APPROVED – 03/26/2020

Amending an Approved IRB Study

Amending Exempt Research

If a proposal has been determined to be "Exempt" by the IRB, minor modifications to exempt research may be done at the discretion of the Principal Investigator without prior IRB approval. These changes have been determined to be minor changes that do not result in increased risk or burden to participants, and which are unlikely to reduce benefits. For a list of minimal changes that do not need to be submitted to the IRB for review and approval, see below. All other changes will require IRB approval before being implemented. A PI must notify azorsp@midwestern.edu (in writing) of the minor change made.

Amending Expedited Research

All proposed changes to research which has been deemed "Expedited" must be submitted for IRB review and approval prior to initiating the change. Minor changes (which are those listed below) will be reviewed in an expedited fashion by a single reviewer.

Amending Research Which Required Full Committee Review

All proposed changes to research which has undergone full IRB review must be submitted for IRB review and approval prior to initiating the change. Minor changes (see list below) to proposals which initially required full review may be reviewed in an expedited fashion by a single reviewer.

Minor Changes Not Requiring Review (Exempt Studies) or Which May Receive Expedited Approval (Other Studies)

1. Changes to Recruitment Materials

a. Changes within the approved recruitment material medium (e.g., changes from flyer to newspaper advertisement, since they are both in print). If changes are made to a different medium (e.g., from print medium such as a flyer to internet recruiting) 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 (PI or key personnel) is added to the study. Addition of a new PI or key personnel member is considered a substantive change to the study, which must be submitted to the IRB for review and approval.

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

d. Updating dates and times related to when research activities will occur (so long as such dates/times and number of data collection activities occur within the approved protocol period).

e. The addition of online recruitment sites which fall within the initial site agreement (e.g., adding new Facebook groups as recruitment sites).

2. Changes to Consent or Assent Documents

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

b. Changes in contact information except where a new investigator (PI or key personnel) is added to the study. Addition of a new PI or key personnel is considered a substantive change to the study, which 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.

3. Changes in Scheduling:

a. Rescheduling data collection when a participant misses an appointment, or when data collection is incomplete due to circumstances that do not increase risk to participants (e.g., power failure results in equipment not functioning, etc.).

b. Rescheduling of certain specimen collections (identified below) of adult participants who miss an appointment. Rescheduling if specimen collection is incomplete due to unforeseen circumstances, so long as this does not increase risks to participants. If specimen collection has to be rescheduled, it is possible that the total amount of specimen collected would be greater than that originally approved. For example, a study might requires consecutive blood collection every 60 minute for 4 hours, but unforeseen circumstances interrupt the collection at the 3rd hour, the total session would need to be rescheduled resulting in an increase of the total amount of specimen collected.

Specimens in this category are:

- collection of blood via finger, heel or ear stick;
- hair and nail clippings that do not cause disfigurement;
- excreta and external secretions (including sweat);
- saliva, either unstimulated, or stimulated (chewing gum or wax, or application of dilute citric solution to the tongue);
- mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
- sputum collected through expectoration.

c. Removal of study instrument(s) provided that it does not reduce any previous 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, removal of that instrument from the study is substantive in nature and must be submitted to the IRB for review and approval.

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