



Department	Title	Dates
Research Integrity and Protection	Human Subject Protection Education and Training for IRB Members and Staff	Effective: 10/23/2017
		Approved: 3/9/2017
Policy ID		Last Revised: n/a
IRB-SOP-802		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 review or oversight of human subject research at Ascension Wisconsin are required to be trained in human research protection topics prior to involvement in research.

DEFINITIONS

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

PROCESS**1. Human Subject Training**

- 1.1 All IRB members and IRB/RI&P staff must complete the CITI training modules for human subject research that are assigned based on their role.
- 1.2 Those IRB members and IRB/RI&P staff involved in the HIPAA review related to research must also complete the HIPAA module.
- 1.3 The required training has been customized for different learner groups based on research activities 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. Individuals should maintain their own records and will need to submit this certificate to the Research Integrity and Protection Staff.
- 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 The National Institutes of Health training, titled Human Participant Protections Education for Research Teams, will be accepted for IRB staff and IRB members 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 based on position.

- 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/discussions are provided by RI&P staff and/or IRB members on an ongoing basis. Whenever possible, the IRB Chair and staff provide lectures pertinent to IRB matters. Outside speakers may also be invited to present.

3. IRB Members, Chair and IRB/RI&P Administrative Staff Orientation

- 3.1 Each newly selected IRB member:
 - Must attend at least one IRB meeting as an observer before undertaking the review of research protocols.
 - Must complete an individualized, comprehensive orientation with the IRB staff and/or IRB Chair. At this orientation the history of human subject protections, ethical principles, pertinent federal regulations, and specific institutional policies and practices are discussed.
 - Are encouraged to seek the assistance of other or outgoing members as they begin to review protocols.
- 3.2 IRB members and RI&P staff are provided with the Belmont report, 45 CFR 46, Food and Drug Administration regulations, institutional policies and procedures, a list of resources that includes pertinent web sites, and any other material that is deemed necessary at that time. Any updates to the materials are presented and provided as well as made available on the RI&P website/eIRB, when appropriate.
- 3.3 Each newly hired RI&P/IRB staff member receives intensive individualized training as appropriate. Staff is also provided with the office operating procedures.

4. Institutional Official(s)

- 4.1 The Institutional Official has access to all pertinent federal regulations and institutional policies and procedures. RI&P/IRB staff meets with the Institutional Official periodically as needed. The Institutional Official is kept apprised of new regulations, mandates and changes in federal policy as well as Ascension Wisconsin RI&P/IRB actions and updates.
- 4.2 The CITI training module for Institutional Officials is recommended but not mandatory.

5. Verification and Documentation of Training

- 5.1 **Review of training materials.** The Director or RI&P/IRB staff will ensure the appropriate training is complete during the orientation process, prior to participation in the review of research, and for ongoing training as appropriate.
- 5.2 **Documentation of training.** IRB/RI&P staff will maintain documentation of education and training material and activities, as well as, completion and evaluations as applicable.

REFERENCES

None

RELATED MATERIAL

IRB Guidance: Completing CITI Training

REVISION HISTORY

Version #	Date Revised	Reason for/Brief Description of Change	Revised By
01	4/11/2017	New- Initial Integration Update	J. Blundon