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President Eric Kaler, Faculty Senate Chair Professor Eva von Dassow, Faculty Senate Vice-Chair Members of the University of Minnesota Senate University of Minnesota 427 Morrill Hall 100 Church St SE Minneapolis, MN 55455

April 23, 2014,

Re: Markingson Case and Independent Inquiry

Dear President Kaler, Professor von Dassow, and Members of the Senate,

On December 5, 2013, the University of Minnesota Faculty Senate passed a resolution calling for an external and independent inquiry into the "current policies, practices, and oversight of clinical research on human subjects at the University." This resolution was prompted by continuing questions and criticisms of the University's dealing with the Markingson case and its aftermath.

In our letter of December 12, 2013, we urged you to ensure that the independent inquiry recommended by the Senate would: specifically consider the problems associated with the Markingson case; examine whether other similar cases exist; receive a wide mandate to look at specific past and present research practices, procedures and guidelines; and assess the response of the University when research involving human subjects goes wrong. We also pointed out that, in order to ensure the credibility of the inquiry, the investigating committee should receive substantive input from individuals who have been explicitly asking for a further investigation.

None of these conditions appear to be satisfied in the "request for proposal" (RFP) recently posted on the contracting service website of the University. Furthermore it seems that the RFP was not distributed widely within the academic community and was not announced to people who have been calling for an inquiry.

The procedure followed, and the terms of contract proposed, are clearly not in line with what our original letter, signed by more than 170 scholars, requested. The administration had several options for initiating this inquiry, including setting up an ad hoc subcommittee of the Senate to identify and convene a panel of external, independent experts, and consulting stakeholders from inside and outside the university to identify the appropriate persons for an independent inquiry. Instead the administration chose to use a standard RFP procedure, as if this request is nothing more than a regular contract offered by the administration to a contractor – akin to a request to supply light bulbs or stationery. Because the administration selects the contractor and the proposed arrangement requires the contractor to report directly to the administration, a serious conflict of interest will be created.

It will be difficult, if not impossible, for the contractor to critique the administration's handling of research controversies, a central part of the inquiry. The language of the RFP confirms that the administration is in control and limits the inquiry to a narrow focus on current procedures and practices, with no reference to past problems. The RFP precludes a thorough investigation of past practices and the influence of those practices on the current treatment of research subjects, even though the Senate explicitly mentioned the ongoing controversy surrounding the Markingson case as a key factor for setting up the inquiry. The RFP asks the review to be "forward looking, productive, transparent and independent review of current practice" with a focus on "best practices and norms." The "selected Respondent will be the Respondent whose Proposal is the most advantageous to the University." The University has "sole discretion" to select the contractor.

The RFP is in our opinion so flawed as to preclude any chance the resulting report will be seen as legitimate, except perhaps by those vindicated by it. We will persist with our efforts to see a transparent, independent investigation of the type we and so many others have been demanding. The members of the University of Minnesota community—including especially the patients treated and studied at your medical facilities—deserve no less.

Yours sincerely,

Trudo Lemmens, LLM, DCL

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