Key Personnel Definition and Training Policy

Definition: Those individuals responsible for the design, conduct or reporting of a research project. The conduct of research refers to anyone who will interact with research participants: (recruit, consent participants, or collect data) or have access to research data (through data retrieval, entry, analysis or storage).

Guidance: The following are NOT considered key personnel:

1. Any research team member responsible for **only one** of the following activities:
   - approval for conduct of the research in that environment
   - entry or analysis of non identifiable data
   - manuscript evaluation or revision

2. Any Non AU-affiliated research team member who meets one of the following criteria:
   - Assisting a CITI-trained AU researcher, who is present and directly supervising the assistant at all times.
   - Anyone who is interacting with participants, whether under direct supervision or not, who has received clear written instructions, including basic training in human subjects protections provided by the Principal Investigator. The instructions/training must be included in the protocol and be IRB approved.

CITI Training Required for Key Personnel

Category 1: All AU *and* AU-affiliated personnel or students

Complete the required modules within the AU CITI program associated with your Learner Group, including elective courses. It is strongly encouraged to choose electives associated with your research. Optional modules are recommended for new investigators, IRB members, office staff, and key personnel.

Category 2: Non AU-affiliated but have requirements for Human Subjects Protection training at their home institution (university, school, business or hospital/clinic/medical center)

AU will accept the CITI program completion required by their home institution, NIH training dated after 3/1/2008 or an equivalent program.

Category 3: Non AU-affiliated where their institution has not implemented a training program

Complete an abbreviated course plus all additional specialized modules related to that protocol. Documented completion of a hard copy version will also be accepted if no Internet access is possible or feasible.