Definitions

1. **Key study personnel** - Individuals who conduct one or more research procedures including interacting or intervening with subjects, identified biospecimens, or identified health information.

Qualifications

1. Key study personnel must either be employed by UnityPoint Health - Meriter or be on Medical Staff or must meet the requirements of qualification 2 below.

2. Key study personnel who are not employees or members of the Medical Staff must meet the same requirements set forth by the Medical Education Office for medical students, residents, and other staff if they will be interacting with patients in the hospital or one of our clinics.
   
   a) Requirements include, up to date vaccines, flu shots, etc., a caregiver background check, and verification of liability insurance.
   
   b) Key study personnel must provide the Medical Education Office information to complete verification of their qualifications prior to initial approval of their study or prior to being added to an ongoing study.
   
   c) The Medical Education Office sends Meriter IRB a notification confirming that key study personnel have fulfilled the requirements and expiration dates associated with the requirements. This information is entered into the key study personnel’s user account in the IRB tracking software.

See page 2 for a flow chart on the process described in 2a – 2c.
Medical Education Office (MEO) Process for Non-Employed Researcher Staff to Meet Health and Safety Requirements to Enter Meriter Hospital and Clinics

1. Research staff person independently contacts MEO.
2. MEO forwards email to IRB Office for research role clarification.
3. IRB Office clarifies research staff role.
   1. interacting with patients
   2. access to patient floors only (no patient interaction)
4. IRB Office emails name of research staff to MEO.
5. MEO emails packet of requirements to research staff person.
6. Group 1 Requirements: Research Staff will interact with patients/subjects in Meriter clinical units.
   • Proof of vaccinations and recent TB test.
   • Proof of liability insurance
   • Documentation of a successful care-giver background check
   • Confidentiality Waiver
7. Group 2 Requirements: Research Staff will not interact with patients in Meriter clinical units. Access to patient floors only.
   • Proof of vaccinations and recent TB test.
   • Confidentiality Waiver
8. Research staff directs questions about requirements to MEO.
9. Research Staff returns completed packet to MEO.
10. Once MEO is satisfied that all requirements are met, the MEO emails a requirements approval message to IRB Office. Research staff person is copied on.
11. Non-employed research staff can be added (via an amendment) to a Meriter IRB approved protocol or to a yet to be approved new protocol.