Submission Guidance

When UW-Madison Employees Conduct Research at Meriter

UW Health and Meriter have a Joint Operating Agreement. That agreement does not dictate how or where IRB submissions are made. All research involving Meriter employees, Meriter patients and/or records, or requiring access to Meriter space, will require that some information is submitted to both institutions. This guidance will help researchers through those submissions.

Which institution will conduct the IRB review:

For studies where the PI is a UW employee and IRB review is not ceded to an external IRB (commercial IRB, NCI, or other institution), a UW-Madison IRB will conduct the IRB review.

For studies where there is UW involvement, but a Meriter employee is the PI, UW RELIANT and the Meriter Research Compliance Office will collectively choose the best IRB to conduct the review. This will be a rare scenario.

Contact irbreliance@wisc.edu if you have questions about who will conduct the IRB review.

If your project is exempt:

The first step is to determine if your project is exempt. If you believe your project is exempt (use the guidance and exemption tool here), submit an exemption application to the UW-Madison IRB via ARROW using the non-protocol-based application (nPBA). The exemption application should describe how Meriter is involved, including how you will be using Meriter's EMR (link to section below).

Following receipt of an exempt determination from the UW-Madison IRB, submit a streamlined research compliance application to Meriter. The application will prompt you to attach a snapshot of your ARROW application and the UW exempt determination letter.

If your project is NOT exempt:

If your study is not exempt, the next step is to determine if Meriter is engaged in the research. Use this Meriter Engagement Worksheet (link) to make that determination. If you have questions about completing the worksheet, contact the Meriter Research Compliance Office (liz.michaels@unitypoint.org).

If Meriter is NOT engaged in your non-exempt project:

You will start with submitting the appropriate application type in ARROW.
- If your study will be ceded to an external IRB, submit a cede request.

- If a UW Madison IRB will conduct the IRB review, select the appropriate application according to New Study guidance. The ARROW application and/or protocol must accurately describe when and how Meriter is involved.

In both scenarios, you will submit a streamlined research compliance application to the Meriter IRB so Meriter can verify that all its institutional requirements have been met.

Information required for Meriter's research compliance application:

The Meriter streamlined research compliance application allows UW study teams to provide a Snapshot of the approved UW IRB application and/or protocol along with the UW IRB approval or exempt determination letter. These documents replace many of the old, required fields in the Meriter IRB application. Additional information includes checks for the following:
- Physician PI and site investigators are on Meriter's Medical Staff
- UW study coordinators and other research personnel entering Meriter Hospital have completed the Meriter Medical Education Office (MEO) health and safety certification
- Support letter from the Meriter employed unit manager or director where research occurs.
- Permission to use Meriter PACS if applicable
- HIPAA requirements

If Meriter is engaged in your non-exempt project:

You will follow existing workflows as outlined briefly here.

If a UW Madison IRB will conduct the IRB review, submit to UW the appropriate ARROW application for the study with a request to serve as IRB of record for Meriter. After IRB approval is granted, submit a request to Meriter for the Meriter IRB to cede review to UW.

If an external IRB (non-UW and non-Meriter) will conduct the IRB review, submit a request to UW for UW-Madison to cede review. After local consent forms have been finalized, submit a request to Meriter for Meriter to cede review. Submit the UW finalized consent form in the Meriter request to cede review.

Describing Meriter's involvement in ARROW:

Accurately describing Meriter's involvement in your ARROW application and/or protocol is critical to timely approval of your research. This includes describing when Meriter health care records will be used. Failure to do so may result in delays to approval.

For non-protocol Based Applications (nPBAs), you should describe Meriter involvement in the following locations:

- Research Design and Procedures
  - Describe Meriter involvement (including use of records) in the Study Procedures and Interventions question.
- External Collaborations page
  - Indicate in the "Activities at Non-UW Locations" question how Meriter will be involved.
- Subject Identification: Medical Records page
  - If you are using Meriter's EHR to identify subjects, this should be described in this section of the application.
- Review of Health Care Records page
  - If you are using records/data/images from Meriter's EHR, this should be described in the "Data Source" question under other sources.

For Protocol Based Applications (PBA), your protocol should describe how and when Meriter is involved. For example, in HRP-503 – TEMPLATE PROTOCOL – Biomedical, *Section 7.0 Recruitment Methods* should describe how Meriter subjects are recruited, and *Section 10.0 Setting* should describe where research procedures will be performed. Also describe Meriter involvement in the sections above that appear in the PBA.