

<b>Title</b>	<b>Guidance for Amending a Study</b>
<b>Related SOP</b>	404.002 - Ongoing Review Activities
<b>Effective Date</b>	07-November-2016

### Amending a Study

Any changes to approved research must be reviewed and approved by HREBA before the changes become effective, except in situations where an immediate risk needs to be eliminated.

#### Amending (modifying) your electronic study

HREBA uses an electronic platform, IRISS, to receive and process all **new** submissions for ethics review; this program uses the term 'modification' to refer to an amendment. Studies that were initially submitted using IRISS will have modifications submitted and reviewed through this system. Step by step instructions on [how to modify a study](#) using IRISS are available on the HREBA [IRISS resource page](#). It is important to note that the IRISS application **MUST** also be updated to reflect changes in the protocol and informed consent form (ICF); failure to do so may result in delay in the review of the modification.

#### Amending your paper study

Ethics applications which were originally approved in hard copy by HREBA will continue to be managed in this manner; all ongoing activities for these studies must be reported to HREBA in hard copy along with the [amendment form](#) summarizing the purpose of the submission and the relevant revised documents, if appropriate.

#### Amendments/modifications for full board or delegated review

Amendments to the protocol (including consent form changes) that present greater than minimal risk to the participants are to be reviewed at a convened full committee meeting. It is at the **Chairs or Associate Chairs discretion** as to whether an amendment should be reviewed by the full committee or sent for delegated review. If an amendment is processed by delegated review and the reviewer does not agree with the proposed change(s), the amendment is put forward for review at a future full committee meeting.

**Examples of amendments/modifications that may be eligible for delegated review include:**

- A minor increase or decrease in the number of participants;
- Narrowing of the inclusion criteria to enhance safety;
- Broadening the exclusion criteria to enhance safety;
- Changes to the dosage form (i.e., tablet to capsule or oral liquid) of an administered drug, when the dose and route of administration remain constant;
- Decreasing the number of biological sample collections, provided that such a change does not affect the collection of information related to safety evaluations or data integrity;
- An increase in the number of study visits for the purpose of increased safety monitoring;
- A decrease in the number of study visits, provided the decrease does not affect the collection of information related to safety evaluations or data integrity;
- Changes to documents including Informed Consent Forms that improve the clarity of statements or to correct typographical errors, provided that such changes do not alter the content or the intent of the statements;
- Reportable events, including adverse events and safety updates such as reports from Data Safety Monitoring Committees (DSMC/DSMB) and protocol deviations

The Chair or designee may also use expedited review procedures for review of modifications/amendments when one of the following conditions is met:

- a. The research is permanently closed to enrollment of new subjects, all research-related interventions have been completed and the study remains open only for post-treatment or long-term follow up (e.g. survival status); or
- b. No subjects have been enrolled and no additional risks have been identified; or,
- c. The remaining research activities are related to data analysis.

**If the proposed change represents more than minimal risk, it may be reviewed by the Committee at a convened Full Committee meeting.**

Examples include:

- emergency amendments that arise because of participant safety concerns that are submitted after implementation;
- addition of genetic testing, new genetic tests, or tissue banking where genetic testing may, or will be performed;
- addition of an open label extension phase following a randomized trial;
- changes to the informed consent form(s) that may reasonably be considered to negatively affect participants risk-benefit ratio in the research study and the participants willingness to continue in the study;
- a change in drug dosing/duration of exposure, chemistry and/or manufacturing information of the investigational product;
- a change in recruitment that may affect confidentiality or the perception of coercion;
- a change in experimental procedure or research population;
- a change that affects the selection, monitoring, or withdrawal of participants;
- a change that affects the evaluation of the clinical efficacy and/or safety aspects of the investigational product.

<b>SOP Code</b>	<b>Effective Date</b>	<b>Summary of Changes</b>
SOP404.001G	01-July-2016	Original version
SOP404.002GA	01-July-2016	Version 2 - updated hyperlinks
	07-Nov-2016	Updated hyperlink to online form