IRBNet Instructions for Central Michigan University

www.irbnet.org

XI. How do you submit requests for changes to the protocol, annual updates or adverse events once the study has already been approved?

1. Go into IRBNet and select your study.
2. Click on "Project History"
3. In Step 1, make sure to choose your IRB Committee (1 if you are from Health Professions or Humanities, Social, and Behavioral Sciences, 2 if from any other department)
4. You can choose a form to download from “Select a Document” or you can create your own Word document, depending on the request from the committee
5. Click on “Add New Document” to upload your changes, clarifications, additions, etc.
6. Click on "Create New Package" Note that a second package is created. The Study History indicates all packages in the study lifecycle
7. Here you will see documents from the previously submitted package are referenced. At this point, you can choose to add a new document, by clicking on “Add new Document” (though you may have already done this). You can also save some time and simply update an older document. To do this, download the previous version to your computer, modify as required and save. Click on the pencil (update) icon. You will notice that the updated document no longer shows in the list of documents. This is okay.
8. When the materials for your request are complete, click on “submit this package.”
9. You will not be required to obtain electronic signatures again for this step.

Pick a “submission type’ that best fits what you are sending. For example:

1. Adverse Event – when reporting an adverse event (such as unexpected injury)
2. Continuing Review/Renewal – when submitting a “Request for Annual Continuation”
3. Modification/Amendment – when submitting a “Request for Change in Protocol”
4. Reportable Event (Non-AE) – when reporting events that were unexpected such as participant complaints, information that would affect consent, risks, etc.
5. Other – to submit any other documentation

- **Change in Protocol:** Any amendment to your previously approved study should be documented on the “Request for Change in Protocol” form, with clear explanations of and rationale for the proposed changes. In addition to the completed form, you should also submit any documents that have been updated or changed, such as consent/assent forms, copies of revised or additional data collection materials, recruitment materials, etc.
- **Annual Update (Continuation Request):** Requests for approval to continue your study for another year must be submitted via the “Request for Annual Continuation” form.

- **Adverse Event/Unanticipated Problem:** Unanticipated problems (including adverse events) must be submitted via the "Adverse Event Form". On this form, clearly describe the event and all measures that were used to correct it.
- **Reportable Event (Non-Adverse Event)** – when reporting events that were unexpected such as participant complaints, information that would affect consent, risks, etc.

You will get an e-mail notification once action had been taken on the submission.