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RESEARCH CORPORATION

MEMORANDUM

TO: Elaine Eaker and Paul Hurwitz January 29, 2008

FROM: Kerry Levin
Kerry Levin
Acting Chair, Institutional Review Board

SUBJECT: IRB Review and Approval
**National Children Study**
Contract No. HHSN275200503395C
Project 8208
FWA5551

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On January 8, 2008, the Westat Institutional Review Board (IRB) conducted its review of the following: **National Children's Study (NCS)**, Contract No. HHSN275200503395C, Project 8208. This review covers all procedures before and during the mother's pregnancy through the birth visit and the one month visit. Data collection activities with the mother, father and child after the one month visit will be presented and addressed at a subsequent IRB meeting. Westat's IRB reviews all studies involving human research before activities may begin under 45 CFR pt 46.

Due to the complexity of the study, project staff organized several informational steps to help familiarize the Board with the goals and objectives of the study prior to a voting decision. First, an informational session during the December 11th IRB meeting was held. During this meeting, project staff provided the Board with an overview of the project and presented a sample of the video consent process. Following this session, the IRB Board Chair circulated a series of questions from Board members to project staff. The final review of study materials and procedures took place during the January Board meeting which was also included a discussion of the answers provided to all of the questions and requests for further clarification regarding answers to some questions.

Following the January Board meeting, additional information was submitted by the NCS project staff to supplement answers to questions which had been submitted previously. These answers now appear in the final record and are included as an attachment to the study protocol. Some of the answers will require modification to the study protocol at a future time. It is anticipated that a copy of the revised protocol reflecting the answers to questions will be sent to this IRB for the record.

Lastly, even if the protocol does not change, if Westat's role with regard to data collection should change, those aspects of the study must be reviewed by the Westat IRB.

The Board determined that NCS presents no greater than minimal risk to the pregnant woman and their unborn children. It was also determined that the number of ultrasounds being conducted does not place the women or child at increased risk, based on documentation provided to the Board.

Because this study presents no greater than minimal risk, the Board waives the requirement for the father's consent for the child or unborn fetus [45 CFR 46.116 of Subpart A and 46.408 (b)]. The father however, will be required to provide written consent for his own participation in the study. In addition, a waiver for permission from both parents has been granted for emancipated pregnant minors as long as it does not conflict with local jurisdiction requirements. Each Study Center will be responsible for adherence to their local jurisdictional requirements regarding the consent and enrollment of pregnant minors. The Coordinating Center will prepare procedures to be used when the pregnant minor is legally allowed to provide consent, and when she is not, and the Study Centers will be required to adhere to their local laws.

Based upon this approval, the project must submit a Certificate of Confidentiality to the IRB as soon as it is received; no reference to the Certificate may be made to the women whose consent for enrollment is sought until the Certificate is obtained.

It is understood that no data collection will begin until approval of the study by the NICHD IRB. In addition, no data collection will begin at any study center site until the approval of the study, including all activities of the study center and their subcontractor or organizations, by that Center's IRB. It is anticipated that the NICHD agency IRB will serve as the central NCS IRB to review any protocol changes from the package approved here by the Westat IRB. Any such approvals of changes made by the NICHD IRB will be transmitted to the Westat IRB for our records and use in oversight of Westat's Coordinating Center activities.

In accordance with 45 CFR 46, the Board unanimously approved this study for the phases submitted, which includes procedures before and during the pregnancy of the mother, up to the birth of the child.

You are obligated to submit the study for an annual review on or before January 29, 2009. In the interim, you are responsible for notifying the Office of Research Administration as soon as possible if there are any injuries to the subjects, problems with the study, or changes to the study design that relate to human subjects.

cc: Institutional Review Board