1. POLICY:

In accordance with 45 CFR 46.108(a)(3), Institutional Review Boards (IRBs) must review changes to previously approved research. Such changes must be reviewed and approved by the IRB prior to implementation of the changes. Approval of an Amendment does not change the expiration date of the protocol.

1.1 Exceptions

1.1.1 When an immediate change is necessary to eliminate a hazard to research participants, the proposed change does not need to be reviewed by the IRB prior to its implementation. However, Investigators must notify the IRB of the change in the protocol immediately thereafter using the Unanticipated Problem Report and/or Adverse Event form as a formal mechanism of reporting to the Human Research Protection Program.

1.1.2 Some specific changes have been determined to present no increased risk or burden to research participants, nor result in decreased benefits to them. These changes represent momentary deviations from a set schedule required by the irregularities of life that do not alter the integrity of the study or the rights of the subjects. These changes do not require IRB review and approval prior to implementation; however, updated forms (if applicable) must be provided to the IRB to ensure the accuracy of of the IRB research study file. See Section 3.3 below.

These policies and procedures apply to all IRB reviewed research conducted under the jurisdiction of the Purdue University IRB.

2. DEFINITIONS

2.1 *Amendment or Modification*: A change to IRB-approved research that must have IRB review and approval prior to implementation. Note: The term Amendment and Modification are used synonymously in the processing of protocols.

2.2 *Minor Change*: A change that does not introduce new risks to the subject population or negatively alter the risk/benefit analysis. Minor changes may be reviewed using expedited procedures. Examples: changes in funding source that do not trigger a conflict of interest, revision of project title, removal of research personnel (other than the Investigator), alteration of recruitment media, updating of contact information, reduction of subject interventions or interactions that do not change the risk/benefit ratio of the study as originally reviewed by the IRB.

3. PROCEDURES

3.1 Modification Submission Requirements

The following materials are required for the submission and review of an Amendment (forms available at www.irb.purdue.edu):

3.1.1 Completed electronic Modification form.

3.1.2 Documented or electronic system authorization by the Principal Investigator.

3.1.3 A revised application that documents the modified protocol, using tracked changes.

3.1.4 A copy of all altered study materials using tracked changes (i.e., recruitment materials, consent forms, data collection forms, supporting agreements).

3.1.5 For externally sponsored projects involving procedural changes, the HRPP may request confirmation that the project has received the sponsor's approval for a change to the research.

3.2 Amendment Submissions – Office Procedures and Review Process

3.2.1 HRPP Support Staff accepts the complete submissions, and rejects incomplete submissions. The request is forwarded to a Protocol Analyst for administrative review prior to IRB review. Complete submissions may be forwarded directly to the IRB in the event of heightened risk or legitimate need for expedient processing.

3.2.2 The Protocol Analyst documents review considerations and routes the submission for IRB review.

3.2.3 The submission is reviewed either via expedited procedures (for minor changes) or via full IRB review (for all other changes). The criteria for approval are the same as for initial review. See SOP 302: Initial Review. In order to approve the Modification, the expedited review or convened IRB must determine that all of the approval criteria will continue to be met following the implementation of the change. Additionally, the Board considers any significant new findings that have been reported that may relate for participant's safety or willingness to continue participation.

3.3 Changes Not Requiring Review

The changes listed below do not require IRB review and approval prior to implementation. However, any updated forms must be provided to the IRB for completeness of the IRB study file.

3.3.1 Study Procedures

(a) Rescheduling of a data collection when a research participant misses an appointment or data collection is incomplete due to unforeseen circumstances that do not increase risk to the participant (e.g., equipment failure resulting in data collection cancellation, etc.). However, such deviations from the protocol must be reported at continuing review.

(b) Rescheduling of specimen collections (identified below) of an adult subject when that subject misses an appointment or specimen collection is incomplete, due to unforeseen circumstances that do not increase risks to the subject but increase the total amount of specimen collected than what was approved. However, such deviations from the protocol must be reported at continuing review. Specimen collections that qualify for this category are as follows:

(i) collection of blood via finger, heal or ear stick;

(ii) hair and nail clippings collected in a non-disfiguring manner; excreta and external secretions (including sweat);

(iii) uncannulated saliva collected either in an instimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;

(iv) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; and

(v) sputum collected through expectoration.

(c) Removal of study instrument(s) so long as it does not reduce any previously found direct benefit to participants or decrease the validity of the study.

(d) Minor editorial changes to study instruments (e.g., corrections of grammar/language to increase participant understanding).

3.3.2 Recruitment Materials

(a) Changes within the approved recruitment material medium (e.g., changes within print medium, for example, flyer to newspaper advertisement). If changes are made to a different medium (e.g., from print medium like a flyer to phone solicitations) the changes are substantive and must be submitted to the IRB for review and approval.

(b) Changes in contact information, except where a new Investigator or other Key Personnel is added to the study. The addition of new Investigator or other Key Personnel is a substantive change to the study and must be submitted to the IRB for review and approval.

(c) Minor editorial changes (e.g., corrections of grammar/language to increase participant understanding).

(d) Updating dates and times related to when research activities will occur (so long as such dates/times and number of data collection activities are within the approved protocol period and do not increase duration of a subject's participation).

3.3.3 Consent/Assent Documents

(a) Minor editorial changes (e.g., corrections of grammar/language to increase participant understanding).

(b) Changes in contact information except where a new Investigator or other Key Personnel is added to the study. The addition of new Investigator or other Key Personnel is a substantive change to the study and must be submitted to the IRB for review and approval.

(c) Changes noting removal of a study instrument and resulting change of duration of participation. Changes adding study measures are substantive and must be submitted as an amendment to for IRB review and approval.

3.3.4 Changes to non-key personnel. When non-key personnel are added to a study, it is the Investigator's responsibility to keep records of study personnel changes, study personnel's fulfillment of education requirements and be able to produce those records upon request. Non-key personnel may not engage in any aspect of human subjects research until they have passed all required training. Should non-key personnel become key personnel later, this change is substantive and must be submitted as an amendment for IRB review and approval.

4. RESPONSIBILITIES

4.1 Investigator Responsibilities

4.1.1 An Investigator must submit change(s) to an approved protocol using an electronic modification form and receive IRB approval for the change(s) prior to implementing the changes to the protocol.

4.1.2 An Investigator must re-consent currently enrolled subjects should the IRB determine that the changes to the protocol require currently enrolled subjects to be re-consented.

4.1.3 Consent Forms: Investigators making minor changes not requiring review to consent/assent documents for non-exempt studies must submit proposed modifications on these documents to the HRPP office to secure IRB approval.

4.1.4 Exempt Studies: Investigators making any change to an exempt study must submit a request to modify the exempt study submission, to ensure that the regulatory status of the activity has not been altered by the change in the activity.

4.2 IRB Responsibilities

4.2.1 HRPP Support Staff and Protocol Analysts are responsible for managing the submission through the IRB review process, and communicating directly with the investigator The Principal Investigator is responsible for the actions of his/her staff and should be the primary respondent to IRB submission questions.

4.2.2 The IRB Administrator supervises and advises on the processes for review of revision requests. May review or approve amendments as necessary as an expedited reviewer

4.2.3 IRB (either by convened IRB or expedited reviewer, as appropriate) reviews and approves or denies an Amendment request. The reasons for a denial must be communicated to the investigator in writing.

5. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.108(a); 45 CFR 46.110(b)

21 CFR 56.108(3) and (4); 21 CFR 56.110(b)

6. REFERENCES TO OTHER APPLICABLE SOPs

302 Initial Review

303 Expedited Review