



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary  
Office of Public Health and Science

Office for Human Research Protections  
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April 29, 2009

Eugene Z. Oddone, M.D., MHSc  
Vice Dean for Research, School of Medicine  
Duke University Health System, Inc.  
Davison Building, Dean's Suite, room 117A  
DUMC Box 2820  
Durham, NC 27705

**RE: Human Research Protections Under Federalwide Assurance FWA-9025**

**Research Project: Child Neglect–Psychobiological Consequences (IRB # 4148)**

**Principal Investigator: Michael D. De Bellis, M.D.**

**HHS Protocol Number: 5R01MH061744-06**

**Research Project: PTSD & Childhood Sexual Abuse: Psychobiology (IRB #3928)**

**Principal Investigator: Michael D. De Bellis, M.D.**

**HHS Protocol Number: 5R01MH063407-04**

**Research Project: Adolescent Alcohol Abuse, PTSD and Hippocampal Development (IRB #4197)**

**Principal Investigator: Michael D. De Bellis, M.D.**

**HHS Protocol Number: 7R01AA012479**

Dear Dr. Oddone:

Thank you for your March 30, 2009 report in response to our February 17, 2009 letter regarding the above-referenced human subject research.

Determinations regarding the above-referenced research

- (1) In our February 17, 2009 letter we determined, in accordance with the findings of Duke University Clinical Trial Quality Assurance (CTQA) auditors, that a 10-year old subject enrolled in Institutional Review Board (IRB) #4148 who expressed the wish to discontinue testing and interviewing was not permitted to discontinue participation in the research in violation of the Department of Health and Human

Services regulations at 45 CFR 46.116. Subsequently, we received documentation indicating that testing was, in fact, stopped when this subject expressed a desire to discontinue, and that the subject finished participation in Part I of the research on a subsequent occasion. We accordingly modify determination (2)(c) in our February 17 letter to clarify that, given the facts at our disposal, we determine that there is no proven violation of the regulations regarding the allegation that an investigator forced subjects to remain in the exam room to answer all questions about their abuse and symptoms regardless of their level of distress, and even if the subject was crying.

- (2) In our February 17, 2009 letter, we asked you to clarify what steps you took to implement Standard Operating Procedures (SOPs) pertaining to the above-referenced research. Your August 11, 2008 report had indicated that Duke developed SOPs effective January 10, 2008 for clinicians and data technicians trained to complete the informed consent process. The SOPs included strategies for telephone screening of adult and child subjects in the above-referenced research protocols, for ensuring completion of consent forms, and for obtaining and documenting the assent of children. Prior to issuing our February 17 letter, we received a new complaint alleging that researchers were not adequately trained about the SOPs and that the SOPs had never been implemented.

In accordance with information supplied in your March 30, 2009 letter, we determine that research staff did receive training on the SOPs for the informed consent process, and that Duke auditors witnessed the process of obtaining informed consent from two subjects and found that appropriate procedures were followed by the study team. Accordingly, we determine that the allegations of noncompliance regarding the failure to adequately train researchers, or otherwise implement SOPs for the above research, are unproven.

At this time, there should be no need for further involvement by our office in this matter. Please notify us if you identify new information which might alter this determination.

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

Sincerely,

Carol J. Weil  
Division of Compliance Oversight

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Eugene Z. Oddone, M.D., MHS – Duke University Health System, Inc.

April 29, 2009

cc: Ms. Jody F. Power, Executive Director, IRB, Duke University Health System  
Dr. Joseph Farmer, Chair, IRBs #1 & #2, Duke University Health System  
Dr. John Harrelson, Chair, IRBs #3 & #4, Duke University Health System  
Dr. George Parkerson, Chair, IRBs #7 & #8, Duke University Health System  
Dr. John Falletta, Chair, IRBs #5, #6 & #10, Duke University Health System  
Dr. Michael D. De Bellis, Duke University Health System  
Commissioner, Food and Drug Administration  
Dr. Joanne Less, Food and Drug Administration  
Dr. Sherry Mills, Office of Extramural Research, National Institutes of Health  
Dr. Joe Ellis, Office of Extramural Research, National Institutes of Health