

UNIVERSITY OF MINNESOTA

Office of the Vice President for Research

420 Johnston Hall
101 Pleasant Street S.E.
Minneapolis, MN 55455-0421
612-625-3394
Fax: 612-626-7431

April 29, 2014

Trudo Lemmens, LicJur, LLM, DCL
Associate Professor
Scholl Chair in Health Law and Policy
Faculty of Law, University of Toronto
39 Queen's Park Cr.
Toronto Ontario
Canada M5S 2C3

Dear Professors Lemmens, De Vries, Dreger, Shepherd, Reverby and Kassirer,

Thank you for your letter of April 23, 2014 regarding the independent inquiry into human subject research at the University of Minnesota. We are responding on behalf of President Eric Kaler (Chair, Faculty Senate), Professor Eva von Dassow (Vice Chair, Faculty Senate), and faculty governance.

The University of Minnesota is committed to being best in class when it comes to research practices involving human subjects. We regularly evaluate our practices. We have a strong Institutional Review Board (IRB). We have mechanisms in place to allow and encourage anyone, whether inside or outside of the University, to speak up and report suspicions or research misconduct and we investigate those concerns.

Evidence of our commitment to ethical human subject research can be seen in the fact that we have received Association for the Accreditation of Human Research Protection Programs (AAHRPP) re-accreditation twice in the last ten years. We are currently preparing for a third re-accreditation. This is an extremely rigorous process that is "best in class" nationally. As it states on the AAHRPP web site, "When you earn the AAHRPP seal, you earn a place among the world's most respected, trustworthy research organizations."

The resolution passed by the University of Minnesota Faculty Senate on December 5, 2013 calls for an inquiry to examine the current policies, practices, and oversight of clinical research on human subjects at the University of Minnesota, in particular clinical research involving adult participants with diminished functional abilities.

The resolution further calls for the University of Minnesota administration, in collaboration with appropriate faculty governance committees, to constitute an independent panel and to support its inquiry. The full resolution is posted at:

<http://www1.umn.edu/usenate/resolutions/131205panelres.html>

We are now in the process of setting up the inquiry called for by the faculty senate resolution. President Kaler charged Vice President Brian Herman with overseeing the process on behalf of the administration. A copy of that charge letter is attached. Faculty governance is engaged in the process, with Professor William Durfee, Chair of the Faculty Consultative Committee, and Professor Maria Gini, Chair, Senate Research Committee, representing faculty governance.

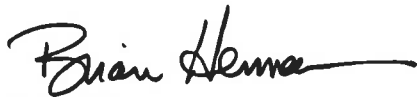
Your letter references the University's request for proposals to initiate the review by engaging an independent contractor to manage the inquiry. You have no doubt noted that the text in the RFP mirrors the text in the resolution supported by the University's faculty. President Kaler's goal, consistent with the wishes of the faculty, is that this process be independent, thorough and transparent. In order to achieve this goal, we will contract with an external, independent entity, as stated in the resolution. This external contractor will be responsible for independently managing the process, including selecting and engaging the experts who will conduct the inquiry.

The external expert panel is charged with conducting a thorough, independent and transparent review. If any deficiencies are found in our current human subject research program, the review will include recommendations for remedying them.


When the inquiry is complete, the panel's report will be public and reported to the Faculty Senate. It is our goal to have a member of the panel present that report and answer questions about their findings.

Thank you for your inquiry.

Sincerely,



Brian Herman
Vice President of Research



William K. Durfee
Professor, Department of Mechanical Engineering
Chair, Faculty and Senate Consultative Committees

Cc: Raymond De Vries, PhD, Professor, University of Michigan Medical School
Alice Dreger, PhD, Professor, Northwestern University Feinberg School of Medicine
Lois Shepherd, JD, Professor, University of Virginia
Susan M. Reverby, PhD, Professor, Wellesley College
Jerome P. Kassirer, M.D., Professor, Tufts University School of Medicine
Eric W. Kaler, President, Chair, Faculty Senate, University of Minnesota
Eva von Dassow, Vice Chair of Faculty Senate, University of Minnesota

UNIVERSITY OF MINNESOTA


Twin Cities Campus

Office of the President

202 Morrill Hall
100 Church Street S.E.
Minneapolis, MN 55455

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