|  | **Ascension Wisconsin Research Institute**  **Institutional Review Board (IRB)** |
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| **HRP-510** | **Local Site Supplement and Checklist for Continuing Reviews (except HUDs)** |

**INSTRUCTIONS**

* Complete this form for **all Continuing Reviews (except HUDs)** where the WI IRB will serve as the IRB of record to provide additional local details to support the WI IRB review.
* **This form must be uploaded in Continuing Review report under “Supporting Documents**.”
* **Provide only site-specific information here**, unless otherwise specified.
* **Keep an electronic copy of this supplement.** You will need to revise this copy when submitting subsequent Continuing Reviews for IRB review. When you make changes, use the Track Changes.
* **DO NOT SUBMIT MORE THAN ONE SUBMISSION AT A TIME IN THE eIRB.** System functionality will allow you to enter the information, but not correct processing. If you enter more than one submission at a time, you will need to discard them and begin again.
  + If you have any revisions, submit this as a combined Continuing Review/Modification report.
  + If there are any reportable events meeting immediate reporting requirements but not previously reported, submit a separate Reportable New Information report. ([IRB SOP-204](https://ascensionwisconsinresearchinstitute.org/-/media/Project/SXA---WI/AWRI/Files/RIP/IRB-SOPs/IRB-SOP-204-Reportable-Events-New-Information_v03_11-8-18.pdf?la=en&hash=C750EF083FEE31D9812C021F38CC5FB676E980C0), [Guidance](https://ascensionwisconsinresearchinstitute.org/-/media/Project/SXA---WI/AWRI/Files/RIP/IRB-Guidance/IRB-Guidance_Reportable-Events_12-21-17.pdf?la=en&hash=847031E00D2ED9DAAC83139000972AC7B4D73BDB))

**COMPLETE FL REVIEW**

| **COMPLETE FOR ALL SUBMISSIONS** | | | |
| --- | --- | --- | --- |
| **IRB Number** | Enter text | **Version Date** | Enter text |
| **PI** | Enter text | | |
| **Short Title** | Enter text | | |

1. **Enrollment and research milestones details**
   1. **What is the enrollment goal?**

Local site:

Study-wide, if multisite:

* 1. **Has recruitment and enrollment proceeded as anticipated?**Enter text
  2. **What is the Current Enrollment status?**

☐ Closed to enrollment (including record review where no new charts will be accessed)

☐ Open to enrollment (including record reviews that are identifying new subject charts)

***If open to enrollment: upload the current stamped ICF in the CR SmartForm under***

***“Supporting Documents.”*** *(not applicable if a waiver of informed consent was granted)*

1. **Detailed enrollment status for all participants at this site.** At the time of completing this form, provide the enrollment status of each participant:

| **Subject Status** | **Total Number**  **of Subjects** | **From Last Report: Total Number**  **of Subjects** |
| --- | --- | --- |
| Enrolled under a waiver of consent (e.g. chart reviews) to date |  |  |
| Screening failures (provided consent but ineligible) |  |  |
| Currently active/on study |  |  |
| Completed active study & in long-term follow-up only (no research activities) |  |  |
| Who completed study |  |  |
| Who have died |  |  |
| Withdrawn per subject's request |  |  |
| Withdrawn due to adverse events or PI/Sponsor decision |  |  |
| Lost to follow-up |  |  |
| **TOTAL NUMBER OF SUBJECTS**  (who provided consent or were enrolled under a waiver of consent)  ***The total listed here must match the enrollment number in the CR SmartForm.*** |  |  |

1. **Provide a brief summary if any subject(s) withdrew from the study for any reason since the previous review.**

Enter text or N/A

1. **Provide a brief summary (in non-technical language) to remind the IRB of the nature of the project.**

Enter text

1. **Describe any significant preliminary findings and overall study progress since the last IRB review.** Upload any related documents in the CR SmartForm under “Supporting Documents.” Enter text
2. **Informed Consent Summary (mark all that apply):**

☐ No subjects have been enrolled yet.

☐ A waiver of informed consent was granted. Consent documents are not used.

☐ Verbal script or consent letter is used (consent documents not signed by subjects).

☐ The script/letter that was used is identical to what was approved by the IRB.

☐ Written consent form signed by subjects.

☐ Consent was obtained using the correct IRB approved, stamped consent document and the form is on file.

1. **Since the last report, have subjects from any of the following groups been enrolled?** Check all that apply.

☐ N/A- *consent not required/waiver of consent granted*

| ☐ Pregnant Women (subjects/ pregnant partners)  ☐ Children  ☐ Wards of the State  ☐ Employee(s)  ☐ Prisoner | ☐ Non-English speaking persons  ☐ Consent by legally authorized representative (LAR) for cognitively impaired adults  ☐ Anyone who cannot read (blind or illiterate)  ☐ NONE |
| --- | --- |

1. **If any of the above are checked, describe:** Enter Comments
2. **Documentation to Upload with the Submission under “Supporting Documents:”**

☐ This completed form

☐ Pertinent informational materials or newsletters provided by the sponsor

☐ Noncompliance with the protocol, IRB requirements or regulations that were considered minor

☐ Local adverse events that did not meet immediate reporting requirements and were considered minor

☐ Review or audit by an external monitor/ sponsor/agency

☐ New findings (such as interim reports or publications)

☐ Data and Safety Monitoring Board reports

☐ Cases where subjects sought compensation for injury or made complaints about the conduct of the study