



Office of Research Compliance

July 21, 2004

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Texas A&M University Research Park

MEMORANDUM

TO: Dr. Anne Sweeney
Department of Epidemiology and Biostatistics
MS 1266

FROM: Dr. Alvin Larke, Jr., Chair
Institutional Review Board
MS 1112

SUBJECT: IRB Protocol Review

Title: "Longitudinal Investigation of Fertility and the Environment (LIFE) Study"
Protocol Number: 2004-0255
Review Category: Full Review
Approval Period: June 16, 2004 - June 15, 2005

The approval determination was based on the following Code of Federal Regulations: 45 CFR 46 Subpart A.

Remarks: None

The Institutional Review Board - Human Subjects in Research, Texas A&M University has reviewed and approved the above referenced protocol. Your study has been approved for one year. As the principal investigator of this study, you assume the following responsibilities:

Renewal: Your protocol must be re-approved each year in order to continue the research. You must also complete the proper renewal forms in order to continue the study after the initial approval period.

Adverse events: Any adverse events or reactions must be reported to the IRB immediately.

Amendments: Any changes to the protocol, such as procedures, consent/assent forms, addition of subjects, or study design must be reported to and approved by the IRB.

Informed Consent/Assent: All subjects should be given a copy of the consent document approved by the IRB for use in your study.

Completion: When the study is complete, you must notify the IRB office and complete the required forms.



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