Title	**Guidance on the Delegation of Duties in Human Subjects Research**
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Scope	The purpose of this guidance is to assist Principal Investigators in determining when an individual's contribution to human subject research (HSR) (e.g., observational and interventional clinical research studies) activities would be considered "significant" and warrant: 1) being listed as study personnel on the IRB application, the Delegation of Authority (DOA) log, and/or training logs and 2) training in human subjects protection, Good Clinical Practice (GCP), and the study protocol.
Definitions	**Drug:** For the purposes of this guidance document, any drug, biologic, or other substance used for a clinical investigation as named in the investigational protocol/IRB application and a dose or frequency is specified. Such agents might be either commercially available or not commercially available and used according to, or outside of, the FDA-approved indications.
Policy	This guidance is consistent with i) the International Council for Harmonisation (ICH) Good Clinical Practice (GCP) 4.1.5 which specifies that an investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated **significant** trial-related duties and ii) the National Institutes of Health (NIH) requirements for training of investigators and staff involved in conduct, oversight, and management of clinical trials in both human subjects protection and ICH GCP.
Procedure	**Individuals whose performance of research duties *would not be* considered significant per this guidance:** This category would include any individual who: a. Performs clinical procedures on research participants that follow the standard scope of practice for their assigned specific role (e.g., phlebotomists, EKG technicians, lab technicians, medical technicians, clinical unit nursing staff, medical assistants, pharmacy technicians, office staff, etc.). b. Provides ancillary or intermittent care for the study participants related to standard scope of practice. c. Performs administrative routine duties or supportive tasks (e.g., clinical appointment scheduling, reminder appointment calls, etc.). Examples of procedures performed within the standard scope of practice that may be utilized for research include: i) assessing and recording vital signs; ii) collecting a

research blood sample during a clinical draw; and/or iii) conducting routine clinical assessments that will be utilized for the research study (e.g., pain assessment score, EKG, PFT, etc.).

Since these activities fall within standard clinical care, those individuals involved would not need to be added to the IRB study personnel list, DOA log, and training log nor be required to complete HSR or GCP training.

However, if the study protocol dictates that the procedures be performed in a manner that drastically differs from standard clinical care and/or requires study specific equipment and/or training (e.g., duties such as evaluating study specific adverse events, consenting study participants, and/or completing study specific assessments, etc.), then the individual should follow the significant-related research guidance listed below.

Individuals whose performance of research duties *would be* considered significant:

This category would include any individual who:

a. Interacts with human participants in a significant manner. (e.g., conducting the informed consent process, manipulating a study participant's environment for research purposes, or conducting invasive or non-invasive research procedures);

b. Is involved with collecting, reporting or analyzing identifiable subject data (human or basic science); and/or

c. Provides protocol specific training and oversight of research study staff.

Such individuals must be:

a. Listed as study personnel in the IRB electronic system;

b. Listed on the DOA log with designated role outlined;

c. Added to any study specific training logs and;

d. Trained in human subjects protection, GCP, the study protocol, and designated study procedures with such training documented in the regulatory files.

Study Drug Dispensing, Administration, & Distribution:
Dispensing drugs: Occurs when a supply of drug that is not patient-specific or that requires manipulation (counting, mixing, preparing, reconstituting, etc.) is provided to a study participant. Drugs may only be dispensed upon receipt of a valid order or prescription.

Examples of dispensing drugs include: i) Selecting a quantity of drug from a general bulk supply and placing it in another container for a study participant; or ii) measuring or packaging a drug before providing it to a study participant.
Who can dispense? Unless the Investigational Drug Services (IDS) grants an exception, dispensing may only be done by a pharmacist or other practitioner who is licensed to dispense.

Administering drugs: Drug administration occurs when a drug is ingested, injected or enters a study participant through any route of administration.
Who can administer? Drug administration may only be performed by a person who has a current state license that permits drug administration, or by a person who is credentialed to administer drugs by Lurie Children's (e.g., nurse, physician, respiratory therapist, nurse practitioner, physician assistant, dentist, podiatrist, or optometrist, etc.).

Distributing drugs: For the purposes of this guidance document, a drug is distributed when it is given to the recipient in a pre-labeled container with specific study participant identification (participant's name or participant- specific identification code), and does not require manipulation (counting, mixing, preparing, etc.) before it is provided to the recipient.
Who can distribute? Drugs may only be distributed by personnel who have received training about the distribution process and are listed as authorized study team members.

Principal Investigator (PI) Responsibilities:

The PI is ultimately responsible for the conduct and oversight of the clinical trial and ensuring that any individuals delegated to perform study specific tasks are qualified and properly trained. Before relying on clinical staff to perform research-related tasks, the PI must seek approval from clinical staff managers to ensure those tasks fall within their standard scope of practice and do not interfere with other responsibilities.

Research Support Services:

At Lurie Children's, any staff member whose role is to provide a specific research support service (i.e., the Investigational Drug Services (IDS) Pharmacy, the Clinical Research Unit (CRU), the Special Specimen Processing Center, Medical Imaging, etc.) does not need to be listed as study staff for the IRB, as these individuals are providing services within their scope of practice and have completed required

	training. It is important to note, however, that each sponsor may have different requirements regarding the DOA and/or training logs. Therefore, as a best practice it is recommended that: a. At least one individual from each research support service be listed on the DOA log as the point person responsible for ensuring the staff are trained on any protocol specific requirements in the completion of their tasks.
References	• ICH GCP 4.1.5 • IRB P&P 5.1A • OHRP 2008 Guidance on Engagement in HSR • FDA Guidance for Industry: Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects (https://www.fda.gov/media/77765/download)
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