

PROTOCOL TITLE:

Meriter Site Supplement INSTRUCTIONS

Use the Meriter Site Supplement when Meriter is one of multiple study sites.

This template will help the Meriter Research Integrity Office understand how your study will be operationalized at Meriter and what parts of the research will happen at Meriter compared to other sites.

- Instructional text should be removed from the template.
- Use regular black font (not italicized).
- Spell out acronyms and abbreviations the first time they are used.
- Use bolded section headings. Some have been provided for you.
 - Delete section headings that are not relevant to your research.
 - Add novel section headings if necessary.
 - Modify section headings to customize this template to your research.
- **This supplement is a standalone document.** It must describe what research activities will be occurring at Meriter, how, where, when and who is responsible for the activities (Meriter employees vs UW research staff).
- Do NOT *haphazardly* copy and paste information from other study materials into the Meriter Site Supplement. A thoughtful response to the prompts is best. Content from other materials may be useful.
- Attach the completed supplement to your electronic Meriter submission. Put a *version number and date* in this document footer that matches the upload screen in the Meriter submission system.

Find Meriter Research Integrity Standard Operating Procedures (SOPs)

They are referenced in the template below.

1. Log into iRIS, the *Meriter* research electronic submission and review system.
2. Click the Help icon in the upper right.
3. SOPs are arranged by number and grouped by topics.

Template Date 9/2026

PROTOCOL TITLE:

MERITER SITE SUPPLEMENT

PROTOCOL TITLE

Type the full protocol title here.

SITE PRINCIPAL INVESTIGATOR

Name:

Department:

Telephone Number:

Email Address:

MERITER PRINCIPAL INVESTIGATOR

If different than the site PI. If site PI is the same as Meriter PI, delete this part.

Name

Department

Telephone Number

Email Address

1.0 Study Summary/Overview

Write a short paragraph that includes the following.

- *Provide the condition being studied and the study purpose.*
- *Identify the general study population and **Meriter clinical unit** (e.g., OR, ICU, NICU, Labor & Delivery, etc.) involved.*
- *Include the anticipated **number of subjects** at **Meriter** compared to other locations and overall study sample size required for the study.*
- *Give an indication of the duration of the study for subjects.*
- *State if this study takes place only in Madison or if it includes institutions from a larger geographical area.*
- *Include a statement about funding.*
 - *Is your research federally funded? State the agency.*
 - *Is your research commercially funded? State the company.*

2.0 Study Procedures

- *Describe procedures that will occur at **Meriter** Hospital or UnityPoint Health clinics in Madison.*
- *Describe if standard of care at **Meriter** will require modification to allow for study procedures.*
- *Describe if **Meriter** employed staff will be helping facilitate or support your research. Explain how they will do this. For example,*
 - *solicit permission from patients to allow research staff to contact them.*
 - *Save forms patients complete for research staf.,*
 - *provide storage space for research specimens, etc.*

3.0 Study Intervention/Investigational Agent

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If applicable.

3.1 *If the research involves drugs or device, describe your plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized study staff.*

- *Describe how the control of the drugs or devices used in this protocol will be accomplished. Will you be using the UW Pharmaceutical Research Center, **Meriter Pharmacy**, or some other method?*

4.0 Data and/or Specimen Management

Complete this section if specimens and/or data are collected at Meriter. If your study is only handling data, delete Specimen in the heading.

4.1 *Describe how and where specimens and/or data are collected. Describe who collects specimens and data and chain of custody. **Meriter Research Integrity Office** is interested in when non-research Meriter staff are involved and when UW research staff are involved.*

4.2 *Describe where the specimens will be stored, how long they will be stored, how the specimens will be accessed, and who will have access to the specimens both for the current research and for future research.*

4.3 *List the data, including HIPAA identifiers to be stored or associated with each specimen banked locally.*

4.4 *Banking Data for data research: Describe where the data will be stored, how long it will be stored, and who will have access to the data both for the current research and for future research.*

4.5 *Describe the procedures to release locally banked data or specimens, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.*

5.0 Study Population

Complete if study population comes from the Meriter patient population.

5.1 *Describe any inclusion or exclusion criteria used for Meriter. Point out if a subset of subjects is recruited at **Meriter**. For example, if the protocol requires neonates to children aged 6 years, but you will only enroll neonates at **Meriter**, indicate that here.*

5.2 ***Special Populations recruited, enrolled, or consented at Meriter:** If the research involves individuals who are vulnerable to coercion or undue influence, include justification and describe additional safeguards included to protect their rights and welfare.*

6.0 Screening and Recruitment Methods

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This section is for screening and recruitment methods you will use at Meriter. If subjects are not recruited at Meriter, state that and skip 6.1 – 6.4.

- 6.1 Describe how recruitment will happen at **Meriter Hospital**. How will Meriter patients be identified as prospective subjects?
- 6.2 Describe how enrollment will happen at **Meriter Hospital**. Who will be the first to approach potential subjects? Where will subjects be recruited? Will a Permission to Contact form be used? Will the study team contact subjects in person, by phone, etc.
- 6.3 Describe materials that will be used to recruit **Meriter** subjects. (Attach copies of these documents with the application.)
- 6.4 Describe the amount and timing of any payments to **Meriter** subjects.

7.0 Consent Process

- *Complete this section if subjects will be consented at Meriter Hospital, Inc. or the Madison area UnityPoint Clinics.*
- *Complete this section if consent occurs because of being a patient or family member of a patient at Meriter Hospital, Inc. or the Madison area UnityPoint Clinics.*
- *If consent only occurs outside of Meriter, state that. Skip 7.1 – 8.0.*

7.1 Indicate whether you will be obtaining consent, and if so describe:

- Where will the consent process at **Meriter** take place?
- Any waiting period available between informing the prospective subject and obtaining the consent.
- Whether you will be following **Meriter SOP 2.8 - Informed Consent**. If not, describe:
 - The role of the individuals listed in the application as being involved in the consent process.
 - The time that will be devoted to the consent discussion.
 - Steps that will be taken to minimize the possibility of coercion or undue influence.
 - Steps that will be taken to ensure the subject's understanding.

Consent for Special Populations

Select only those that apply to your study.

Non-English-Speaking Subjects at Meriter

- Indicate what language(s) other than English are understood by prospective subjects or representatives.
- If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language. Indicate the language that will be used by those obtaining consent.

Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception)

- Review *Meriter SOP 2.8 Informed Consent* - Waiving or Altering All or Some of the Informed Consent to ensure you have provided sufficient information for the IRB to make these determinations.

Subjects who are not yet adults (infants, children, teenagers)

- Describe the criteria that will be used to determine whether a prospective *Meriter* subject has attained the legal age (18 years) for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted.
- Describe your procedure for whether to obtain subject assent and how that will be done. See *Meriter SOP 2.8*.
- Describe how a minor's legally authorized representative will be identified. Reference *Meriter SOP 3.2*

Adults Lacking Capacity to Consent

- Describe the process to determine whether an individual is capable of consent.
- If legally authorized representatives (LAR) will be used, describe how the LAR will be identified. What documentation will you use to support the need for a LAR? Reference *Meriter SOP 3.2 Research on Adults Lacking Capacity to Consent*.

8.0 Process to Document Consent in Writing

Complete only if consent occurs at Meriter or remotely with Meriter patients and/or families.

- 8.1 Describe whether you will be following written documentation of consent. If not, describe whether and how consent of the subject will be documented in writing. Include whether you'll be using a wet ink signature or a digital signature (e.g. DocuSign).
- 8.2 If you are requesting a waiver of documentation of consent, explain how your study meets the regulatory requirements for a waiver of documentation. See *Meriter SOP 2.8*.