<td>New FTEs; Reengineer PAR function; Includes work with Compass Point to further refine methodology.</td>
</tr>
<tr>
<td>Human Research Participants Who Have Impaired or Fluctuating Capacity to Consent</td>
<td></td>
<td>Miles</td>
<td>Implement tool to assess capacity; Train and communicate change to researchers</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dykhuis</td>
<td>Implement LAR policy changes; Implement 72-hour hold policy</td>
</tr>
<tr>
<td>Department of Psychiatry</td>
<td></td>
<td>Paller</td>
<td>Transition to CTSI management of trials; Engage consultant for climate assessment, plan</td>
</tr>
</tbody>
</table>
| 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 HRPP training  
Curriculum development  
Training delivery |
| Accountability Metrics | Waldemar | Track and report accountability metrics |
| Conflict of Interest | Durfee | Implement updated policy |

√= Completed  
○= In Progress  
□= 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