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Key Personnel Guidance Document

Key personnel are persons engaged in the conduct of the research activity such that they **directly interact with research participants to obtain consent and/or research data**, or will have access to participants' private and identifiable private information during data collection or data analysis**.** Key personnel do not have to be affiliated with WSU or an affiliate institution.

Individuals whose regular duties are generally for research endeavors are considered key personnel when they meet the above definition. Examples include:

- Co-Investigators
- Study Coordinators, Research Nurses, and Research Assistants
- Fellows and Residents
- Lead/Staff/Clinical Pharmacists involved in the direct enrollment of participants, or research protocol authorship.
- Statisticians and Consultants who do not have direct interaction with participants or identifiable private information but who do contribute in a manner to qualify for authorship.
- Collaborators
- Research support staff (e.g. transcriptionists, administrative support) with access to private and identifiable private information, including audio or visual recordings.

Some individuals may interact or have access to private identifiable information as part of their regular paid duties. If involvement in research is limited to performing regular paid duties without contributing to the research endeavor, then these individuals are not considered key personnel. Examples include:

- Phlebotomist
- Radiology technician
- Staff nurse
- Staff pharmacist responsible for dispensing Investigational Product (IP) in the course of their routine workday. The responsibilities include only the IP preparation, dispensing and IP record documentation but not the direct enrollment of participants.
- Lead Pharmacist responsible for the oversight of the IP policy and procedures, and IP management (receipt, storage, dispensing).

Public Health Service (PHS) FAQ:

https://grants.nih.gov/grants/policy/coi/coi_faqs.htm#3178

Who is considered an "Investigator" for the purpose of this regulation? Is it only the Principal Investigator? (Institution and Investigator)

> ***No.*** *"Investigator" means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS (e.g., NIH), or proposed for such funding, which may include, for example, collaborators or consultants. Institutions should consider the role, rather than the title, of those involved in research and the degree of independence with which those individuals work. When the definition of investigator is limited to titles or designations (e.g., to principal investigators, key personnel, faculty) the risk is that an unidentified FCOI may compromise the research enterprise increases.*
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> *In addition, the Investigator's spouse and dependent children have been eliminated from the definition of "Investigator" under the 2011 revised regulation; however, they are referenced in the definition of "Significant Financial Interest" because the Investigator must also disclose Significant Financial Interests of his/her spouse and dependent children. A Financial Conflict of Interest exists when the Institution, through its designated official(s), reasonably determines that an Investigator's Significant Financial Interest is related to a NIH-funded research project and could directly and significantly affect the design, conduct or reporting of the NIH-funded research.*

Office for Human Research Protection (OHRP)

Who are "investigators"?

The HHS regulations at 45 CFR part 46 use the term "investigator" to refer to an individual performing various tasks related to the conduct of human subjects research activities, such as obtaining informed consent from subjects, interacting with subjects, and communicating with the IRB. For the purposes of the HHS regulations, OHRP interprets an "investigator" to be any individual who is involved in conducting human subjects research studies. Such involvement would include:

- *obtaining information about living individuals by intervening or interacting with them for research purposes;*
- *obtaining identifiable private information about living individuals for research purposes;*
- *obtaining the voluntary informed consent of individuals to be subjects in research; and*
- *studying, interpreting, or analyzing identifiable private information or data for research purposes.*

Investigators can include physicians, scientists, nurses, administrative staff, teachers, and students, among others. Some research studies are conducted by more than one investigator, and usually one investigator is designated the "principal investigator" with overall responsibilities for the study. In every human subjects research study, investigators have certain responsibilities regarding the ethical treatment of human subjects.

Federal Drug Administration (FDA) – 1572 Information Sheet

31. Who should be listed as a sub-investigator in Section #6?

FDA's regulation at 21 CFR 312.3(b) states: "In the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team. 'Subinvestigator' includes any other individual member of that team." 21 CFR 312.53(c)(1)(viii) requires the investigator to provide "a list of the names of the subinvestigators (e.g., research fellows, residents) who will be assisting the investigator in the conduct of the investigation(s)."

The purpose of Section #6 is to capture information about individuals who, as part of an investigative team, will assist the investigator and make a direct and significant contribution to the data. The decision to list an individual in Section #6 depends on his/her level of responsibility (i.e., whether he/she is performing significant clinical investigation-related duties). In general, if an individual is directly involved in the performance of procedures required by the protocol, and the collection of data, that person should be listed on the 1572. For example, if the protocol notes that each subject needs to visit a specified internist who will perform a full physical to qualify subjects for the clinical investigation, that internist should be listed in Section #6.

32. Should research nurses, other nurses, residents, fellows, office staff, or other hospital staff be listed in Section #6?

Hospital staff, including nurses, residents, or fellows and office staff who provide ancillary or intermittent care but who do not make a direct and significant contribution to the clinical data, do not need to be listed individually. It is not necessary to include in this section a person with only an occasional role in the conduct of the research, e.g., an on-call physician who temporarily dealt with a possible adverse effect or a temporary substitute for any research staff (see ICH E3, Section 6).

33. Should pharmacists or research coordinators be listed in Section #6?

The decision about whether to list a pharmacist or research coordinator on the 1572 is a matter of judgment, dependent upon the contribution that the individual makes to the study. For example, a

research pharmacist may prepare test articles and maintain drug accountability for many clinical studies that are ongoing concurrently at an institution. Because the pharmacist would not be making a direct and significant contribution to the data for a particular study, it would not be necessary to list the pharmacist as a sub-investigator in Section #6, but he/she should be listed in the investigator's study records. Generally, a research coordinator has a greater role in performing critical study functions and making direct and significant contributions to the data. For example, a research coordinator often recruits subjects, collects and evaluates study data, and maintains study records. Therefore, the research coordinator should usually be listed in Section #6 of the 1572.