



ASSURING QUALIFICATIONS FOR RESEARCH PERSONNEL (KEY PERSONNEL POLICY)

11/22/2023

This document is intended to describe the process by which the Duke University Health System Institutional Review Board (DUHS IRB) confirms the qualifications for employees of DUHS, and those hired through Duke Temp Services, to conduct research involving human subjects.

- For the purposes of this document, “Key Personnel” for a research study are individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the protocol. This includes, but is not limited to, individuals involved in conducting the research with human subjects through an interaction or intervention for research purposes, including participating in the consent process by either leading it or contributing to it; and those who are directly involved with recording or processing identifiable private information, including protected health information, related to those subjects for the purpose of conducting the research study.
- Outside or External Key Personnel include all individuals who are not DUHS employees – See Outside Key Personnel section below.
- The Duke University Health System Department of Human Resources is responsible for confirming the qualifications of all DUHS employees at the time of initial employment. Each DUHS employee is responsible for self-reporting any conflicts of interest, as defined by the DUHS Conflict of Interest policy, in a timely manner to the appropriate institutional officials at DUHS.
- When submitting an application to the DUHS IRB for either review of a new research study or continuing review of a current research study, the Principal Investigator will be responsible for providing a complete and accurate list of all Key Personnel on the study. The electronic iRIS software system receives information from the CITI Modules web site (www.citiprogram.org) concerning Key Personnel credentialing. The iRIS system will flag key personnel without the required training or with expired CITI training/credentialing. IRB Specialists send notices of expired credentialing to study teams via the modifications process in iRIS at continuing review. In addition, all research personnel are sent e-mailed reminders at 60, 30, 7 and 1 day(s) prior to expiration of ethics credentials.

Requirements for credentialing are posted on the Duke Office of Clinical Research (DOCR) CITI Training Support Page.

- Individuals who are Not Key Personnel: An individual who will be interacting with research participants during the course of a research study, but only in their regular non-research employment capacity. For example, a clinic receptionist, nurse or phlebotomist, or a radiologist or radiology technician, should not be listed as Key Personnel for the study, if the person will perform only genuinely non-collaborative services meriting neither professional recognition nor publication privileges and not associated with individual financial gain, and will not contribute to the design, governance and/or analysis of the study.
- For information regarding adding Duke students, unpaid volunteers, and visiting trainees to study personnel, visit the DOCR web site and refer to the document, “Process for Adding Duke Students, Unpaid Volunteers, and Visiting Trainees/Interns to Study Personnel”.

Key Personnel who are not DUHS Employees (Outside Key Personnel)

All Key Personnel who are not DUHS employees, including adjunct faculty, should be listed on the Outside Key Personnel Section in iRIS AND (with the exception of individuals with no access to PHI and no subject interaction) must meet the following requirements:

- Outside Key Personnel Relying on Duke’s IRB when the DUHS IRB is not serving as the sIRB: If the external site is relying upon the DUHS IRB to serve as the IRB of record, Key Personnel at that site must fulfill DUHS credentialing requirements by either providing proof of research ethics certification from their institution or registering at the CITI web site and completing the required Duke Health CITI modules. These studies must have a completed SMART IRB Cede letter, IRB Authorization Agreement (IAA) or Individual Investigator Agreement (IIA) executed between Duke and the individual/site to establish the DUHS IRB as the IRB of record for the specific study.
- A description of the research activities to be conducted by the Outside Key Personnel should be included in the Research Summary, i.e., name, role in the study, and access to data/PHI.
- Outside Key Personnel Relying on Duke’s IRB when the DUHS IRB is serving as the sIRB: The relying sites are instructed to fill out the staff listing and are not required to provide proof of their research ethics training but just confirmation within the staff listing that it has been completed.

- Outside Key Personnel Relying on Another IRB: If the non-Duke employees are based at an external (non-Duke) site and the site is using its own or another IRB (such as an independent IRB) as the IRB of record, and not relying on the DUHS IRB, then the DUHS IRB will not collect proof of research ethics training for the Outside Key Personnel. These studies must have an uploaded copy of that individual's institutional IRB approval. A description of the research activities to be conducted by the Outside Key Personnel should be included in the Research Summary, i.e., name, role in the study, and access to data/PHI.
- On a multi-site study, when an external (non-Duke) site is using an IRB other than the DUHS IRB, only the site's Principal Investigator must be named in the multi-site section in the iRIS application.
- The DUHS IRB will not issue a Notice of Approval for a new study submission or continuing review submission until all Key Personnel have fulfilled all credentialing requirements.

Review of Personnel Changes

A Key Study Personnel (KSP) change form should be submitted in iRIS to make a change in research personnel, other than a change in Principal Investigator and/or co-Principal Investigator or the addition of personnel external to DUHS. The KSP change may be reviewed and approved by a trained IRB staff member. The IRB staff member will confirm that the added personnel member has a Duke staff/faculty role and has fulfilled DUHS requirements for research ethics credentialing prior to issuing approval of the change. A regular amendment should be submitted to make a change in PI, co-PI, or the addition/removal of personnel external to DUHS. The amendment will be forwarded by the trained IRB staff member to the IRB Executive Director, IRB Chair or Administrative Reviewer for review and approval.

Previous Version Date(s): 7/18/2008, 8/24/2009, 2/14/2012, 2/29/2016, 1/11/2017, 8/31/2017, 4/19/2021