GUIDANCE: Modifications to Human Subjects Studies Determined Exempt under 45 CFR 46 by the IRB

This information for the Icahn School of Medicine at Mount Sinai (ISMMS) research community explains which types of modifications require IRB review after a study has been previously determined to meet one of the Exemption criteria under the Federal Regulations.

How do I know if my study was determined to be Exempt?

An exempt determination means that your study presents no greater than minimal risk to subjects and fits into one or more regulatory-defined exempt categories. If your study is determined exempt, the category/categories will be indicated in your approval letter and/or in your completed HRP-503E Exempt Determination Application.

Do I need to submit a modification for my Exempt study?

Unlike research approved at the expedited or full board level, modification submissions are not always required for exempt studies. Typically, minor changes to an exempt study do not require IRB review if the changes do not affect the Exempt category determination. However, significant changes to the study may require IRB review, for example: if the risk level is impacted, the determined exempt category may no longer apply, or an additional/different category may apply.

I'm not sure if my modification requires a formal IRB submission – what should I do?

Several examples of modifications that would or would not require a formal IRB submission are provided below, but it is impossible to provide every example. If your proposed change(s) does/do not clearly fit into one of these examples, please email your IRB analyst or the IRB inbox (IRB@mssm.edu) with a brief description and the PPHS staff will review your information and let you know if a modification submission is or is not required.

Examples of modifications that DO require a modification submission:

- Adding an intervention to the study methodology or substantially changing the study procedures or aims;
- Adding a vulnerable population to your inclusion criteria (i.e. children, incapacitated adults, prisoners);
- Adding a new funding source;
- Adding sensitive information to data collection (such as information related to illicit drug use, mental health, reproductive health, etc.);

- Adding collection of HIPAA identifiers when previously anonymous;
- Changing the Principal Investigator (PI);
- Updating study team member information.

Examples of modifications that DO NOT require a modification submission:

- Adding non-sensitive questions or other minor changes to survey materials or interview guides (for example, adding basic demographic questions without identifiers, changing the way a question is asked, removing questions, formatting changes). Note that we may need to review this type of modification if the amount of changes to be made are substantial. Contact the PPHS analyst or email IRB@mssm.edu to confirm if we would consider your changes substantial.
- Editorial/grammatical updates to any study materials;
- Increasing or decreasing the number of subjects;
- Updating the study timeline.

What do I do if I have a study that was determined exempt prior to the RUTH IRB system that requires modification?

Exempt studies were not migrated when the IRB submission system switched to RUTH. If you need to modify your exempt study, it must be submitted as a new application in RUTH with the following:

- Complete the HRP-503E Exempt Application
- In the “Brief Description” field in RUTH, add a line stating that this study was given an Exempt determination prior to RUTH and reference the original study number
- Provide a copy of the Exempt determination letter from the IRB
- Provide copies of all previously approved study documents
- Attach a memo detailing the changes requested since the original Exempt determination
- Please refer to the HRP-450 RUTH Initial Submission Checklist for other general submission requirements