Ascension Wisconsin IRB Guidance

Huron eIRB - Local Guidance for Completing Study SmartForm

This Guidance includes Ascension Wisconsin specific guidance for study teams who are completing the eIRB SmartForms for initial review or follow-on reports (e.g Modifications, Continuing Reviews, Reportable New Information (RNI) reports).

See the IRB website for additional information on the eIRB - including user manuals, tip sheets, videos, and training.

This document is not complete and is being updated regularly. Contact the IRB Office or RI&P staff with additional questions and/or suggestions.

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Main Study SmartForm

Each study requires completion of a study SmartForm. The SmartForm includes branching, and sections or individual questions will display (or be hidden), depending on responses entered. All SmartForm sections and questions will be included below; in the eIRB system, not all sections will be visible based on the protocol.

Research Resources Page

Not all protocols require this section of the SmartForm to be completed. This section displays only when the study is marked as being interventional in nature (e.g. drug or device trial; comparative effectiveness trial; etc.) in a previous section.

The Research Resources section of the study SmartForm provides the IRB information to assess whether there are adequate resources to ensure that the study is conducted and overseen in a way that ensures protection of subjects as well as overall integrity.

Question 1

> * **1. How many actively accruing research studies does the PI listed for this study have open?**
>   (including studies reviewed by IRBs other than your Ascension Ministry Market IRB)?
>
> [   ]

➔ This is a required question.
➔ The number should include all studies that the PI has open that are currently open to enrollment.

➔ Clinical Research Department: You can identify studies open for each PI, including the study status, in the CTMS. The study status in the CTMS should be kept up-to-date. To find this list, you can use the CTMS to search all studies that are status "Enrollment Allowed" for a PI.

Question 2

> * 2. **How many study participants are currently receiving study intervention for studies on which you are the PI** (including studies reviewed by IRBs other than the Ascension IRB)?

➔ This is a required question.
➔ The number should include the number of subjects who are actively receiving a study specific intervention; this is a total from all studies for this PI.

Question 3

> * 3. **How many research staff are supporting the PI in conducting the studies identified above?** (research nurses/coordinators, data analysts, other)

➔ This question is NOT required.
➔ This question should be left blank; the Ascension Wisconsin IRB will not require this information.

Question 4

> * 4. **Describe the average amount of time per month that you, as the PI, will devote to conducting and completing the research** (your response should be in the form of hours/month):

➔ This is a required question.
➔ The Ascension Wisconsin IRB does not require the hours/month format. While a text response is acceptable, it should provide some quantitative rationale. The description may need to vary for different studies to be sure to provide accurate information.
➔ An example for a clinical trial of an investigational drug/device may be: Through the study start-up and feasibility process, the PI has budgeted adequate time (approximately 30 minutes per subject visit) which will vary throughout the course of the study based on the number of subjects and visits. This time is allocated to complete consent, conduct of activities, and general study oversight.

Continuing Review SmartForm

For studies that require continuing review, the PI must submit a Continuing Review for IRB review to ensure there is no lapse in IRB approval. Be sure to plan accordingly to allow sufficient time for the board to complete the review; if the expiration date for the study approaches and the review is not complete the study will lapse and all research-related activities must cease, including data, until approval is reinstated.

You can create and submit a Continuing Review (CR) <u>OR</u> a combined Modification/Continuing Review (MOD/CR) if there are also changes to make to the IRB approved protocol.

First CR in eIRB System - Requirement for a CR/MOD to Populate SmartForm Questions
At the time of the first CR in the new eIRB system, some studies will require a MOD/CR to be submitted. This is required for system functionality and to facilitate the IRB review and is based on the study status (open to enrollment, etc). See the <u>eIRB Guidance for Populating the SmartForm</u> for more details.

If the study team submits a standalone CR report when a CR/MOD is required the IRB office will return it with Clarifications Requested and instructions to **Discard** the CR and re-create the CR/MOD combination report.
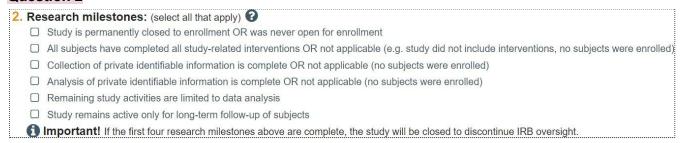
Continuing Review SmartForm Questions
Questions 1-4 provide the current study information since the initial/previous Continuing Review. These include the enrollment count, study status, and any other information that the board should be made aware of. Here are a few tips:

Question 1

1. * Specify enrollment totals:			
Subjects Enrolled	Total		Since Last Approval
At this investigator's sites:	❓		
Study-wide:	❓		

➔ Enrollment total(s) must include any participant that signed a consent form; the IRB considers this enrolled. The subsequent status of the subject (i.e. screen failure, withdrawal, etc) does not affect their enrollment status.
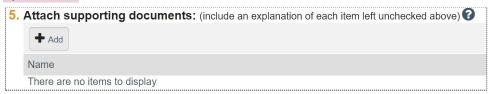
Question 2

2. **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.

➔ Pay attention to the "OR" statements and read each option carefully.
➔ **If you Select the first 4 milestones- the study will be closed automatically.** If the study is complete, BUT the site does not have confirmation from the sponsor to close it with the IRB, <u>DO NOT</u> select all 4 of the top milestones. It is best practice to select 3 out of the 4 (typically the first 3), and then select "Remaining study activities are limited to data analysis."

Question 4

> **4. 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

➔ Read each option carefully. <u>If an item is NOT selected</u>, the Help Text for Question 5 (shown below) instructs the study team to upload an explanation.

➔ For the last two checkboxes:
  - ◆ <u>Check the box</u> if there have been MODs or RNIs since the last review and all have been reported.
  - ◆ <u>Check the box</u> if there have been no MODs or RNIs since the last review (and therefore none outstanding that need to be reported)
  - ◆ <u>Leave the box unchecked</u> if there are items that the site is aware of that require reporting to the IRB but have not yet been reported; this option requires an explanation uploaded in #5.

Question 5

> **5. Attach supporting documents:** (include an explanation of each item left unchecked above) ❓
>
> ➕ Add
>
> | Name |
> | --- |
> | There are no items to display |

➔ The PI/Study team must upload the following (if applicable):
  - ◆ Adverse Event and Protocol Deviation Logs
  - ◆ Publications or interim analysis
  - ◆ Relevant post-approval reports (e.g., Data and Safety Monitoring, audit reports)
  - ◆ Redacted consent forms used for vulnerable populations, if applicable
  - ◆ Any other materials provided by the investigator
  - ◆ Explanations relating to the unchecked items in Question 4

<u>NOTE</u>: eIRB only allows Word and/or PDF documents as uploads.

Other Resources
- ● eIRB Resources page Includes references and training for the Huron eIRB.