LSU Health NEW ORLEANS Human Research Protection Program	RESEARCH PERSONNEL DEFINITION, ROLES AND TRAINING			
	P & P	VERSION DATE	REPLACES P & P	PREVIOUS VERSION DATE
	5.03	12.09.2021	5.03	09.17.2021

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 individual is designated as ***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 HSC and non-HSC individuals who qualify as ***research personnel*** must be listed on the IRB application in the protocol personnel section and obtain IRB approval for their participation in the research.

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 publication/presentation of research results.

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 for research purposes, 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 Administrator:** Individuals at an organization who need "read-only" access to view research protocols conducted at their organization for administrative purposes (financial, reporting, auditing responsibilities, etc.).
- **Administrative Coordinator:** Individuals at an organization who need "full access" to research protocols conducted at their organization for administrative purposes

(financial, reporting, auditing, etc.). Their participation in research is limited to initiating or editing submissions to the IRB for review.

- **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 (e.g., renewal submissions).
- 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):** Lead investigator of a team of research personnel who has the ultimate responsibility for the ethical conduct of the research.

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

- **Research Interventionist:** Delivers behavioral interventions and/or conducts complex assessments for research studies conducted by the PI; performs a variety of duties involved in the collection, compilation, documentation, and interpretation of behavioral intervention and research data. He/She may recruit and obtain informed consent from research participants.

- **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 typically manages participant enrollment including obtaining informed consent.

- **Research Nurse:** Carries out some of the same responsibilities as the Research Coordinator while fulfilling nursing tasks as required by the research study.

- **Regulatory Coordinator:** Typically drafts or edits the protocol document and submits new protocols, amendments, continuing reviews and safety reports to the appropriate IRB for review. He/She is also responsible for maintaining data integrity, reviewing records, assisting with preparation of internal audits, resolving problems associated with noncompliance, tracking study activity, and ensuring that all clinical research proceeds in compliance with institutional and governmental policies and regulations.

- **Data Manager:** 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 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 an amendment but will only be approved once the individual has completed all required training.

Non-HSC affiliated *research personnel* training requirements are contingent on their IRB of Record. If their home institution will serve as their IRB of record, they must comply with their home institution's training and COI disclosure requirements. If HSC will serve as their IRB of Record, a fully executed authorization agreement appropriate for the study must be in place and non-HSC personnel must complete HRPP-required training. Additional institution-mandated training and COI disclosure may be required depending on the research activities and whether or not the home institution's Conflict of Interest program is in compliance with Public Health Service Financial Conflict of Interest Requirements. Full details on required training, authorization agreements, and COI disclosure requirements when HSC is serving as the IRB of Record is described in detail here and on our website.

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 Research, Stage 1 – Basic Course.
- If mainly engaged in social and behavioral research, complete Social & Behavioral Research, Stage 1 – Basic Course

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.

HSC Affiliated Research Personnel: 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
Shipping Biological Materials	Every 2 Years	KDS or EH&S and IATA training certification*	Individuals shipping biospecimens in any HSR study

* Unexpired EH&S and IATA training certification will be accepted in lieu of KDS training but renewal of training must be completed in KDS.

Annual COI disclosures are submitted via the Kuali Research (KR) COI module. Instructions for this process can be found here.

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. If an individual is missing a research required training module(s), the IRB office will request module assignment only once the IRB application listing this person as research personnel has been submitted.

Non-HSC Affiliated Research Personnel: Institution-Required Training & Disclosure

This table describes the training and documentation requirements for non-HSC personnel when the HSC IRB serves as their IRB of Record. Under this circumstance, an appropriate IRB authorization agreement is also required as described here.

Preferred Training Course/Disclosure	Frequency	Preferred Provider	Required for
COI in Research Disclosure	Annual	Kuali Research (KR)	All HSR studies (but see below for exemptions)
COI Basic & Refresher	Every 4 years	CITI	All HSR studies (but see below for exemptions)
HIPAA Privacy - Research	Annual	KDS	HSR studies in which external investigator is accessing protected health information from LSUHSC or LSU Health medical records
Bloodborne Pathogen	Annual (high risk) or every 5 years (low risk)	KDS	HSR studies in which external investigator is carrying out research on LSUHSC facilities
Shipping Biological Materials	Every 2 Years	KDS	HSR studies in which external investigator is carrying out research on LSUHSC facilities and shipping biospecimens.

Exceptions:

Conflict of Interest Training & Disclosure: Non-HSC personnel whose home institution is listed in the Financial COI Clearinghouse on the Federal Demonstration Partnership platform is exempt from LSUHSC's COI training and disclosure requirements. Those not listed on the FCOI Clearinghouse must complete the CITI COI training course and KR COI Disclosure, or provide documentation of alternate training and COI disclosure if the home institution has a comparable COI training and disclosure program.

Alternative Training: In most cases, alternative national programs or training programs developed by the external investigator's home institution may be substituted for the preferred courses listed in the table below as long as the content is comparable.

6.0 Obtaining IRB Approval for a Researcher's Participation

- All **research personnel**, regardless of affiliation status, 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.
- Documentation requirements for **non-HSC research personnel** vary based on which institution will serve as the IRB of Record for those individuals. For non-HSC individuals who have approval from their home institution the only requirement is that the IRB approval letter be attached. Their training and COI disclosure requirements are

evaluated by their own institution. Non-HSC personnel requesting that HSC be the IRB of Record must complete an authorization agreement, and fulfill the training and COI disclosure requirements as listed here.

- 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, an amendment 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
- Non-HSC Research Personnel Training and Documentation Requirements

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 publication/presentation of research results.
- **Engagement:** An individual is "engaged" in human subjects research if he/she intervenes or interacts with human subjects or accesses the subjects' identifiable data for research purposes 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 (including individuals with a gratis appointment), staff, students or employees of LSUHSC-NO.
- **Non-HSC research personnel**: Research personnel on an HSR study who are not faculty, gratis, staff, students or employees of LSUHSC-NO.