SOP

Department	Title	Dates
Research Integrity and Protection	Human Subject Protection Education and Training for Researchers	Effective: 10/23/2017
		Approved: 3/9/2017
Policy ID		Last Revised: 10/23/2017
IRB-SOP-804		Expiration: n/a

PURPOSE

Ascension Wisconsin recognizes the importance of having a strong, comprehensive educational program that ensures that any individual involved in the review or conduct of human subject research understands the ethical principles and regulatory requirements related to the protection of human subjects. This policy defines the educational and training requirements for all Ascension Wisconsin employees or agents engaged in human subject research.

SCOPE

All individuals engaged in the conduct of human subject research at Ascension Wisconsin are required to be trained in human research protection issues prior to their involvement in human subject research.

DEFINITIONS

Research Personnel For purposes of this policy, research personnel refers to all individuals who contribute substantially to the scientific development and/or the day-to-day execution of a research study.

Investigator refers to the Principal Investigator (PI) who is responsible for the overall conduct of the research study, as well as Co- or Sub- Investigators.

PROCESS

1. **Human Subject Training**
   - **1.1** Any research personnel involved in the conduct or review of human subject research must complete Collaborative IRB Training Initiative (CITI) human subject research training.
   - **1.2** For research that is subject to HIPAA, all personnel handling PHI must also complete the HIPAA module**.**
   - **1.3** The required training has been customized for different learner groups based on activities (i.e. medical and nonmedical investigators) and may be updated based on, for example, institutional policy or regulatory updates or availability of CITI training modules.
   - **1.4** At the completion of the required modules, the learner can download, save and print a certificate of completion from the CITI website. Individual investigators must maintain their own records and will need to submit this certificate in order to be added to any research study.
   - **1.5** Additional CITI modules, other than human subject training, may be required for other entities or departments, such as GCP or Conflict of Interest training.
   - **1.6** Senior/key personnel on NIH-funded human subject research must complete training in human subjects protections. No renewal is required. More information is available on NIH's website.
   - **1.7** The National Institutes of Health Human Participant Protections Education for Research Teams will be accepted for legacy researchers during a transition period to Ascension Wisconsin.

2. **Ongoing and Continuing Education**
   - **2.1 Human subject training** must be completed through CITI every three years. The appropriate refresher course will be assigned.
   - **2.2 Regular ad hoc communications and updates** are provided from the Institutional Official, Director and Research Integrity and Protection (RI&P) staff about relevant changes to procedures, policies, regulations, guidelines, etc.
   - **2.3 Lectures/presentations** are provided by RI&P/IRB staff and/or IRB members on an ongoing basis. Outside speakers may also be invited to present.
   - **2.4 Case presentations** presented by RI&P/IRB staff offer units the opportunity to have research case-based discussions with their associates at a group meeting. This gives investigators and their staff the opportunity to consider human subject protection issues as they apply to an example protocol/topic.
   - **2.5 Online Resources** such as the website or eIRB will be used to provide educational and instructional material for investigators and research staff such as institutional policies and procedures, IRB-related forms, and links to web sites that address human subject protection issues.
   - **2.6 Individualized training** is provided by RI&P/IRB staff on an ongoing basis. Investigators are encouraged to seek the assistance of the staff when planning a protocol or when responding to other IRB questions and concerns. IRB staff members are trained to identify each requirement, describe what it is, and provide a rationale for why it is required. In this way, human subject protection training is continually reinforced.
   - **2.7 Research Education and Quality Management (REQM)** contributes to ongoing, individualized training. Education efforts and are provided by QIP staff on an ongoing basis and include study start up support on routine reviews of study conduct, as outlined in the related SOPs.

3. **Verification and Documentation of Training**
   - **3.1 Review of training materials** will occur at the time of IRB review. RI&P/IRB staff will review materials to determine whether or not appropriate training has taken place. Staff will review each study team member listed on the protocol and his or her role in the project. Additionally, PI qualifications, including all required education and experience, are considered by the IRB member reviewer as part of the criteria for approval.
   - **3.2 Documentation of training** will be maintained by RI&P/IRB staff in Mentor. Researchers are encouraged to save a copy of the completion certificates for their own records. Researchers and/or RI&P/IRB staff can update the documents in Mentor.
   - **3.3 Noncompliance with training requirements.**
     If an investigator has not completed training, the submission will not be approved.
     If research personnel listed on the protocol have not completed training, he or she will be informed of this as part of the IRB review. The staff member must complete the training in order to remain on the protocol. If the training is not completed his or her name will be removed from the protocol at the time of approval. If a person is removed by this process, they may be added to the study after training is completed using the amendment process.

REFERNCES

None

RELATED MATERIAL

Ascension Wisconsin Policy: Human Subject Research

REVISION HISTORY

Version #	Date Revised	Reason for/Brief Description of Change	Revised By
01	4/11/2017	New- Initial Integration Update	J. Blundon
02	10/23/2017	Addition of Related Material, References and Revision History sections.	J. Blundon