



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Office of Public Health and Science

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June 11, 2012

Clyde L. Briant, Ph.D.  
Vice President for Research  
Office of the Vice President for Research  
Box 1937  
Brown University  
Providence, RI 02912

RE: Human Research Subject Protections under Federalwide Assurance FWA-4460

Dear Dr. Briant:

Thank you for your May 21, 2012 response to our April 12, 2012 request that Brown University implement corrective actions to address determinations that resulted from our August 15-17, 2011 on-site evaluation of your institution's compliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR part 46).

In our April 12, 2012 letter, we made the following determination:

- 1) Based on the information we reviewed, the IRB on multiple occasions approved research contingent upon substantive modifications or clarifications that were directly relevant to the determinations required by the IRB under HHS regulations at 45 CFR 46.111 without requiring additional review by the convened IRB. We note that when the convened IRB requests substantive clarifications or modifications regarding the protocol or informed consent documents that the IRB needs in order to make the determinations required by the IRB under HHS regulations at 45 CFR 46.111, IRB approval of the proposed research must be deferred, pending subsequent review by the convened IRB of responsive material, unless the research is eligible for review under an expedited review procedure.

**Corrective Action:** We acknowledge that the Research Protections Office (RPO) has implemented a procedure to ensure that the IRB does not approve research contingent upon substantive modifications or clarifications that are directly relevant to the determinations

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required by the IRB under HHS regulations at 45 CFR 46.111 without requiring additional review by the convened IRB.

Specifically, before the IRB votes on IRB submissions, the Board reviews issues discussed during the meeting and "...clearly [indicates] for RPO staff and for minute-taking purposes, which issues would prevent the IRB from approving the protocol because the Board cannot make one or more of the determinations required for approval by the HHS regulations at 45CFR46.111 and, if applicable, subparts B, C, or D of 45 CFR part 46. The IRB also clearly identifies which issues would be considered non-substantive conditions that could be addressed by the PI subsequent to the meeting and then verified as satisfactory by a qualified individual identified by the IRB."

We determine that the corrective actions noted above, along with those outlined in our April 12, 2012 letter, are appropriate under your institution's FWA. At this time, there should be no need for further involvement by our office in this matter.

We appreciate the continued commitment of your institution to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Lisa R. Buchanan, MAOM  
Compliance Oversight Coordinator  
Division of Compliance Oversight

cc:

Ms. Dorinda Williams, Human Protections Administrator  
Dr. Regina White, Associate Vice President for Research Administration  
Dr. Ronald Seifer, IRB Chairperson  
Dr. Brandon Krupp, IRB Vice Chairperson  
Dr. Margaret Hamburg, Commissioner, Food and Drug Administration  
Dr. Joanne Less, Food and Drug Administration  
Mr. Joseph Ellis, National Institutes of Health, Office of Extramural Research  
Dr. Sherry Mills, National Institutes of Health