



OFFICE OF RESEARCH SUPPORT
THE UNIVERSITY OF TEXAS AT AUSTIN

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FWA # 00002030

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
- ☐ You have been granted waiver of informed 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.

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