

Human Research Protection Program
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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

- 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.