

## 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 <sup>2</sup>                                   | Yes <sup>3</sup> | Yes <sup>4</sup>                       |
| Study personnel changes including PI     | Yes                     | Yes <sup>1</sup>                                   | Yes <sup>1</sup> | Yes <sup>1</sup>                       |
| Reportable Events                        | Yes                     | No <sup>5</sup>                                    | NA               | No <sup>5</sup>                        |
| 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, additional research procedures or departments, added 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.