

Meriter Research Compliance Review Requirements After Initial Determination

Reporting Requirement	Human Subjects Research	Ceded Research (Meriter is Relying on another IRB)	Exempt Research	Meriter is Not Engaged in the Research
Annual Continuing Review/Annual Check-in	Yes	No	No	No
Protocol Changes	Yes	Yes ²	Yes ³	Yes ⁴
Study personnel changes including PI	Yes	Yes ¹	Yes ¹	Yes ¹
Reportable Events	Yes	No ⁵	NA	No ⁵
Study Closure	Yes	Yes	Yes	Yes

1. **Study Personnel Changes** - Submit a *Study Personnel Changes* form with revised study application if study personnel **at UnityPoint Health - Meriter** are changing.
 - a. Study personnel must meet institutional requirements for conducting research on a Meriter clinical unit.
 - b. Personnel accessing Meriter private health information (PHI) must be on record.
2. **Protocol Changes for Ceded Research** – Submit a protocol change for the following.
 - a. You are changing how **UPH-Meriter Private Health Information** (PHI) from Meriter is solicited, stored, transferred, protected, or the timeline for destroying identifiers is altered.
 - b. There are changes to the protocol or study documents affected by state law or intuitional policy (e.g., HIV testing, new HIPAA authorization) **for the part of your study that occurs at UPH-Meriter**.
 - c. There is a revised study protocol with substantive changes impacting **the part of the study that occurs at UPH-Meriter**. For example, new inclusion criteria for subjects recruited at Meriter, additional research procedures at Meriter, or additional Meriter departments are involved.
 - d. **Changes/Additions to Patient Facing Materials**
 - i. Submit **Consent** form changes when the research procedures take place at Meriter or soliciting the signature on the consent occurs at Meriter.
 - ii. Addition or substantive changes to **flyers, posters, educational materials, etc.** that subjects will see as patients of a UnityPoint Health - Meriter facility.
3. **Protocol Changes for Exempt Research** - Submit a protocol change for the following.
 - a. The changes may impact the Exempt status of your study.
 - b. See #2 Protocol Changes for Ceded Research above.
4. **Protocol Changes when Meriter is Not Engaged** – Submit a protocol change for the following.
 - a. Meriter's engagement in your research is changing.
 - b. See #2 Protocol Changes for Ceded Research above.
5. **Reportable Events** – Submit a report for the following.
 - a. The reviewing IRB requires an event be reported to Meriter HRPP (Human Research Protection Program).
 - b. An event occurs of such severity or significance (e.g., serious and/or continuing noncompliance, an unanticipated event that poses substantial risks to subjects or others) that Meriter HRPP will be assisting the reviewing IRB in addressing the event.