IRB requirements for listing research personnel

The following information provides guidance for adding research personnel to the Ethical Oversight Submission System (ETHOS). This guidance applies to both new applications and updates to existing, approved applications. Note that changes in personnel must be submitted to the IRB as they occur.

1. Research Personnel – Definition

For purposes of applying to the IRB, research personnel are individuals who:

a. Interact with human subjects (e.g., informed consent process, manipulating subject’s environment for research purposes, conduct invasive or non-invasive research procedures), or
b. Are involved with collecting, reporting, or analyzing identifiable subject data, or

c. Function outside of regular work practice to conduct research (e.g., student administering research testing),* or

d. Are faculty advisors providing direct oversight of research involving human subjects, or human subjects’ private information, or

e. Are listed on FDA Form 1572 (Statement of Investigator) even if (a) – (d) do not otherwise apply.

* If an individual is functioning within his or her regular work practice (e.g., performing his/her job providing clinical care as a physician but referring potential participants to a research study; a phlebotomist following standard practice collecting blood for research tests; or an x-ray technician following standard practice performing an x-ray for research, etc.) and involvement in the research is limited to only those work responsibilities without further contribution to the research, then such individuals do not need to be listed in ETHOS.

Note: Funding agencies may have their own definition of research personnel (i.e., “key personnel”) however, researchers are required to comply with this IRB guidance when listing personnel in ETHOS.

2. Individuals with the following roles must be included in the ETHOS study record:

- Principal Investigator – the person responsible for the conduct of the study including leading the study team, when applicable
- Advisor of Student Principal Investigator – the person responsible for direct oversight of the study including leading the student principal investigator
- Sub-Investigator(s) (or co-investigators) – any individual member of the study team who will perform study procedures and make research protocol decisions
- Study Coordinator
- Any other member of the study team to whom the investigator delegates responsibility for making research protocol decisions, including:
  - Staff obtaining consent for research participation
  - Staff collecting, reporting or analyzing identifiable subject data
  - Staff who will have subject contact and/or access to identifiable subject data