Title: AMENDMENTS TO PREVIOUSLY APPROVED APPLICATIONS

1.0 Purpose:

The purpose for this standard operating procedure (SOP) is to provide guidance for submission, review and approval of amendments to previously approved applications.

2.0 Policy:

It is the policy of the SU IRB to review all requests for amendments to previously approved research applications or claims for exemption to determine if a change in the risk/benefit ratio of the study has occurred.

Investigators may not initiate any changes in research procedures or consent/assent form(s) without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to the participant. Examples of modifications that require IRB review include, but are not limited to, changes in:

- Study personnel;
- Advertising materials (flyers, radio spots, etc.);
- Research procedures;
- Participant populations (e.g., age range);
- Location where research will be conducted;
- Consent/assent form;
- Recruitment procedures;
- Date for completion of study.

If the investigator makes protocol changes without prior IRB approval to eliminate apparent hazards to the participant(s), investigators must report the changes within 10 days to the IRB for review and a determination as to whether the change is consistent with the participants' continued welfare. Such changes are reviewed by the IRB as possible unanticipated problems involving risks to participants or others.

Investigators must submit the exact text of an amendment or other revision to the protocol and any proposed changes to the Informed Consent Document (ICD) to the IRB. When there are numerous changes to the research protocol, a summary of the changes should also be submitted.

Modifications to the ICD must take into account both prospective research participants and, if applicable, research participants already enrolled in the study. The latter may be addressed using an addendum to the initial ICD or, less preferably, by re-consenting the participant using the modified ICD.

2.1 Minor Amendments.

Minor changes proposed for previously approved research may be reviewed in an expedited manner. Examples of minor modifications may include, but are not limited to, the following:

2.1.1 Minor wording or formatting changes in the consent form(s), recruiting materials, interviews, or questionnaires;
2.1.2 Minor changes in compensation;
2.1.3 Time of participation;
2.1.4 A change in the study title;
2.1.5 Adding or deleting study sites;
2.1.6 The addition or deletion of qualified Investigators;

2.2 Major Amendments.

When a proposed change in a research study is not minor, then the IRB Chair or designee must review and approve changes for expedited protocols, and the IRB committee reviews and approves changes at a convened meeting for Full Board protocols before changes can be implemented. Examples of major modifications may include, but are not limited to, the following:

2.2.1 Broadening the range of inclusion criteria;
2.2.2 Narrowing the range of exclusion criteria;
2.2.3 Alterations in the dosage or route of administration of an administered drug;
2.2.4 Extending substantially the duration of exposure to the test material or intervention;
2.2.5 The deletion of laboratory tests, monitoring procedures, or study visits directed at the collection of information for safety evaluations;
2.2.6 The addition of significant risks to the Informed Consent Document; or
2.2.7 Changes, which, in the opinion of the IRB chairperson or his/her designee, do not meet the criteria or intent of a minor modification.

2.3 Re-consent/Notification of Participants.

The IRB will render a determination of whether the changes to the research activities require a change in the ICDs and therefore warrant re-consenting of currently enrolled participants or notification of participants who have completed research interventions.

2.4 Exempt Research.

Any proposed or anticipated changes in an exempt study must be submitted to the IRB for approval prior to initiation of the change. The research proposal will then be evaluated for appropriate IRB review.

2.5 Expedited Research.

Any substantive changes or modifications in research approved by the IRB on an expedited or full IRB basis must be approved by the IRB.

3.0 References and Reference Documents:

45 CFR 46.110(b)(2)

4.0 Procedure:

4.1 Investigator Responsibilities.

The Investigator will complete the “IRB Amendment” Form and include the exact text of the revisions to the application, protocol, informed consent documents (ICDs) or other documents associated with the requested change along with a justification for the change. When there are numerous changes, a summary of the changes is also required with the submission. All revisions must be incorporated into the corresponding documents.

Changes to the IRB application and ICDs are to be underlined and clean copies of the ICDs are to be included for date-stamping.

4.1.1 If, in the Investigator's opinion, the risk/benefit ratio has changed, necessitating re-consenting of currently enrolled participants, the Investigator will provide an amendment to the currently approved ICDs.

4.1.2 The IRB Committee may also request re-consenting of the participants.

4.1.3 Any proposed or anticipated changes in an exempt study, within one year of the date of IRB approval, must be submitted to the IRB for approval prior to initiation of the change. The research proposal will then be evaluated for appropriate IRB review. If a change in exempt research occurs after the first year of approval, the Investigator will complete a new "Request for Exemption" incorporating the proposed change for IRB review and approval.

4.1.4 When the Investigator makes changes to avoid an immediate hazard to the participant, the Investigator completes a "Report of Unanticipated Problems Involving Risk to Participants or Others". The Investigator is required to submit the form to the IRB within 10 working days of the deviation.

4.1.5 Investigators must promptly notify the IRB in writing of any change in a protocol's status, such as discontinuation or completion of a study.

4.2 IRB Committee Responsibilities.

The IRB Chairperson or his/her designee may review and approve research that meets the definition of a minor amendment. When a proposed change in a research study is not minor, then the IRB Chair or designee must review and approve changes for expedited protocols, and the IRB committee reviews and approves changes at a convened meeting for Full Board protocols before changes can be implemented. All Committee members will receive:

4.2.1 The cover letter, if applicable;

4.2.2 The amendment form;

4.2.3 All amended information or additional information including the amended protocol, amended IRB proposal and amended informed consent document if applicable, or the most current informed consent document if not amended;

4.2.4 Any additional pertinent material (e.g., questionnaires, advertisements, DSMB reports, etc.).

4.3 ORIP Responsibilities.

4.3.1 The ORIP/IRB Administrator or designee will review the requested amendment and determine whether it reflects a major or minor change.

4.3.1.1 Requested changes meeting the criteria for minor amendments or major amendments for expedited protocols will be stamped for review and signature by the IRB Chairperson or his/her designee.

4.3.1.2 Requested changes meeting the criteria for major Full Board amendments will be prepared for IRB Committee review by assignment of Reviewers, placing the study on the next available Committee agenda, and collation of Reviewer and Committee member packets. Access to the full file will be available at the Committee meeting.

4.3.1.3 Changes to exempt research may be approved by the ORIP Director if changes do not change the review status of the study.

4.3.2 Letters denoting the IRB Committee determinations will be drafted using the

appropriate template.

4.3.3 The ORIP/IRB Administrator or designee will assist in obtaining any additional information requested by the IRB Chair or Reviewer.

4.3.4 At any time, the ORIP/IRB Administrator may consult with the IRB Committee Chairperson for assistance in determining the type of review that is required to process the amendment.

4.3.5 Amendments requiring modifications in the ICDs must be date-stamped and processed according to IRB policies and procedures.

4.3.6 The ORIP/IRB Administrator will make the appropriate database entries including Committee notification of approval of minor amendments on the next available agenda.

SOP 014: AMENDMENTS TO PREVIOUSLY APPROVED APPLICATIONS

Approved by: BR Ware 7-20-08

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