



KEY PERSONNEL POLICY

2/27/2025

This document is intended to describe the process by which the Duke University Health System Institutional Review Board (DUHS IRB) confirms the qualifications of study personnel to conduct research involving human subjects.

DEFINITIONS:

- Individuals are **engaged in human subjects research** if they are involved in conducting 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.
- **Key Personnel** are individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, regardless of whether they receive salaries or compensation under the protocol. This definition encompasses anyone who is **engaged in human subjects research**, but may also include Duke personnel who are not considered engaged (e.g., exempt submissions). Please see the sections further defining key personnel considerations for internal vs. external roles.
- **Key Personnel (internal to Duke):** includes employees of the Duke University Health System, faculty, staff and students of the Duke Schools of Medicine and Nursing; those employees hired through Duke Temp Services, and some faculty or employees of Duke University who are:
 - engaged in human subjects research; or
 - contributing to the scientific development or execution of a project in a substantive, measurable way, regardless of whether they receive salaries or compensation under the protocol; or
 - submitting an exempt project to DUHS IRB for an authoritative determination of exemption
- **Outside or External Key Personnel** include all individuals who are not included above (such as adjunct faculty, Duke undergraduates who are not paid, Duke affiliates, other contract employees, external collaborators, visiting students/CRISP interns, and others) who are **engaged in human subjects research**.

For information regarding adding Duke undergraduate students, unpaid volunteers, and visiting students/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".

- **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. Examples include clinic receptionist, nurse or phlebotomist, IDS/ICS pharmacy staff, or a radiologist or radiology technician. These personnel are not considered 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.

KEY PERSONNEL QUALIFICATIONS:

The Duke University Health System or Duke University Department of Human Resources is responsible for confirming accurate affiliation status (faculty versus staff versus student) of all DUHS/Duke employees. This affiliation status is the basis for determining whether the personnel are considered internal (faculty and staff) or external (affiliate, student and emeritus).

When applying to the DUHS IRB for either review of a new research study or other submission type, the Principal Investigator will be responsible for providing a complete and accurate list of all Key Personnel (internal and external) on the study.

The DUHS IRB will not issue a Notice of Approval until all Key Personnel have fulfilled all credentialing requirements.

Internal Key Personnel

The iRIS system will flag Duke key personnel who are not compliant with CITI training/credentialing. The electronic iRIS software system receives information from the CITI modules web site (www.citiprogram.org) concerning Key Personnel credentialing.

IRB Specialists send notices of expired credentialing to study teams via the modifications process in iRIS when indicated. In addition, all research personnel are sent e-mailed reminders from CITI 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 Page.

Outside Key Personnel

Only include outside key personnel who are **engaged in human subjects research** in the Outside Key Personnel Section in iRIS. A description of the research activities to be conducted by the Outside Key Personnel should be included in the iRIS submission, i.e., name, role in the study, and access to data/PHI.

Notes:

- Duke undergraduate students and CRISP interns who are engaged in research do not require a separate reliance agreement.
- For individuals who are not engaged in the research but are accessing de-identified Duke Health data (e.g., via PACE), the name and role of the person may be listed in the Research Summary - Data Management section, if needed.
- Required documentation (agreements, background check, etc.) as defined in the DOCR policy are submitted to DOCR. Only reliance agreements, if required, are submitted to DUHS IRB.

Treatment of Outside key personnel can differ based on how or if they are affiliated with another institutional IRB:

- **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, External 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 (depending on the type of reliance agreement). 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.
- **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 must confirm that research ethics training has been completed (no requirement to provide the documentation).
- **Outside Key Personnel Relying on Another IRB (where Duke is overseeing the multisite research):**
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, these studies must have an uploaded copy of that individual's institutional IRB approval.

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.

Note: Community partners engaged in research (who are not affiliated with an institution of higher education) may complete select modules. Refer to this link for a description of the training required:

<https://myresearchpath.duke.edu/citi-training-community-partners>

REVIEW OF PERSONNEL CHANGES

A Key Study Personnel (KSP) change form should be submitted in iRIS to make a change in internal research personnel, other than a change in Principal Investigator and/or co-Principal Investigator. The reviewer of the KSP change form 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 to add or remove 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, 11/22/2023