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 for the following:
    a. Changes to study personnel who are entering UnityPoint Health – Meriter hospital clinical units.
        i. Study personnel must meet institutional requirements for conducting research on Meriter clinical units.
    b. Changes to study personnel accessing UPH-Meriter Private Health Information (PHI) (see appendix). This includes anyone accessing Meriter PHI. from Epic, Peridata, other Meriter databases.

2. **Protocol Changes for Ceded Research –** Submit a protocol change for the following:
    a. Changes to how **UPH-Meriter PHI** is solicited, stored, protected, or the timeline for destroying identifiers is altered. This includes changes in how UPH-Meriter PHI data is transferred from Meriter to the UW or how UW directly transfers Meriter PHI to another third party.
    b. 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. 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. New/revised **consents** when the changes relate to research procedures that take place at Meriter or when soliciting the signature on the consent occurs at Meriter.
    e. New/revised **patient facing materials** (flyers, posters, diaries, instruments, educational materials, etc.) with substantive changes when subjects will see the material as patients of a UPH-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 Research Compliance Office.
    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 Research Compliance Office will be assisting the reviewing IRB in addressing the event.

APPENDIX

Private Health Information (PHI) is clinical data that is accompanied by any of the 18 HIPAA identifiers listed below.

HIPAA Identifiers

- Name
- Address (street, city, county, state, zip code)
- Telephone/Fax Numbers
- Social Security Numbers
- Dates (except for years), includes the following:
    - Birth Date
    - Admission Date
    - Discharge Date
    - Service Date
    - Date of Death
    - Any Other Date
- Ages greater than 89 and all elements of dates indicative of such age.
- E-mail Addresses/URLs
- Medical Record Numbers
- Health Plan Beneficiary Numbers
- Account Numbers
- Certificate/License Numbers
- Vehicle Identifiers and Serial Numbers (e.g. VINs, License Plate Numbers)
- Device Identifiers and Serial Numbers
- Biometric Identifiers (e.g. finger or voice prints or full-face photographic images)
- Any other unique identifying number, characteristic, or code, including a study code