

# UNIVERSITY OF MINNESOTA

---

Twin Cities Campus

Center for Bioethics

N504 Boynton  
410 Church Street S.E.  
Minneapolis, MN 55455-0346  
612-624-9440  
Fax: 612-624-9108  
E-mail: [bioethx@tc.umn.edu](mailto:bioethx@tc.umn.edu)  
<http://www.bioethics.umn.edu>

September 7, 2014

Elyse I. Summers, JD  
President and Chief Executive Officer  
Association for the Accreditation of Human Research Protection Programs  
2301 M Street, NW, Suite 500  
Washington D.C. 20037

## **Re: AAHRPP's Sham Review and Conflicts-of-Interests**

Dear Ms. Summers:

I am writing to inform you that I will not meet with the three individuals AAHRPP has hired to "review" the University of Minnesota's research protections program. Your organization is not conducting a credible investigation. On moral grounds I refuse to participate in the sham review the University of Minnesota is paying you to conduct. I am attaching copies of my previous letters to you. They provide context for my decision. I also wish to inform you that I am going to contact lawmakers and journalists concerned with corporate influences on oversight of human subjects research and urge them to investigate AAHRPP's many conflicts-of-interest, including your organization's ties to Pfizer.

As you know, the University of Minnesota hired AAHRPP to "facilitate" a review of "current policies, practices and oversight of clinical research on human subjects at the University of Minnesota." No credible organization concerned with protecting research subjects from harm would agree to my employer's narrow and self-serving terms. As everyone who has paid attention to longstanding allegations of psychiatric research misconduct at the University of Minnesota knows, there is no point in limiting a review to "current" policies and practices. Instead, there needs to be a thorough investigation of over a decade's worth of psychiatric clinical trials conducted here. Particular consideration needs to be given to the notorious CAFÉ study in which Dan Markingson was a research subject. The very act of acceding to the University's terms means that AAHRPP is far down the road to producing a whitewash report. Such a document is going to be very dangerous because university administrators will use it to claim that the University has "yet again" been exonerated of wrongdoing and there is therefore no need for any further inquiries into reports of serious abuses of vulnerable, mentally ill individuals. The reason AAHRPP was hired is because you do not investigate specific allegations of wrongdoing, you do not report research misconduct to regulatory authorities, and you have agreed not to examine the very ethical, legal, and scientific controversies that prompted faculty senators to pass the *Resolution on the matter of the Markingson case* and call for an investigation of clinical research at the University of Minnesota.

Let me review four of the many reasons why AAHRPP is not a suitable body for reviewing so-called “research protections” at the University.

First, the University of Minnesota has already paid AAHRPP for the service of accrediting its research protections program in 2004, 2007, and 2010. The next accreditation is scheduled for 2015. You cannot have a client-provider relationship with the University of Minnesota for a decade and then claim that you are managing an “independent” review. AAHRPP is in a conflict-of-interest because it is reviewing research protections program that it has already accredited and given its “Gold Seal of Approval.” What is needed is a review by a truly independent body composed of suitably qualified experts. Such an investigative panel needs to examine and address not only *past and present* research policies and practices at the University of Minnesota, *but also whether AAHRPP failed to detect research misconduct while conducting its accreditation reviews*. AAHRPP has a longstanding financial relationship to the University of Minnesota. You cannot investigate yourself.

Second, AAHRPP’s personal, professional, and financial ties to past and present members of the University of Minnesota’s research protections program compromise AAHRPP’s supposed “independence.” Dr. Susan Berry, Chair of the University of Minnesota’s IRB Executive Committee, is one of AAHRPP’s paid site visitors. Moria Keane is an AAHRPP site visitor and the former Chair of AAHRPP’s Council on Accreditation. Ms. Keane worked for the University of Minnesota for over twenty-five years. She is the former Executive Director of the University of Minnesota’s Human Research Protections Program. (It was in this capacity that she was deposed in the lawsuit filed against the University of Minnesota by Dan Markingson’s mother, Mary Weiss.) Given these ties, AAHRPP has no right to claim that it is providing an “independent” review of the University’s research protections program. A credible investigation needs to be conducted by an organization that has no such ties and is willing to investigate whether past and present staff members of the University of Minnesota’s research protections program were and are fulfilling their ethical and legal duties.

Third, there are serious problems with the three reviewers hired by AAHRPP. Dr. Jeremy Sugarman has been a consultant for Quintiles and Genentech. Both companies have funded clinical studies conducted by faculty members in the Department of Psychiatry. Quintiles was the Contract Research Organization for AstraZeneca’s infamous CAFÉ study. This conflict-of-interest cannot simply be “managed” and “disclosed.” Rather, what the University of Minnesota needs is a credible investigation conducted by individuals who *do not have* conflicts-of-interest. There is no shortage of such experts in research ethics and governance of human subjects research. You have portrayed Joan Rachlin as an “independent reviewer” with no ties to AAHRPP. However, you are on record stating that Ms. Rachlin is your longtime friend and mentor. She also happens to be the former Executive Director of PRIM&R, the organization that created your employer, AAHRPP. Dr. Melissa Frumin is a particularly mystifying choice. She has no publications or research grants related to research ethics, institutional review boards, or governance of human subjects research. She has not made any contributions to peer-reviewed psychiatric research since 2007. At the time of her selection as an AAHRPP reviewer an alleged victim of research misconduct was suing her for negligence. AAHRPP claims that these three individuals are “world-renowned experts,” but in fact you hired a physician-ethicist with an egregious conflict-of-interest, a friend and personal advisor, and a psychiatrist with no history of contributing to scholarship in research ethics and a dated record of research in her home discipline.

Fourth, for an organization that evaluates and accredits research protection programs, AAHRPP has indefensibly close ties to the very pharmaceutical companies that fund clinical trials reviewed by those research protection programs. As a company your organization accredits, Pfizer is one of AAHRPP's clients. A senior executive at Novartis Pharmaceuticals Corporation sits on your Board of Directors. Three former senior executives of Pfizer serve on your Board of Directors. There might be additional individuals with serious conflicts-of-interests but while preaching transparency you refuse to disclose whether other AAHRPP directors, members of AAHRPP's Accreditation Council, staff members, and site visitors have ties to the pharmaceutical industry. AAHRPP conferences have been paid for by Pfizer, an AAHRPP publication was funded by Pfizer, and a Pfizer employee played a key role in developing AAHRPP's business plan for expansion in China. Shortly after AAHRPP's reviewers visit the University of Minnesota, you will speak at yet another AAHRPP conference funded by Pfizer.

The reason why AAHRPP's many ties to the pharmaceutical industry are problematic is that Pfizer, Novartis, and other companies fund clinical studies reviewed by research protection programs at the University of Minnesota and elsewhere. We therefore have a scenario in which all parties participating in review and governance of human subjects research – including individual principal investigators and co-investigators, academic departments and department chairs, institutional review board members and IRB chairs evaluating clinical protocols and informed consent forms, AAHRPP, and “independent” reviewers hired by AAHRPP – can potentially have financial ties to the pharmaceutical industry. At no level of oversight is there the fundamental assurance that a watchdog body free of influence by the pharmaceutical industry is protecting research subjects. I suspect that most individuals familiar with AAHRPP are unaware of your organization's numerous connections to the pharmaceutical industry.

Given AAHRPP's refusal to investigate particular allegations of research misconduct, financial and professional ties to past and present members of the University's research protection program, longstanding client-provider relationship to the university, and numerous ties to the pharmaceutical industry, there is no basis for expecting that your organization is going to conduct a credible investigation. I fear that you are being paid \$141, 900 for the service of whitewashing the University of Minnesota's reputation. I cannot prevent AAHRPP from engaging in such behavior but I can refuse to participate in this charade. I will have nothing to do with your sham review. I hope that my colleagues join me in condemning AAHRPP's review and call for a genuine investigation of alleged psychiatric research misconduct. The safety of research subjects is at stake.

Yours sincerely,



Leigh Turner, PhD  
Associate Professor  
University of Minnesota Center for Bioethics

cc: William Durfee, Ph.D., Past Chair, Faculty Consultative Committee  
Melissa Frumin, M.D., Assistant Professor, Harvard Medical School  
Brian Herman, Ph.D., Vice President for Research, University of Minnesota  
Joan Rachlin, J.D., M.P.H., Former Executive Director, PRIM&R  
Jeremy Sugarman, M.D., Meyerhoff Professor of Bioethics & Medicine, Johns Hopkins University