



Office for Human Research Protections
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November 24, 2010

N. John DiNardo, Ph.D.
Vice Provost for Academic Affairs
Drexel University
Office of the Provost
3141-51 Chestnut Street
Philadelphia, PA 19104

Richard Homan, M.D.
Philadelphia Health & Education Corporation
New College Building
245 N. 15th Street, 19th Floor
Philadelphia, PA 19102

RE: Human Research Subject Protections Under Federalwide Assurance (FWA) -1852 and 5917

Dear Drs. DiNardo and Homan:

Thank you for your November 19, 2010 report in response to our October 26, 2010 letter regarding our not-for-cause evaluation of compliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR part 46). Based on our review of your response, we make the following determinations:

- (1) HHS regulations at 45 CFR part 46, subpart B require that when reviewing research involving pregnant women, institutional review boards (IRBs) make certain determinations. The HHS regulations at 46 CFR 46.204(e) require that if the research holds out the prospect of direct benefit solely to the fetus, then the consent of both the pregnant woman and the father must be obtained, except that the father's consent need not be obtained in certain circumstances. OHRP determines that the Drexel University (Drexel) IRB failed to make the required determinations for research involving pregnant women for protocol IRB # 18895; Antenatal Late Preterm Steroids (ALPS): A Randomized Placebo Controlled Trial; Chhibber, Geeta; 1U01HL098354-01. In particular, we note that the IRB reviewer checklist for pregnant women, human fetuses, neonates or fetal material indicated the research holds the prospect of direct benefit solely to the fetus; however, the IRB-approved informed consent form does not provide signature lines for both parents, and the protocol does not include any discussion about obtaining permission from the father.

Corrective Action: We acknowledge that Drexel has modified your guidelines and the checklist and trained your IRB members to follow the regulations outlined in subpart B. As per the regulations, a signature line will be provided for the father on the informed consent form for the above-referenced study as well as for any other studies when the research holds out the prospect of direct benefit solely to the fetus. The boilerplate consent form will be amended to include the father's signature line. Investigators and IRB members will also be trained to be aware that a father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.

- (2) HHS regulations at 45 CFR 46.117(a) require that informed consent be documented by the use of a written consent form approved by the IRB and that is signed by the subject, or the subject's legally authorized representative, unless the IRB waives this requirement in accordance with 45 CFR 46.117(c). We determine that the Drexel IRBs sometimes approve research involving a waiver of documentation of informed consent without appropriately waiving this requirement in accordance with 45 CFR 46.117(c). In specific, we note IRB #18370; Project INCITE: Identifying Novel Correlates of Indoor Tanning Experiences; Kloss, Jacqueline—the study involves telephone or electronic consent but there was no evidence of waiver of documentation of informed consent.

Corrective Action: We acknowledge that Drexel has amended the policy for waiver of documentation of consent to indicate that whenever the study involves telephone or electronic consent, the investigator using the revised (Version 4, September 20, 2010) "Application for Waiver or Alteration of Informed Consent and Waiver of documentation of Consent" shall also request a waiver of documentation of consent. The IRB will then make a determination whether waiver of documentation will be granted. The minutes will contain such discussions and decisions.

We determine that the corrective actions adequately address the above determinations. 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.

OHRP appreciates the continued commitment of your institution to the protection of human research subjects. Please feel free to contact me should you have any questions.

Sincerely,

Kristina C. Borrer, Ph.D.
Director,
Division of Compliance Oversight

Cc: Dr. Sreekant Murthy, Vice Provost for Research Compliance, Drexel
Dr. Abhay J. Dhond, IRB Chairperson, Drexel IRB #1
Dr. Frank Linnehan, IRB Chairperson, Drexel IRB # 3

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Dr. Daniel Conway, IRB Chairperson, Drexel IRB # 4

Dr. Margaret Hamburg, Commissioner, Food and Drug Administration (FDA)

Dr. Joanne Less, FDA

Dr. Sherry Mills, National Institutes of Health (NIH)

Mr. Joseph Ellis, NIH