

Changes Not Requiring Review

I. Summary

The Institutional Review Board (IRB) must prospectively review and approve changes to previously approved research except when necessary to eliminate apparent immediate hazards to the subject. 45 CFR 46.103(b) (4). However, some specific changes have been determined to present no increased risk or burden to subjects, nor decreased benefits to them. These changes have been listed below and do not require IRB review and approval prior to implementation. However, updated forms must be provided to the IRB for completeness of the IRB study file.

II. Guidelines and Procedures

Study Procedures

1. Rescheduling of a data collection when a subject misses an appointment or data collection is incomplete due to unforeseen circumstances that do not increase risk to the subject (e.g., equipment failure resulting in data collection cancellation, etc.). However, such deviations from the protocol must be reported at continuing review.
2. 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. Example: A study that requires consecutive blood collection via finger stick at 30 minute intervals over 3 hours, but unforeseen circumstances interrupts the specimen collection an hour into the 3-hour session. The 3-hour session may be rescheduled even though it results 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, heel 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, or decrease the validity of the study.

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

Recruitment Materials

1. 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.
2. 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.
3. Minor editorial changes (e.g., corrections of grammar/language to increase participant understanding).
4. 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

1. Minor editorial changes (e.g., corrections of grammar/language to increase participant understanding).
2. 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.
3. Changes noting removal of a study instrument and resulting change of duration of participation.

Other

1. 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 section on the HRPP website for CITI requirements.

III. Investigator Responsibility

4. **Consent Forms:** Investigators making minor changes not requiring review to consent/assent documents for non-exempt studies must submit these documents to the HRPP office to secure the IRB approval indication on the documents.
5. **Non-Exempt Studies:** 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.
6. **Exempt Studies:** Investigators making any change to an exempt study that is not covered in this document must submit a request to amend the exempt study submission, to ensure that the regulatory status of the activity has not been altered by the change in the activity.

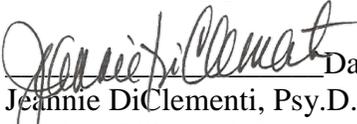
IV. IRB/HRPP Responsibility

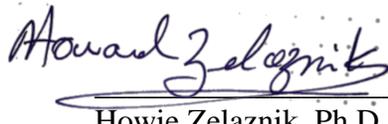
HRPP support staff is responsible for verifying changes made to consent/assent documents do not require IRB review and approval. After verification the documents will be made available to the investigator with the IRB information on the document.

V. 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)

Internal Approval Signatures

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