MEMORANDUM

January 24, 2014

TO: Brian Herman, Vice President for Research
FROM: Eric W. Kaler, President
RE: Human Subject Research Review

On December 5, 2013, the Faculty Senate approved a resolution requesting an external review of clinical research on human subjects at the University of Minnesota. Specifically the Senate resolution stated:

BE IT RESOLVED that a panel external to and independent from the University of Minnesota be constituted for the purpose of conducting an inquiry examining current policies, practices, and oversight of clinical research on human subjects at the University, in particular clinical research involving adult participants with diminished functional abilities. The administration, in collaboration with appropriate faculty governance committees, shall initiate the constitution of such an independent panel and shall support its inquiry. The panel shall have authority to obtain any records it deems necessary for a thorough inquiry, to the extent consistent with applicable law. At the conclusion of the inquiry, the panel shall issue a report that will be made publicly available, within the limitations of regulations governing the protection and privacy of individuals, including research participants, and the results will be reported back to the Faculty Senate so that senators have an opportunity to ask questions and discuss the report.

The intent of this review is to ensure that the University's processes for clinical research on human subjects meet or surpass the established best practices and norms and to instill confidence among faculty and the public that the University of Minnesota research is beyond reproach. It is to be a forward-looking, productive, and independent review of current practice by an external expert panel.

I support the University Senate's resolution. To that end, I am charging you with the responsibility of conducting an inquiry examining policies, practices and oversight of
clinical research on human subjects at the University, in particular clinical research involving adult participants with diminished functional abilities. This review should be managed by an external partner and if any deficiencies in our current practices are found, the review should include recommendations for remedying them.

It is critical that this review be conducted thoroughly, professionally, independently and transparently. Please ensure that reviewers have appropriate access to information, resources and individuals needed to meet their charge. At least one member of the panel should be prepared to speak publicly to their process, findings and any recommendations for improvement. The final report will be public.

I look forward to receiving the report of the independent panel and am confident that the results will demonstrate that our faculty, policies and practices meet the highest quality standards.

EWK:jk

c:    Aaron Friedman, vice president of Health Sciences and dean of the Medical School
        Professor Will Durfee, chair, Faculty Consultative Committee
        William Donohue, general counsel, Office of the General Counsel
        Keith Dunder, Academic Health Center counsel, Office of the General Counsel
        Amy Phenix, chief of staff, Office of the President