PRESIDENTIAL COMMISSION FOR THE STUDY OF BIOETHICAL ISSUES

November, 23, 2011

Arthur J. Ammann, M.D.
President

Kerry M. Gough, J.D.
Global Strategies for HIV Prevention
104 Dominican Drive
San Rafael, CA 94901

Dear Messrs Ammann and Gough:

I am writing on behalf of Dr. Amy Gutmann and the Presidential Commission for the Study of Bioethical Issues (PCSBI or Commission) to thank you for taking the time to submit your inquiries and concerns regarding the protection of vulnerable subjects in clinical research.

You have raised specific concerns about a particular study, one investigating the safety and efficacy of HIV hyperimmune globulin in preventing the transmission of HIV from mothers to their infants, and the quality of review this study received. As detailed in your letter, the study was funded by the NIH, meaning that it was subjected to expert study section review in its proposal stages. Further, the study passed through review by an IRB prior to implementation and, upon completion of the trial, journal editors again provided peer review for the study's scientific adequacy before publishing an article in the *Journal of Acquired Immune Deficiency Syndrome*.

Your allegations of inadequate data and improper IRB review are serious.

President Obama's Executive Order establishes the Commission as a federal advisory committee tasked to advise him on bioethical issues, specifically to "identify and examine specific bioethical, legal and social issues," "recommend… legal, regulatory, or policy actions," and "critically examine diverse perspectives." As an advisory commission, the PCSBI is not a regulatory body.

While the PCSBI may be able to consider this study in making its report to the President on human subjects research protections in a few short weeks, the Order which established the Commission specifically states that the "the Commission shall not be responsible for the review and approval of specific projects." This means that the PCSBI is not generally authorized to make an investigation or provide targeted ethical review of the particular research study in question.

There is, however, existing regulatory authority to deal with concerns about the quality of IRB review and the application of appropriate federal regulations for the protection of human subjects in federally funded research. The Office of Human Research Protections (OHRP), located within the Department of Health

and Human Services (HHS), is responsible for assuring that all human subjects research, sponsored by HHS, complies with federal human subjects protections. OHRP performs compliance oversight investigations when there are indications of noncompliance, but also when an individual or organization comes forward to make a substantive allegation against an institution. Any concerns you have regarding the quality of IRB review or other issues of compliance with federal regulations that protect human subjects may be directed to OHRP. More information on OHRP can be found at http://www.hhs.gov/ohrp/.

Furthermore, under 42 C.F.R. pt. 93, allegations of scientific misconduct, including concerns about the quality of scientific publications and possible omission of data, should be directed to the Office of Research Integrity (ORI), also located within HHS. More information on ORI can be found at http://ori.hhs.gov/.

Thank you for your comments. The Commission truly appreciates the time that you have taken to share your concerns, and hopes that the matters you raised can be resolved to your satisfaction.

Sincerely,

Valerie H. Bonham, J.D.
Executive Director

Cc: Amy Gutmann, PhD
Chair