Meriter IRB 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 if study personnel ***at Meriter*** are changing. Study personnel must meet institutional requirements for conducting research at Meriter, such as health and safety certification to enter Meriter clinical units.

2. **Protocol Changes for Ceded Research –** Submit a protocol change if:
    a. you are changing how **Meriter Private Health Information** (PHI) from Meriter is solicited, stored and 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 document) **for the part of your study that occurs at Meriter**.
    c. There is a revised study protocol with substantive changes impacting **the part of the study that occurs at Meriter.** For example, new inclusion criteria for subjects recruited at Meriter, additional research procedures at Meriter, or additional Meriter departments are involved.
    d. **Consent form changes** when the research procedures take place at Meriter or soliciting the signature on the consent occurs at Meriter.

3. **Protocol Changes for Exempt Research -** Submit a protocol change if:
    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 if:
    a. Meriter's engagement in your research is changing.
    b. See #2 Protocol Changes for Ceded Research above.

5. **Reportable Events –** Submit a report:
    a. When the reviewing IRB requires an event be reported to Meriter HRPP (Human Research Protection Program).

b. When 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.