DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

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December 8, 2009

Laura Foster Huenneke, Ph.D.
Vice President for Research
Northern Arizona University
1501 South Knoles Drive
Box 4087
Flagstaff, AZ 86011-4087

Re: Human Research Subject Protections under Federalwide Assurance (FWA) - 357

Dear Dr. Huenneke:

Thank you for your responses to our Office for Human Research Protection's (OHRP's) March 24, 2009 and September 16, 2009 requests for information in order to conduct an evaluation of the Northern Arizona University (NAU) system for protecting human subjects. The evaluation was conducted as part of our program to evaluate human subjects protection programs of institutions that receive Department of Health and Human Services (HHS) support for research in compliance with 45 CFR part 46.

We reviewed the materials you provided and made the following determinations:

A. Corrective actions related to prior determinations regarding your institution's system for protecting human subjects:

(1) In our September 16, 2009 letter, we determined that an individual who was not a member of the NAU institutional review board (IRB) reviewed and approved research at the time of initial and continuing review, as well as minor changes to already approved research, purportedly under an expedited review procedure, in violation of HHS regulations at 45 CFR 46.103(b), 46.109(a) and 46.110(b).

Corrective Action: We acknowledge that the NAU IRB has re-reviewed all active HHS-supported research and changes to HHS-supported research previously reviewed and approved by individual(s) other than the NAU IRB chairperson, or by one or more experienced reviewers designated by the chairperson from among the members of the IRB, in accordance with HHS regulations at 45 CFR 46.103(b), 46.109(a), and 46.110(b).

Further, we acknowledge that the NAU IRB policies and procedures have been revised to reflect procedures that are in compliance with HHS regulatory requirements regarding expedited review.

(2) In our September 16, 2009 letter, we determined that the NAU IRB written policies and procedures did not include, or in some cases did not provide sufficient details for, the procedures required by HHS regulations at 45 CFR 46.103(b)(4) and (5), specifically:

- procedures which the IRB will follow for determining which projects require review more often than annually;

- procedures which the IRB will follow for determining which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review;

- procedures which the IRB will follow for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject; and

- procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, any department or agency head, and our office of: (a) any unanticipated problems involving risks to subjects or others; (b) any serious or continuing noncompliance with 45 CFR part 46 or the requirements or determinations of the IRB; and (c) any suspension or termination of IRB approval.

Corrective Action: We acknowledge that NAU IRB written policies and procedures have been revised or corrected to provide information in sufficient detail about IRB procedures and now satisfy all requirements outlined in HHS regulations at 45 CFR 46.103(b).

B. Additional determinations regarding your institution's system for protecting human subjects and related corrective actions:

(1) HHS regulations at 45 CFR 46.110(c) require that all IRB members be advised of research, including minor changes in previously approved research, which has been approved under an expedited review procedure. We have reviewed the expedited review reports (which provide only a count of the number of submissions that were reviewed under an expedited procedure) that are used to notify NAU IRB members of research approved under an expedited review procedure. Based on the information provided, we determine that IRB members were not adequately advised of minor changes in research approved under an expedited review procedure.

Corrective Action: We acknowledge that the NAU IRB policies and procedures have been revised to ensure that IRB members are provided with sufficient information about research, including minor changes in previously approved research, that is approved under an expedited review procedure in compliance HHS regulations at 45 CFR 46.110(c).

(2) The NAU IRB Policy 4.06 states that continuing review applications "…are reviewed by the Human Protections Coordinator. If no problems are reported and the research seems to be going along as planned, the project is approved for another period of up to 364 days from the previous approval date." Based on this and other information provided, we determine that research that does not qualify for expedited review and approval at the time of continuing review is not reviewed by the IRB at convened meetings.

Corrective Action: We acknowledge that the NAU IRB policies and procedures have been revised to ensure that research that does not qualify for expedited review and approval at the time of continuing review is reviewed by the IRB at convened meetings in compliance with HHS regulations at 45 CFR 46.110(c).

We also note that additional modifications and clarifications have been made to the NAU IRB procedures which adequately address the questions, concerns and recommendations outlined in our September 16, 2009 letter.

We determine that the above corrective actions adequately address our determinations and are appropriate under the NAU 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, CIP
Division of Compliance Oversight

cc:
Dr. Paula McAllister, Human Protections Administrator, NAU
Dr. Robert T. Trotter, IRB Chairperson, NAU
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