MedStar Health

It's how we treat people.

May 13, 2025

How to Submit a Study Closure

MedStar Health Research Institute

Before submitting the study closure…

Please consider the status of publications/presentations. Sometimes, editors or conference organizers may request additional information requiring new data analysis. In this case, active IRB approval is required as data analysis is a research activity. To avoid additional submissions to the IRB, it is recommended that the IRB application remain open and active until all anticipated publications and presentations have been accepted.

Who can submit study closures?

- Only the PI and PI proxies
  - Any approved team member may <u>create</u> and edit study closures in pre-submission state but **cannot submit**.
  - Study team members, other than the PI, must be assigned as proxies to submit.

MedStar Health

- **When you log into the system, you will be brought to your inbox. Select the IRB tab to find your study.**

- **Select the Active tab to show your currently approved studies. Then use the search box to find the study you would like to close.**

- **This is a study home page. Select Create Modification/CR to begin the study closure application.**

- **Select Continuing Review.**

- **Complete items #1-4.**
  - **Use the question mark icon to get more information about each item.**
- **Review item #4. If the first four research milestones are selected, then the study closure acknowledgement will appear (item #5).**

Modification /
Continuing Review

Continuing Review / Study Closure Information

Continuing Review / Study Closure Information

1. *** Specify enrollment totals at this investigator's sites:** ❓

   `21`

2. *** Specify enrollment totals at this investigator's sites since last approval:**

   `0`

3. *** Specify enrollment totals study-wide:** ❓

   `54`

4. **Research milestones:** (select all that apply) ❓
   - ☑ Study is permanently closed to enrollment OR was never open for enrollment
   - ☑ All subjects have completed all study-related interventions OR not applicable (e.g. study did not include interventions, no subjects were enrolled)
   - ☑ Collection of private identifiable information is complete OR not applicable (no subjects were enrolled)
   - ☑ Analysis of private identifiable information is complete OR not applicable (no subjects were enrolled)
   - ☐ Remaining study activities are limited to data analysis
   - ☐ Study remains active only for long-term follow-up of subjects

   ℹ **Important!** If the first four research milestones above are complete, the study will be closed to discontinue IRB oversight.

5. *** I acknowledge that this study will be closed:** ☑

MedStar Health

MedStar Health Research Institute

- **Complete items #6-8.**
- **Attach the <u>required</u> Progress Summary document in item #8. This template can be found in the ORI website. If applicable, please attach other documents such as multi-center trial reports, DMC reports, SAE reports, IND annual reports, and protocol deviation logs.**

Modification / Continuing Review

Continuing Review / Study Closure Information

6. **Do any investigators or research staff have a financial interest related to the research that was not described in a previous application?** ❓
○ Yes ● No Clear

7. **Check the items that are true since the last IRB approval for all sites involved in the study:** (initial review or last continuing review)
- ☑ NO subjects experienced unexpected harm
- ☑ Anticipated adverse events have NOT taken place with greater frequency or severity than expected
- ☑ NO subjects withdrew from the study
- ☑ NO unanticipated problems involving risks to subjects or others
- ☑ NO complaints about the study
- ☑ NO publications in the literature relevant to risks or potential benefits
- ☑ NO interim findings
- ☑ NO multi-center trial reports
- ☑ NO data safety monitoring reports
- ☑ NO regulatory actions that could affect safety and risk assessments
- ☑ NO other relevant information regarding this study, especially information about risks
- ☑ In the opinion of the PI, the risks and potential benefits are unchanged
- ☑ All modifications to the protocol have been submitted to the IRB
- ☑ All problems that require prompt reporting to the IRB have been submitted

8. **Attach supporting documents:** (include an explanation of each item left unchecked above) ❓

[+ Add]

Name
📄 Progress Summary for Continuing Review or Closure Template.docx(0.01) ⋯

[⊗ Exit] [🖫 Save] [**Continue** →]

MedStar Health Research Institute

- **On the final page of the study closure, click Finish.**
- **This will send you to the study homepage.**
- **This does not submit the study closure.**

Modification /
Continuing Review

Continuing Review /
Study Closure
Information

Editing: CR00004438

◀ Go to forms menu   🖶 Print ▾   ❓ Help

Final Page ❓

You have reached the end of the IRB submission form. Read the next steps carefully:

1. Click **Finish** to exit the form.

2. **Important!** To send the submission for review, click **Submit** on the next page.

Note! Clicking "Finish" does not submit the study closure.

❌ Exit   💾 Save   Finish

MedStar Health

MedStar Health Research Institute

- **After clicking Finish, you will be returned to the study closure home page.**
- **Once on the home page, click Submit to submit the study closure.**
- **Only the PI or the PI proxies can submit.**
  - **If you are not the PI or PI Proxy, you will not see the Submit option.**

MedStar Health Research Institute

- **After clicking Submit, the status in the orange box should indicate "Pre-Review".**

Congratulations! You have successfully submitted to the MHRI IRB.

It's how we treat people.

MedStar Health