

OFFICE OF RESEARCH SUPPORT

THE UNIVERSITY OF TEXAS AT AUSTIN

P.O. Box 7426, Austin, Texas 78713 (512) 471-8871 -FAX (512 471-8873) North Office Building A, Suite 5.200 (Mail code A3200)

Date:

PI(s): Department & Mail Code:

Title:

IRB APPROVAL – IRB Protocol #

Dear:

In accordance with Federal Regulations for review of research protocols, the Institutional Review Board discussed the above referenced protocol at the convened meeting of the Board on and voted your study for the following period of time:

Your continuing review has been approved from - .

Please use the attached approved informed consent

You have been granted waiver of documentation of informed consent in lieu of verbal consent

RESPONSIBILITIES OF PRINCIPAL INVESTIGATOR FOR ONGOING PROTOCOLS:

- (1) Report immediately to the IRB any unanticipated problems.
- (2) Proposed changes in approved research during the period for which IRB approval cannot be initiated without IRB review and approval, except when necessary to eliminate apparent immediate hazards to the participant. Changes in approved research initiated without IRB review and approval initiated to eliminate apparent immediate hazards to the participant must be promptly reported to the IRB, and reviewed under the unanticipated problems policy to determine whether the change was consistent with ensuring the participants continued welfare.
- (3) Report any significant findings that become known in the course of the research that might affect the willingness of subjects to continue to take part.
- (4) Insure that only persons formally approved by the IRB enroll subjects.
- (5) Use only a currently approved consent form (remember approval periods are for 12 months or less).
- (6) Protect the confidentiality of all persons and personally identifiable data, and train your staff and collaborators on policies and procedures for ensuring the privacy and confidentiality of participants and information.
- (7) Submit for review and approval by the IRB all modifications to the protocol or consent form(s) prior to the implementation of the change.

- (8) Submit a **Continuing Review Report** for continuing review by the IRB. Federal regulations require **IRB review of on-going projects no less than once a year** (a Continuing Review Report form and a reminder letter will be sent to you 2 months before your expiration date). Please note however, that if you do not receive a reminder from this office about your upcoming continuing review, it is the primary responsibility of the PI not to exceed the expiration date in collection of any information. Finally, it is the responsibility of the PI to submit the Continuing Review Report before the expiration period.
- (9) Notify the IRB when the study has been completed and complete the Final Report Form.
- (10) Please help us help you by including the above protocol number on all future correspondence relating to this protocol.

Sincerely,

Jody L. Jensen, Ph.D.

Professor

Chair, Institutional Review Board