1.0 Introduction

This policy describes the conditions, qualifications and the training required for individuals to be listed as ***research personnel*** on a human subjects research (HSR) protocol that must be approved by the LSUHSC-NO (hereafter HSC) IRB.

2.0 Policy Statement

An employee, faculty, staff or student of HSC is a ***research personnel*** on a HSR study if he/she is considered to be a "key personnel" or "**engaged"** in research as the term is defined by regulations. All individuals who qualify as ***research personnel*** must be listed on the IRB application and obtain IRB approval for their participation in the research. Additionally, research personnel who are involved in the informed consent process should be distinguished on the research personnel list.

Because the Principal Investigator (PI) is responsible for making an initial determination of whether an activity meets the definition of HSR and also for the overall conduct of the research, the PI is ultimately responsible for ensuring compliance with this policy. The PI may delegate specific responsibilities to other research personnel provided the individuals are appropriately qualified and trained.

3.0 Defining Research Personnel

The PI (or designee) should first ensure that an individual is a "key personnel" on, or "engaged" in, the HSR study before listing them as ***research personnel*** on the protocol or IRB application.

A **key personnel** is any individual with full or partial responsibility for the design, conduct, OR reporting of research.

Engagement: The Office for Human Research Protections (OHRP) considers an institution "engaged" in HSR when its employees or agents, for the purposes of a research project, obtain:

- Data about the subjects of the research through intervention or interaction with them;
- Identifiable private information about the subjects of the research; or
- The informed consent of human subjects.

Therefore, individuals who intervene or interact with human subjects, or access subjects' identifiable data, are considered engaged in research and must obtain IRB approval for their participation as ***research personnel***.

Not all individuals involved in research are engaged in the human subjects portion of research. These individuals do not need to obtain IRB approval for activities related to the research. For more information, see the OHRP Guidance on Engagement.

Examples of individuals NOT engaged in HSR include:

- **Site Administrators:** Individuals at an organization who have administrative responsibilities (financial, reporting, auditing, etc.) for the research conducted at the organization.

- **Department Administrator:** Individuals within a department who have administrative responsibilities (financial, reporting, auditing, etc.) for the research conducted in the department.
- Individuals who are receiving only de-identified samples or data.
- Individuals who access identifiable data for auditing or monitoring.
- Individuals who facilitate recruitment by informing potential subjects about the research, sharing recruitment materials or other information about the research with potential subjects, direct potential subjects to the study team, or seek or obtain potential subjects' permission for the study team to contact them.
- Individuals who perform commercial or other services for investigators, when (1) services performed do not merit professional recognition or publication privileges, (2) services performed are typically performed by those institutions/individuals for non-research purposes; and (3) the individuals do not administer the study intervention being tested or evaluated under the protocol.
- Individuals at an institution not selected as a research site who perform protocol-dictated services/procedures which would typically be performed as part of routine clinical monitoring or follow-up of subjects enrolled at a study site. *Please contact IRB office for details and specific requirements.*
- Investigator(s) at an institution not selected as a research site who administer the study interventions being evaluated under the protocol on a one-time or short-term basis. *Please contact IRB Office for details and specific requirements.*

Please note that funding agencies may have their own definition of study personnel as it applies to grant or other funding applications.

4.0 Research Personnel Roles

- **Principal Investigator (PI):** The lead investigator of a team of research personnel who has the ultimate responsibility for the ethical conduct of the research.

- **Sub-Investigator (Sub-I):** Investigator who may perform all or some of the PI functions, but does not accept primary responsibility for the research study.

- **Research Coordinator:** Research Coordinator oversees and coordinates the daily activities of clinical research studies. He/She works closely with the clinical teams and investigators to ensure that all protocol required procedures and visits occur according to protocol specified guidelines. He/She often typically manages participant enrollment including obtaining informed consent.

- **Research Nurse:** An individual who has some of the same responsibilities as the Research Coordinator and is also able to carry out nursing tasks as required by the research study.

- **Regulatory Coordinator:** The Regulatory Coordinator is typically responsible for drafting or editing the protocol document and submitting new protocols, protocol amendments, continuing reviews and safety reports to the appropriate IRB for review. He/She is responsible for maintaining regulatory binders in accordance with sponsor specifications and general industry standards.

- **Data Manager:** The Data Manager is responsible for the overall data management of a research study.

- **Student Researcher:** Students may not serve as PIs on a human subjects research project. Their engagement in research must be supervised by an LSUHSC-NO faculty mentor who will function as the PI of the project. They may participate in any aspect of the research as deemed appropriate by the PI.

- **Trainee Researcher:** Fellows, residents, and others in training without a faculty appointment with the same restrictions and responsibilities as a Student Researcher.

5.0 Training and Disclosure Requirements

All **HSC affiliated *research personnel*** must complete initial HRPP- and institution-mandated research training and conflict of interest disclosure prior to participation in any HSR activity. To maintain eligibility to participate in HSR, they also must refresh each training type and disclosure at regular intervals as dictated by policy.

New ***research personnel*** may be added to an IRB-approved protocol through a study modification request but will only be approved once the individual has completed all required training.

Non-HSC affiliated *research personnel* are required to comply with the training requirements of their home institution and/or complete HSC HRPP-and institution-mandated research training. Non-HSC affiliated personnel training requirements and documentation of training are contingent on their role and their IRB of Record and is described here.

HRPP-Required Training

HSC-NO has selected the Collaborative Institutional Training Initiative (CITI Program) as the provider of the online courses necessary to fulfill the initial and continuing HRPP-required training on human subject protection.

Personnel must complete one of the following courses through the CITI Program:

- If mainly engaged in biomedical research, complete Biomedical Researcher, Stage 1.
- If mainly engaged in social or behavioral research, complete Social/Behavioral/Educational Researchers, Stage 1.

Required Training for Clinical Practice

Interventional clinical trials and any National Institutes of Health (NIH)-funded clinical trials also require Good Clinical Practice (GCP) training every three years.

- GCP is an international standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials. It also serves to protect the rights, integrity, and confidentiality of clinical trial subjects.
- GCP training is available through the CITI Program.

NIH requirements

The NIH requires that all investigators and any clinical trial staff responsible for the conduct, management, and/or oversight of any NIH-funded clinical trials complete the following:

- Good Clinical Practice course

- Academic training program
- Certification from a recognized clinical research professional organization

All research personnel must complete this training before the clinical trial begins and every three years until the end of the clinical trial.

Institution-Required Training & Disclosure

Training Course/Disclosure	Frequency	Training Provider	Required for
Conflict of Interest in Research Disclosure	Annual	Kuali Research	All HSR studies
Conflict of Interest in Research Training	Every 4 years	KDS	All HSR studies
HIPAA Privacy - Research	Annual	KDS	All HSR studies
Bloodborne Pathogen	Annual (high risk) or every 5 years (low risk)	KDS	All HSR studies

Annual COI disclosures are submitted via the Kuali Research (KR) COI module.

Knowledge Delivery System (KDS) is a web-based training program managed by the Office of Compliance Programs (OCP). For more information about institutional training requirements and to access KDS, please visit the OCP website. Instructions for requesting addition of training module(s) to your personal KDS profile are found here.

6.0 Obtaining IRB Approval for a Researcher's Participation

- All **HSC research personnel** for whom approval is requested to participate in a HSR study must be listed in the research personnel section of the application. Individuals who are not listed on the application cannot be approved to participate in the research.
- Only those **non-HSC research personnel** for whom there is an agreement in place for the HSC IRB to serve as their IRB of Record should be listed on the application. Individuals from other institutions participating in single IRB arrangement for a multi-center study should not be listed on the application. Their participation in the research is evaluated by their own institution.
- All research personnel listed on the application should be assigned an appropriate role. The study team determines the most appropriate role based on the individual's protocol-specific responsibilities.
- To add new, applicable research personnel (including a change in PI) to a study, a modification request must be submitted and approved by the IRB prior to participation in research.

7.0 Related Information/Materials

- Definition of Human Subjects Research
- Modifications to an Approved Protocol

- IRB Reliance

8.0 Definitions

- **Research Personnel:** An individual who is a "key personnel" on, or "engaged" in, a human subjects research study and meets the qualifications and training required to conduct such research.
- **Key Personnel:** An individual with full or partial responsibility for the design, conduct, or reporting of research.
- **Engagement:** An individual is "engaged" in human subjects research if he/she intervenes or interacts with human subjects or accesses the subjects' identifiable data during the course of the study.
- **Investigator**: In research subject to FDA regulations, an individual who actually conducts a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving a subject.
- **Principal Investigator (PI):** Responsible leader of a team of research personnel who has the ultimate responsibility for the ethical conduct of the research.
- **HSC research personnel**: Research personnel on an HSR study who are faculty, staff, students or employees of LSUHSC-NO. Individuals with a HSC gratis appointment may choose to be classified as HSC personnel.
- **Non-HSC research personnel**: Research personnel on an HSR study who are not faculty, staff, students or employees of LSUHSC-NO.