

## 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                                     |
| Amendments for 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               | NA                                     |
| Study Closure                            | Yes                     | Yes  | Yes              | Yes                                    |

- Study Personnel Changes** - Submit a *Study Personnel Changes* form if study personnel at Meriter are changing. The IRB sees if study personnel meet institutional requirements for conducting research at Meriter which may include health and safety checks and other qualifications.
- Amendments for Ceded Research** – Submit an amendment if:
  - you are changing how Private Health Information (PHI) is solicited, stored and protected, or the timeline for destroying identifiers is altered.
  - There are changes to the protocol or study documents affected by state law or institutional policy (e.g., HIV testing, new HIPAA authorization document).
  - There is a new study protocol or new consent document. Examples – New study population or sub-study is added requiring a new consent/new protocol.
- Amendments for Exempt Research** - Submit an amendment if:
  - the changes may impact the Exempt status of your study.
  - you are changing how Private Health Information (PHI) is solicited, stored and protected, or the timeline for destroying identifiers is altered.
- Amendments when Meriter is Not Engaged** – Submit an amendment if:
  - Meriter's involvement in your research is changing
  - you are changing how Private Health Information (PHI) is solicited, stored and protected, or the timeline for destroying identifiers is altered.
- Reportable Events for Ceded Research** – Submit a report:
  - When the reviewing IRB requires an event be reported to Meriter IRB.
  - When an event occurs of such severity or significance (e.g., serious and/or continuing noncompliance, an anticipated event that poses substantial risks to subjects or others) that the Meriter IRB will be assisting the reviewing IRB in addressing the event.