



Human Research Protection Program

Center for Creative Education

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Guidance for When to Submit an FYI xForm

The FYI xForm in IRB Manager is a convenient way to formally submit information about your study to the HRPP office and the IRBs. However, it is important to note when an FYI is appropriate and when it is not.

FYI submissions receive an “acknowledgement” from HRPP staff or an IRB chair (depending on the nature of the FYI), but they do not receive IRB “approval.” Therefore, you may use the FYI xForm to inform us about important *information* we should know, but you may not use it to inform us about *changes* to your research methodology or IRB-approved documents.

Examples of appropriate use of the FYI xForm:

- A change in your study sponsor’s contact information
- You are temporarily pausing enrollment, or resuming enrollment
- Your study’s funding status has changed
- Communication from the sponsor that does not change methods, inclusion criteria, etc.
- Safety updates (such as DSMB reports) that you wish to submit in a timely fashion (rather than with a continuing review submission)
- When directed by the HRPP office

Examples of when to use the Amendment xForm instead:

- Any changes/new submissions of:
 - Protocol documents
 - Informed consent documents
 - Recruitment materials

- Data collection tools
- Any other document needing IRB approval
- Changes to inclusion/exclusion criteria
- Changes to maximum enrollment number
- Sponsor “clarification memos” that indicate a change from the current approved xForm and protocol document
- Any changes to methods or documents not stated above

Even “minor” changes to study methods or documents need to be submitted as an amendment. This is the only way to ensure proper IRB review of the changes and ensure that your reference xForm in IRB Manager is up to date.

If you have something to submit for your study and you aren’t sure which form to use, please contact an [HRPP staff member](#) for assistance.