

MEMORANDUM

To: HREBA.CC, HREBA.CTC, and HREBA.CHC Study Teams
From: Jacqueline Senych, HREBA Director
Date: 7 September 2021
Subject: Required changes to the Modification Application

In November 2018, it was decided that HREBA would only require changes to the modification application if expected recruitment numbers were changed, as this number was automatically put onto the study annual renewal. Any other changes (or lack of changes) were at the discretion of the study team.

However, subsequent to this change, both HREBA administrators and study teams have experienced several issues, including the following:

- Data not being released by AHS when data identifiers have changed, but were not updated in the IRISS application;
- study team members not having access to the application; and
- site contact information incorrect after study site move.

That being the case, we have updated our procedures to ensure the study team will edit the application, when completing a modification, should there be any changes from the time of its initial approval. At minimum, the changes noted in the table below are required:

Update IRISS Application Page	If Modification Made to:
Study Identification Page	<ul style="list-style-type: none"> - Change to Study Title - Change to PI/Co-I (or change to study team members if made as part of a larger modification)
Impact and Operational Approvals Page (always) Recruit Potential Participants Page (only if participants are still being recruited)	<ul style="list-style-type: none"> - Change to study site location
Participant Information Page	Change to number of participants being recruited or change to inclusion or exclusion criteria
Data Identifier Page (Required by AHS for data management; release of information)	<ul style="list-style-type: none"> - Change to collection of/access to personal health information or health identifiers

Documentation Page	<ul style="list-style-type: none">- Adding new or updated documents (require: New Document – Clean version only Updated Document – Clean and Track Changes version) - NOTE: when a Study Protocol has been revised, please upload a clean version, plus a separate Summary of Changes or tracked changes version.
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This change will be effective: October 1, 2021.

If you have any questions, please contact the appropriate Ethics Coordinator:

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Thank you!



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