



OFFICE OF RESEARCH SUPPORT

THE UNIVERSITY OF TEXAS AT AUSTIN

P.O. Box 7426, Austin, Texas 78713 · Mail Code A3200
(512) 471-8871 · FAX (512) 471-8873

FWA # 00002030

Date:

PI:

Dept:

Title:

Re: IRB Exempt Determination for Protocol Number

Dear

Recognition of Exempt status based on 45 CFR 46.101(b)().

Qualifying Period: to . Expires 12 a.m. [midnight] of this date.

A continuing review report must be submitted in three years if the research is ongoing.

Responsibilities of the Principal Investigator:

Research that is determined to be Exempt from Institutional Review Board (IRB) review is not exempt from ensuring protection of human subjects. The Principal Investigator (PI) is responsible for the following throughout the conduct of the research study:

1. Assuring that all investigators and co-principal investigators are trained in the ethical principles, relevant federal regulations, and institutional policies governing human subject research.
2. Disclosing to the subjects that the activities involve research and that participation is voluntary during the informed consent process.
3. Providing subjects with pertinent information (e.g., risks and benefits, contact information for investigators and ORS) and ensuring that human subjects will voluntarily consent to participate in the research when appropriate (e.g., surveys, interviews).
4. Assuring the subjects will be selected equitably, so that the risks and benefits of the research are justly distributed.
5. Assuring that the IRB will be immediately informed of any information or unanticipated problems that may increase the risk to the subjects and cause the category of review to be reclassified to expedited or full board review.

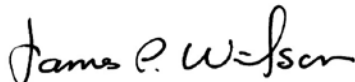
6. Assuring that the IRB will be immediately informed of any complaints from subjects regarding their risks and benefits.
7. Assuring that the privacy of the subjects and the confidentiality of the research data will be maintained appropriately to ensure minimal risks to subjects.
8. Reporting, by submission of an amendment request, any changes in the research study that alter the level of risk to subjects.

These criteria are specified in the PI Assurance Statement that was signed before determination of exempt status was granted. The PI's signature acknowledges that they understand and accept these conditions. Refer to the Office of Research Support (ORS) website www.utexas.edu/irb for specific information on training, voluntary informed consent, privacy, and how to notify the IRB of unanticipated problems.

1. Closure: Upon completion of the research study, a Closure Report must be submitted to the ORS.
2. Unanticipated Problems: Any unanticipated problems or complaints must be reported to the IRB/ORS immediately. Further information concerning unanticipated problems can be found in the IRB Policies and Procedure Manual.
3. Continuing Review: A Continuing Review Report must be submitted if the study will continue beyond the three year qualifying period.
4. Amendments: Modifications that affect the exempt category or the criteria for exempt determination must be submitted as an amendment. Investigators are strongly encouraged to contact the IRB Program Coordinator(s) to describe any changes prior to submitting an amendment. The IRB Program Coordinator(s) can help investigators determine if a formal amendment is necessary or if the modification does not require a formal amendment process.

If you have any questions contact the ORS by phone at (512) 471-8871 or via e-mail at orsc@uts.cc.utexas.edu.

Sincerely,



James Wilson, Ph.D.
Institutional Review Board Chair