# Siena College Human Subjects Certification FAQs

*UPDATE: As of 1/26/18, NIH no longer offers the Protecting Human Research Participants course and does not maintain previously completed certificates. NIH certificates will still be honored by the Siena IRB through their 4-year expiration date.*
*All new training must be completed through CITI.*

Per federal regulations and Siena College's registered Federal-wide Assurance (FWA00004132), any individual engaged in human subject research is required to complete appropriate training on responsible conduct of research. To fulfill this federal mandate, the IRB will utilize the National Institutes of Health (NIH) Office of Extramural Research, *Protecting Human Research Participants* training modules or the Collaborative Institutional Training Initiative (CITI) online training course (https://www.citiprogram.org/). Both the CITI program and the NIH program are designed to increase understanding of the regulations, policies, and ethical standards governing the protection of human subjects, and both meet the training requirements of the Office for Human Research Protections. **All principal investigators and key personnel who are involved in human subject research must participate in education on the protection of human subjects in research.**

**FAQs**



**1. What is the Office for Human Research Protections (OHRP)?**

The Office for Human Research Protections (OHRP) provides leadership in the protection of the rights, welfare, and well-being of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS). OHRP helps ensure this by providing clarification and guidance, developing educational programs and materials, maintaining regulatory oversight, and providing advice on ethical and regulatory issues in biomedical and social-behavioral research.

**2. Who is required to complete the training?**

Any PI(s), Co-PI(s) and the faculty supervisor involved in the administrating and conducting a research project involving human subjects. NIH education training applies to all individuals listed on an IRB application. Additionally, any individual that will have contact with human subjects, either in person or through other technological means (e.g., email, web-based survey instrumentation, direct mail, online interviews), involving confidential data about human subjects, or data that was obtained from human subject for research purposes is required to complete the NIH training program. If you feel that a proposed study falls under Exempt Review, please consult with the Institutional Review Board (irb@siena.edu) prior to submission.

**3. What is the format of the training programs?**

The NIH training program consists of seven modules, four of which are followed by online quizzes. Participants do not need to complete the entire training in one seating. Individuals may save their progress and return back to where they left off. The CITI training has three separate courses (faculty, students, IRB members) that vary in length from three to seven modules, including electives.

**4. What material is covered?**

Issues important in conducting research involving human subjects are covered, including the definition and history of human subjects research, ethical principles for conducting human subjects research, informed consent, confidentiality and privacy of data and patient records, risks and benefits, preparation of a research protocol, institutional review boards, adherence to study protocol, proper conduct of the study, and special protections for vulnerable populations. The CITI program also contains elective modules related to community-based research and social, behavioral, and educational research.

**5. Will I be given a letter of certification for successful completion?**

Yes. A Certification of Completion will be made available upon successful completion of the training and receiving a passing grade for each of the quizzes. Please click on the "Get Certificate" button in the menu at the end of the course.

**6. For how long will my certification be valid?**

The Siena College IRB will recognize a Certificate of Completion that is no more than four years from the date it was completed and issued. The IRB reserves the right to determine the validity of an equivalent certificate from a different institution and to decide if an investigator(s) need to complete additional training.

**7. Will the education course be tied to my protocol approval?**

Effective January 17, 2012, IRB policy requires that all new protocol submissions or resubmissions of expiring protocols will not be reviewed until the investigator(s) and others co- investigators listed on the IRB application have successfully completed the training program. *The IRB is unable to review any IRB application without an NIH or CITI computer- printed Certificate of Completion attached to the IRB application for each investigator listed.*

It is strongly recommended that all principal investigators and key personnel listed on an IRB protocol involving human subjects complete the education program as soon as possible. This will help to eliminate delays in the review process.

**8. Do I still need to participate in a training program if my research with human subjects is exempt?**

Yes. Siena policy requires exempt determinations to be made by the IRB rather than by the investigator or department and that all PIs have training. Additionally, "exempt" does not mean excused from the review process, or that the activities do not require IRB review. Exempt means that the activities have been determined to meet the definition of human subjects research, but are exempt from the regulations and from continuing review. Siena College applies the Belmont Principles (as described in the Federal-wide Assurance) to all human subjects research activities including exempt research. So, you still need to prepare an exempt application with sufficient details, as specified in the application, to be assured that your provisions for protecting your research subjects are adequate and that required training is completed. This approach ensures risks to subjects are minimized and benefits to subjects are maximized.

**9. What if I complete the online training program, but my listed investigators do not?**

An IRB application will not cleared for review until Certificate(s) of Completion, or equivalent, are submitted for the investigator(s) listed on the application.

*If you have any questions, please feel free contact irb@siena.edu*