



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

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January 11, 2010

Deirdre Mageean, Ph.D.
Vice Chancellor for Research
University and Medical Center Institutional Review Board
East Carolina University
600 Moyer Boulevard
Brody School of Medicine, Room 1L-09
Mail stop #682
Greenville, NC 7834

Re: Human Research Subject Protections under Federalwide Assurance (FWA) - 0658

Dear Dr. Mageean:

Thank you for your November 12, 2009 report in response to our October 9, 2009 request that East Carolina University (ECU) respond to questions and concerns arising from our September 9-11, 2009 on-site evaluation regarding compliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR part 46).

The evaluation was conducted as part of our program to evaluate human subjects protection programs of institutions that receive HHS support for research in compliance with 45 CFR part 46.

A. Determinations regarding your institution's system for protecting human subjects:

- (1) We determine that the informed consent documents reviewed and approved by the ECU institutional review board (IRB) for the following research studies failed to include or adequately address basic elements required by HHS regulations at 45 CFR 46.116; and in other studies failed to document that the ECU IRB approved a consent procedure which did not include, or which altered, some of the required basic elements of informed consent in accordance with 45 CFR 46.116(c) or (d):

- (a) Section 116(a)(2): A description of any reasonably foreseeable risks and discomforts.
 - (i) In protocol 08-0232, the informed consent document did not include all of the risks of the research as indicated in the protocol (i.e., hyperglycemia and hypoglycemia).
 - (ii) In protocol 09-0279, the risks of receiving tight blood control are not adequately reflected in the informed consent.
- (b) Section 46.116(a)(4): A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
 - (i) In protocol 08-0730, the informed consent document did not include a statement about available alternatives, and we saw no indication that the IRB waived this element. (This deficiency was identified at IRB review; but the requested modification was never made.)

Corrective Action: We acknowledge that the ECU IRB re-reviewed these studies and they are now in compliance with HHS regulations at 45 CFR 46.116 and 45 CFR 46.116(c) or (d). Further, where appropriate, revised consent documents were given to current research subjects. Lastly, we acknowledge that subsequent to our visit, the ECU IRB Internal Activity Form, used to document the IRB's consideration of regulatory criteria required for altering or waiving informed consent, was modified to reflect all regulatory criteria in 45 CFR 46.116.

- (2) For protocol 09-0553, the ECU IRB waived the requirement to document informed consent to better protect subject confidentiality. However, the research was approved by the ECU IRB as more than minimal risk research and the informed consent document is not the only document linking the subjects to the research. We determine that the ECU IRB failed to require that informed consent be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative and did not satisfy the regulatory criteria for waiving documentation of informed consent.

Corrective Action: We acknowledge that no subjects had been enrolled in the research, and the protocol was re-reviewed and approved by the ECU IRB. The ECU IRB determined the research to be more than minimal risk and now requires 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 in compliance with HHS regulations at 45 CFR 46.117(a).

We also note that the additional actions described in your November 12, 2009 report adequately address the other questions and concerns outlined in our October 9, 2009 letter.

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We determine that the above corrective actions adequately address our determinations and are appropriate under the ECU FWA. 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.

Sincerely,

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

cc: Ms. Suzanne Sparrow, Human Protections Administrator
Ms. Norma Eply, Director, IRB
Dr. Wiley Nifong, Chairperson, IRB #1
Dr. Susan McCammon, Chairperson, IRB #2-4
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