

Meriter Engagement Worksheet

This document should be used to determine if research involving Meriter engages Meriter in human subjects research. Information in this worksheet is based on [OHRP Guidance](#) and [HRP-311 – WORKSHEET – Engagement Determination](#). Consultation with the Liz Michaels in the Meriter Research Compliance Office may be required to assist with this determination (liz.michaels@unitypoint.org).

If Meriter involvement is limited to the scenarios described in this section, Meriter is NOT ENGAGED and no Meriter consult regarding engagement is needed.

1. Study involves solely use of Meriter records in health care record research that falls under Exemption Category 4
2. Other health care records-only research provided that Meriter employees are not obtaining informed consent from subjects.
3. Study procedures are occurring at Meriter, but no Meriter employees are involved in the conduct of those procedures.
 - a. If you are unsure who is a Meriter employee, consult [this chart](#) or reach out to the Meriter Research Compliance Office.
4. Meriter employees are conducting study procedures, but they are limited to their assigned job duties such as:
 - a. Meriter employee collects extra tubes of blood for research.
 - b. Meriter employee procures biospecimen from a standard of care surgery.
 - c. Meriter employee refers a patient to the study team for recruitment.
 - d. Meriter employee collects a permission to contact form to provide to the study team.
 - e. Meriter employee provides health care data for projects described in 1 or 2 above.

If Meriter is not engaged in your study according to the information above, follow steps under the “If Meriter is NOT engaged in your non-exempt research” section of the submission guidance.

Sections below describe situations when Meriter is engaged or possibly engaged in the research. Consultation with the Liz Michaels at the Meriter Research Compliance office should be made to confirm engagement or assist with that determination (liz.michaels@unitypoint.org).

Situations where Meriter is ENGAGED. Consult with Meriter when needed to confirm.

1. Meriter employees are obtaining informed consent from subjects.
2. Meriter employees are conducting study procedures that are outside their normal scope of practice OR require protocol-specific training.

Situations where Meriter may be engaged. Consult with Meriter for determination.

1. Except as described in the section above at 4, Meriter employees are conducting study procedures described in the protocol.

If after consultation Meriter engagement is confirmed, follow the steps under the “What if Meriter is engaged?” section of the submission guidance.