TO: Maria McDonald, BS, Dept. of Sociology, ECU
FROM: UMCIRB
DATE: May 24, 2011
RE: Expedited Category Research Study
TITLE: “Adolescent Stress Induced by Family Structure and its Effect on Adult Health”
UMCIRB #11-0334

This research study has undergone review and approval using expedited review on 5.19.11. This research study is eligible for review under an expedited category number 7 which includes research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)
The Chairperson (or designee) deemed this Department of Sociology sponsored study no more than minimal risk requiring a continuing review in 12 months. Changes to this approved research may not be initiated without UMCIRB review except when necessary to eliminate an apparent immediate hazard to the participant. All unanticipated problems involving risks to participants and others must be promptly reported to the UMCIRB. The investigator must submit a continuing review/closure application to the UMCIRB prior to the date of study expiration. The investigator must adhere to all reporting requirements for this study.

The above referenced research study has been given approval for the period of 5.19.11 to 5.18.12. The approval includes the following items:
- Internal Processing Form (dated 5.11.11)
- Form to Describe Sensitive Data Security Plan
- Research Proposal

The Chairperson (or designee) does not have a potential for conflict of interest on this study.

The UMCIRB applies 45 CFR 46, Subparts A-D, to all research reviewed by the UMCIRB regardless of the funding source. 21 CFR 50 and 21 CFR 56 are applied to all research studies under the Food and Drug Administration regulation. The UMCIRB follows applicable International Conference on Harmonisation Good Clinical Practice guidelines.
IMPORTANT INFORMATION

Continuing and Final Review Obligations

As Principal Investigator, you are required to submit a continuing or final review form to the Office for Human Research Integrity for IRB review. This is a federal requirement to continue or close your research study before the date of expiration as noted on the attached approval letter. This information is required to summarize the research activities since it was last approved. The regulations do not permit any research activity outside of the IRB approval period. Additionally, the regulations do not permit the UMCIRB to provide a retrospective approval during a period of lapse.

You must submit this form even if there has been no activity, no participants enrolled or you do not wish to continue the activity any longer. Research studies that are allowed to be expired will be reported to the Vice Chancellor for Research and Graduate Studies, along with relevant other administration within the institution. The continuing or final review form is located on our website at http://www.ecu.edu/rgs/irb/ along with our meeting submission deadlines. Please contact the UMCIRB office at 252-744-2914 if you have any questions regarding your role or requirements with continuing review.

Required Approval for Any Changes to IRB-Approved Research

As Principal Investigator, you are required, prior to making any changes in your research study must have those changes reviewed and approved by the IRB. The only exception is when those changes are to eliminate an immediate apparent hazard to the participant. In the case when changes must be immediately undertaken to prevent a hazard to the participant and there is no opportunity to obtain prior IRB approval, the IRB must be informed of the changes as soon as possible via a protocol deviation form.

Reporting Unanticipated Problems to the IRB that Affect Participants or Others

As Principal Investigator, you are required to report to the IRB all unanticipated problems that have occurred in your research within the time frame specified in the UMCIRB rule for reporting Unanticipated Problems Involving Risks to Participants or Others.

Version 5/5/11