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Amendments

When you need to make a change to an approved study, you must submit an amendment to the IRB for approval. There are two types of amendments:

1. **Full Board Amendment:** The IRB will review any proposed changes in IRB-approved research, including proposed changes in informed consent documents, at convened meetings at which a majority of the IRB members are present. Full Board Review of amendments is required for the following:
   a. Scientific changes
   b. Eligibility changes
   c. Informed Consent changes
   d. Changes in risk and/or risk assessment
   e. Changes in study design
   f. Any change that results in “greater than minimal” risk

2. **Expedited Review Amendment:** Proposed changes to an IRB-approved study may be reviewed through an expedited procedure if the proposed modification constitutes a minor change in previously approved research during the period for which approval is authorized or the research is not greater than minimal risk and falls within the DHHS-FDA list of research eligible for expedited IRB review. Expedited Review of amendments is allowed for the following:
   a. Editorial and/or administrative changes
   b. Change in study staff/personnel

When making changes in eRIC, the approved study application is the working document and all required changes must be made in the “Modified Study”, which is a copy of the approved study.

The image below is an example of the Amendment workspace:
When the IRB approves the amendment, the Modified Study becomes the approved version of the study. All previously approved versions of the study are stored in the system for recordkeeping and audit purposes in the History folder.

Creating and Submitting a New Amendment

PLEASE NOTE: The eRIC system ONLY allows ONE amendment to be in process at a time. All amendments must be approved, disapproved, or withdrawn before a new amendment is created.

The table below outlines the essential steps for creating a new amendment, editing the modified study, and submitting the amendment to the IRB:
In the approved study's workspace, click the New Amendment button to start the application for a new amendment.

After selecting New Amendment, an Amendment information page is displayed. Click Continue to proceed to the next section.
Please select the type of amendment(s). Once you have done so, you will be asked to answer additional questions pertaining to the specific type of amendment(s) that you have indicated in the form.

By clicking on the “SmartForm” link, you will have the option to make any changes or updates to the study.
NOTE: There are two separate parts to an amendment submission:

1. “Amendment” which is equivalent to an amendment cover letter. It will only ask you what you are changing and why you are changing it.

2. “Modified Study”. This is the protocol that is being modified with the current amendment. Actual revisions to the approved protocol are made here.
Prior to submission of the amendment application, you may also make any changes or updates to the study from the Amendment workspace. Click the Edit Modified Study button in the Amendment workspace to open the study smartforms. Note: this is a copy of the approved study that can be used to make your changes. Make all the changes you detailed in the amendment application. To view changes to the study application, please click on the View Changes button.
When you have finished making changes/updates to the study application AND have filled out the amendment application form, click on the Submit Amendment button to submit your amendment application to the IRB.

Please note: an amendment submission must be made through the amendment workspace, and not the modified study workspace.

Complete the “Submit Amendment” form.

Once you click “Ok” you will no longer be able to modify the amendment application. This activity forwards the submission to the IRB for review.
If submitted successfully, the Current State will change to IRB Staff Review, a “Submit” entry in the history will appear, and the submission will disappear from each study team member’s Inbox.
If an amendment is still in the process of IRB review, submission of additional amendments is not allowed. The eRIC system allows only ONE amendment to be in process at a time.

However, submission of continuing reviews and reportable event reports may be submitted while an amendment is still in the process of IRB review.

Amendments submitted by the study team can be located under the Amendments tab in the main study workspace.
The image below shows an approved amendment:

Withdrawing an Amendment after Submission for IRB Review

In some circumstances, it may be necessary for the study team to withdraw an amendment submission. The chart below describes this process.

The withdrawal of an amendment can occur after it is submitted to the IRB for review.
A reasoning for withdrawing the submission is required. An example explanation is shown here. Click Ok to submit the withdrawal activity.

After being withdrawn, the amendment is unable to be edited any further. The current state will reflect the action of “Withdrawn”, and an entry will be shown in the history of the amendment.