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Office of Research Services

September 14, 2006

Lori Wolfe
Department of Biology
University of North Texas

Re: Human Subjects Application No. 06-321

Dear Ms. Wolfe:

As permitted by federal law and regulations governing the use of human subjects in research projects (45 CFR 46), the UNT Institutional Review Board has reviewed your proposed project titled "Pilot Project for a National Monitoring System for Major Adverse Effects of Medication Use During Pregnancy and Lactation." The risks inherent in this research are minimal, and the potential benefits to the subject outweigh those risks. The submitted protocol and consent form are hereby approved for the use of human subjects in this study. **Federal Policy 45 CFR 46.109(e) stipulates that IRB approval is for one year only, September 14, 2006 to September 13, 2007.**

Enclosed is the consent document with stamped IRB approval. Please copy and **use this form only** for your study subjects.

It is your responsibility according to U.S. Department of Health and Human Services regulations to submit annual and terminal progress reports to the IRB for this project. Please mark your calendar accordingly. The IRB must also review this project prior to any modifications.

Please contact Shelia Bourns, Research Compliance Administrator, or Boyd Herndon, Director of Research Compliance, at extension 3940, if you wish to make changes or need additional information.

Sincerely,

Scott Simpkins, Ph.D.
Chair
Institutional Review Board

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