

February 27, 2015

An Open Letter in Response to the Independent Review of Human Subject Research:

The University of Minnesota is committed to meeting, upholding and exceeding the highest ethical standards in research practices involving human subjects. While our current research program reflects this commitment, we aspire to do better. Our goal is to function at a level that's considered beyond reproach.

To measure ourselves against these standards, our Faculty Senate passed a resolution, which we endorsed, to request an independent review of our processes for protecting human subjects in clinical research with diminished functional abilities during the years 2011-2014. The review was logistically managed by the Association for the Accreditation of Human Research Protection Programs (AAHRPP), the industry's foremost accreditation body, which assembled a panel of independent subject matter experts.

Today, we received the panel's [report](#). It is thorough and outlines a roadmap for the University to become truly exceptional in our human subjects research program. Among its findings:

- Many of the persisting concerns related to human subjects protections point to a relatively small clinical research portfolio related specifically to individuals with diminished decision-making capacity.
- Leaders and members of our research community are committed to protecting human subjects in clinical research. There are many existing examples of carefully designed procedures to assess and protect potential subjects.
- There have been recent policy changes to improve oversight and review of human subjects research.
- There are several specific opportunities to further strengthen our protection of human subjects, such as consistently following and thoroughly documenting our processes.

We are taking action on several of the panel's recommendations, such as increasing staff and resources for enhanced training and monitoring, and adding members with relevant expertise to the Institutional Review Board (IRB). We've also recently created the Research Compliance Advisory Committee that will provide high-level consultation regarding strategic risk management in research.

The team leading the assessment and implementation of the report's recommendations includes Brian Herman, vice president for research; Brooks Jackson, dean of the Medical School

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and vice president for health sciences and; and Debbie Dykhuis, executive director of the Human Research Protection Program. Leadership will also seek input from the University's Faculty Senate to help shape priorities and processes. You can expect an action plan from this team within 60 days. We'll also be providing ongoing communications on our progress at <http://www.research.umn.edu/news/external-review.html>.

Measuring the difference between our current research program and our commitment to becoming beyond reproach was the charge given to the independent review panel. Now, we will be accountable for taking action.

The recommendations in the report, combined with the federal guidance and significant academic input that have emerged over the past decade on human subjects research that involves individuals of diminished functional abilities, will allow us to create a world-class human subjects research program.

Sincerely,



Eric W. Kaler
President



Brian Herman
Vice President, Research