

ATTACHMENT C

RESPONSIBILITIES OF INVESTIGATORS

The enclosed information is designed to outline responsibilities of research investigators conducting research under the auspices of Kessler Foundation's Review Committee (RRC) and Institutional Review Board (IRB). Please read it carefully. Maintain this listing close at hand for reference during the conduct of your research project.

- 1. Ethical Principles for Research Involving Human Subjects**
In designing the study, investigators must take into consideration the three ethical principles that should underlie all research involving human subjects: respect for persons; beneficence; and justice. For definition of these terms, researchers should read the Belmont Report found in the appendix section of the Research Manual.
- 2. Protection of Subjects**
Research investigators must acknowledge and accept their responsibility for protecting the rights and welfare of human research subjects and for complying with all applicable provisions of Kessler Foundation policies dealing with protection of human subjects. If applicable, investigators must review the Federal Wide Assurance Document approved by Office for Human Research Protections (OHRP) for their study to ensure familiarity with Federal regulations.
- 3. Obtaining Certification of Exemption from IRB Review**
Research investigators who intend to involve human research subjects shall not make the final determination of exemption from IRB review. Investigators must submit a full research proposal to the Research Review Committee and to the IRB. Final determination of the IRB review category will be made by designated representatives of the IRB.
- 4. Obtaining IRB Approval of Research**
Investigators are responsible for insuring that all research involving human subjects is submitted to and approved by the RRC and IRB prior to initiation of the research.
- 5. Obtaining IRB Approval for Advertisements**
It is the investigator's responsibility to notify the IRB that he/she is planning to advertise the study to potential subject populations. All advertisements (published and /or posted) must be approved by the IRB prior to distribution or publication.
- 6. Complying with IRB Decisions**
In implementing the research activities, the investigator is responsible for complying with all IRB decisions, conditions and requirements. The research procedures must be implemented only as approved by the IRB.
- 7. Obtaining and Documenting Informed Consent**
The principal investigator is responsible for compliance with all Kessler Foundation policies and procedures governing informed consent. If individuals other than the principal investigator are to be designated to obtain consent/assent, they must be identified on the Cover Page of the Initial Application. It is important that the individuals obtaining informed consent be appropriately qualified to do so.

The Principal investigator is responsible for ensuring that informed consent/assent is documented as approved by the IRB. Only informed consent/assent documents with a valid "IRB Approval" stamp can be used. Changes in the approved informed consent document cannot be made without prior IRB approval.

Unless otherwise authorized by the IRB, investigators are responsible for insuring that assent from research subjects who are minors is obtained and documented in accord with IRB policies and requirements.

The investigator is responsible for ensuring that each person signing a written consent or assent form is given a copy of the signed form unless the IRB has specifically waived this requirement.

8. Retaining Informed Consent Documents

Unless the research falls within the purview of the Food and Drug Administration (FDA), the investigator is responsible for retaining the signed consent and assent documents for at least three years past completion of the research project. For research which falls under FDA authority, the investigator is responsible for retaining the signed documents for the period specified in the applicable FDA regulations (at least six years).

9. Maintaining a chronological logbook documenting conduct of experimental procedures and involvement of human participants

For every research project involving human subjects, researchers must maintain a logbook (not a data book, but a chronological logbook) where the conduct of each experimental procedure is recorded. All experiments must be recorded in the logbook so as to include at least the following information:

- a) Date of experiment
- b) IRB protocol number for this experiment
- c) Subject identification or appropriate coded ID number
- d) Researcher conducting the experiment
- e) Researcher sponsoring the experiment (PI of the study)
- f) Start time
- g) End time
- h) Successful completion of protocol (yes, no)
- i) Data storage location or reference to data storage procedure
- j) Witness present (if any)
- k) Notes on adverse events, conduction of experiment, condition of equipment, or other issues as deemed appropriate by the researcher conducting the experiment

Researchers should maintain the human subject experimental logbook separate from other research documentation, and be prepared to submit the book to the IRB upon request. The logbook serves as a chronological record of the use of human subjects in IRB-approved research, and may be reviewed/audited at any time to review compliance with federal and institutional policies and procedures.

10. Proposed Changes in Previously-Approved Research Studies (Form Attached)

Changes in the research proposal or the informed consent document cannot be initiated by the investigator without IRB review and approval except where necessary to eliminate apparent immediate hazards to the subject. Copies of the Request for

Approval of a Modification should be submitted to the Office of the IRB Coordinator. The request must include the following: 1) the IRB protocol number; 2) the exact title of the protocol as originally submitted to the IRB; 3) a complete description of the nature of the changes; and 4) the signature of the principal investigator. If the proposed changes necessitate a change in the consent form, then a revised consent form in which the revisions are underlined or highlighted should be submitted. In addition, one clean copy of the revised form without underlining or highlighting should be attached.

Approval is granted by the IRB chairperson or a designated representative unless the nature of the proposed changes warrants review by the full board. The investigator is notified in writing of the Board's decision. If approved, the clean copy of the revised consent/assent document(s) with the valid "IRB Approval" stamp will accompany the approval letter.

Note that a change in the principal investigator must also be reported to the IRB Administrator.

11. Submission of Continuation Review Reports

According to federal and institutional regulations, the IRB must conduct continuing review of previously approved research projects at intervals appropriate to the degree of risk, but not less than once per year. The IRB's continuation review procedures are as follows:

1. At intervals specified by the IRB, the Office of the IRB Administrator sends the investigator an Application for Continuation of Approval Form.
2. It is the investigator's responsibility to complete and return the form with all the necessary documents as specified in the instruction section of the form.
3. The Request for Continuation of Approval is placed on the agenda for the next IRB meeting. Provided that the IRB members have no questions, the study is approved for continuation. The informed consent/assent document(s) is stamped with the "IRB Approval" stamp and returned to the investigator.
4. If the research is supported by an external funding agency, it is the investigator's responsibility to transmit the approval letter to the agency.
5. If, during a period for which IRB approval has already been granted, it is determined that additional information is needed or that irregularities have arisen which affect the participation of the human subjects, the IRB or its designated representative(s) may take the following action:
 - a) Request revisions and/or additional information;
 - b) Request that the investigator attend the next IRB meeting;
 - c) Suspend approval pending further investigation by the IRB;
 - d) Terminate IRB approval.

If the investigator fails to return the Continuation Review report form or fails to submit the requested information, IRB approval will be terminated with notification letters sent to the investigator and, if appropriate, the funding agency.

12. Submission of Adverse Reaction Reports or Other Complications (Form Attached)

Research investigators must promptly report to the IRB and to the sponsoring Federal department any injuries, adverse events or other unanticipated problems involving risks to subjects and others in accord with IRB procedure on "Submission of Reports of Adverse Events". If a subject reports unexpected discomfort during an experiment, the experiment must be immediately suspended until the source is identified and adequately addressed. The Procedure is included in the Research Manual which can be obtained from the Department Directors or the Office of the IRB Coordinator at KESSLER FOUNDATION.

13. Notifying the IRB Concerning Investigator Leaving the Institution

If the investigator plans to leave Kessler Foundation and intends to continue the research activities at another institution, the researcher must notify, in writing, the Office of the IRB Administrator so that the active file can be closed out.

If the research activities are to be continued at Kessler Foundation under the direction of another investigator who is affiliated with this institution, then a request for approval of a change of investigator must be submitted to the IRB. The submission and review procedures to be followed are described above in the section on "Changes in Previously Approved Research Studies".

14. Completion of Research Activities

The investigator must notify the IRB Administrator's office when the research project is completed so that the active file can be closed out. If the investigator fails to notify the IRB, then he/she will continue to be responsible for completing the Application for Continuation of Approval/Project Completion forms.

15. Emergency Care

When conducting National Institutes of Health Cooperative Protocol Research Programs (CRP) or any Department of Health and Human Services (DHHS) funded research, no research investigator will seek to obtain research credit for, or use data from, patient interventions that constitute the provision of emergency medical care without prior IRB approval. A physician may provide emergency medical care to a patient without prior full board review and approval, to the extent permitted by law. However, such activities will not be counted as research nor the data used in support of DHHS-funded research without prior IRB approval.