Minor Changes Not Requiring Review

I. Summary

The Institutional Review Board (IRB) must review changes to previously approved research. Such changes must be approved prior to the investigator implementing those changes. However some specific changes have been determined to be minor and result in no increased risk or burden nor decreased benefits to participants. Such minor changes do not require submission and review by the IRB. These minor changes are listed below.

II. Definitions

1. **Minor Changes** are changes identified to result in no increased risk or burden nor decrease in benefits to participants. These changes, identified in this guidance, do not require IRB review and approval. All other changes are substantive in nature and must be submitted to the IRB for review and approval prior to implementation.

2. **Substantive Changes** are changes that are not minor and may result in increased risk or burden or decreased benefits to participants. Such changes must be submitted to the IRB for review and approval prior to implementation.

III. Guidelines and Procedures

Study Procedures

1. Rescheduling of data collections when a participant misses an appointment or data collection is incomplete due to unforeseen circumstances that do not increase risk to participants (e.g., equipment failure resulting in data collection cancellation, etc.).

2. Rescheduling of certain specimen collections (identified below) of an adult participant when that participant misses an appointment or specimen collection is incomplete due to unforeseen circumstances that do not increase risks to participants but the total amount of specimen collected would be greater than what was originally approved. For example, in a study that requires consecutive blood collection via finger stick at 30 minute intervals for 3 hours, but unforeseen circumstances interrupts the specimen collection an hour into the 3 hour session, the 3 hour session would be rescheduled resulting in an increase of the
total specimen amount collected for the study. Specimen collections that qualify for this category are as follows:

- collection of blood via finger stick, heel stick or ear stick;
- hair and nail clippings collected in a nondisfiguring manner;
- excreta and external secretions (including sweat);
- uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
- mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; and
- sputum collected through expectoration.

3. Removal of study instrument(s) so long as it does not reduce any previously found direct benefit to participants. For example, if the study and its consent document(s) state that participants will derive some benefit from the instrument(s) in question, then removal of that instrument from the study is substantive in nature and must be submitted to the IRB for review and approval.

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

**Recruitment Materials**

5. 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.

6. Changes in contact information except where a new investigator (PI or key personnel) is added to the study. The addition of a new PI or key personnel is a substantive change to the study and must be submitted to the IRB for review and approval.

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

8. 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).
Consent/Assent Documents

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

10. Changes in contact information except where a new investigator (PI or key personnel) is added to the study. The addition of a new PI or key personnel is a substantive change to the study and must be submitted to the IRB for review and approval.

11. Changes noting removal of a study instrument and resulting change of duration of participation.

Other

12. Changes to non-key personnel. When non-key personnel are added to a study, it is the PI’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 the required CITI training. Should non-key personnel become key personnel at a later time, this change is substantive and must be submitted as an amendment for IRB review and approval. Please refer to the Education page on our website for CITI requirements. For definitions of study personnel roles, please refer either to our glossary or the University’s Education Policy for Conducting Human Subjects Research.

IV. Investigator Responsibility

1. Investigators making minor changes not requiring review to consent/assent documents for non-exempt studies must submit these documents to the HRPP office for stamping of approval. Two copies must be submitted: one copy using track changes or otherwise highlighting the changes, another copy that is clean (no highlighting/track changes) that will be stamped with approval.

2. Investigators making any change to a non-exempt study that is not covered in this document must submit the change to the IRB as an amendment.

3. Investigators making any change to an exempt study that is not covered in this document must submit a new exemption request to the IRB for review and exempt determination.

1 Consent/assent documents for all non-exempt research must be submitted to the Human Research Protection Program office to be stamped with approval. When submitting these documents for stamping, submit two copies: one copy using track changes or otherwise highlighting the changes, another copy that is clean (no highlighting/track changes) that will be stamped with approval.
V. IRB/HRPP Responsibility

1. HRPP support staff is responsible for verifying changes made to consent/assent documents are minor and do not require review. After verification the documents will be stamped with approval and provided to the investigator.

VI. Applicable Regulations and Guidelines

45 CFR 46.103(b)(4)(iii); 45 CFR 46.110(b)(2)
21 CFR 56.108(a)(3)and(4); 21 CFR 56.110(b)(2)
FDA Information Sheet “Recruiting Study Subjects” (1998)

VII. Related Documents

Researcher Responsibilities
Changes to Previously Approved Research