Citi Recommendations for Committee members:

Required: **(1) IRB Member, (2) Information Privacy & Security. [16 – 22 hours]**
Optional: **Becoming an effective leader, IRB Administration Comprehensive, IRB Protocol review, QA/QI: Human Subjects Research.**

Citi Recommendations for Chair and Co- Chair:

Required**: (1) IRB Member, (2) Information Privacy & Security. [16 - 22 hours]**
Optional: **IRB Administration Comprehensive, IRB Protocol review, QA/QI: Human Subjects Research, Becoming an effective leader.**

Citi Recommendations for CPHS Staff:

Required: **(1) IRB Administration Comprehensive, (2) IRB Protocol review. [7-8 hours]**
Optional: **IRB Member, Becoming an effective leader, QA/QI: Human Subjects Research, Information Privacy & Security.**

Citi Program courses and Summary

1. **IRB Member**

Required modules: History and ethics of human subject research, Basic IRB regulations and review process, Informed consent, social and behavioral research for Biomedical researchers, records-based research, genetic research in human populations, populations in research requiring additional considerations and/or protections, research involving prisoners, research involving children, research involving pregnant woman, fetuses, and neonates, avoiding group harms- international research perspectives, FDA regulated research, recognizing and reporting unanticipated problems involving risks to subjects or others in biomedical research, research and HIPAA privacy protections, conflict of interest in human subjects research, history and ethical principles.

Courses for SBE- Social, behavioral, educational researchers: defining research with human subjects, the federal regulations, assessing risk, informed consent, privacy and confidentiality, research involving prisoners, research involving children, research in public elementary and secondary schools, international research, internet-based research.

unanticipated problems and reporting requirements in social behavioral research, international studies, vulnerable subjects- research involving workers/ employees, hot topics, cultural competence in research, the IRB member model- 'what every new IRB member needs to know', I have agreed to be an IRB community member. Now what?

Plus 40 supplemental modules. (optional)

Total length of course: 15-20 hours

2. IRB Protocol review

The suggested audience is for those individuals directly involved in IRB review of nonexempt human subject's research protocol in keeping with the Common Rule.

Course content: IRB regulatory review criteria, asking the right questions for effective protocol review (biomed case study), asking the right questions for effective protocol review (SBE case study), IRB review of informed consent.

Total length of course: 2 hours

3. QA/QI: Human Subjects Research

The suggested audience is for those individuals directly involved in quality assurance in human research, including those who oversee, coordinate, or conduct internal audits and inspections of researchers, research studies, and sites.

Course content: Overview of a quality assurance/ quality improvement (QA/QI) program, developing an internal audit program, process for conducting internal audits, leased learned: using audit findings for improvement.

Total length of course: 2 hours

4. Information Privacy & Security

IPS consists of two courses, Information Security and the Family Educational Rights and Privacy Act (FERPA), which can be utilized based on organizational needs. Each course includes content for individuals who only need basic information, as well as content tailored to specific roles, applications, devices, and settings. It is suitable for anyone who works with individually identifiable data or FERPA-covered educational records and data or has responsibilities for setting policies and procedures with respect to these types of data.

Total length of course: 1-2 hours

5. Becoming an effective leader

The suggested audience includes individuals who aspire to improve their leadership skills. Individuals who are not yet leaders as well as individuals who already have leadership roles will find value in the topics presented in this course.

Course content: leadership essentials, communication, building positive relationships and conflict resolution, coaching, problem-solving and decision-making skills, ethics in leadership, change in management, team building.

Total length of course: 2-3 hours

6. IRB Administration Comprehensive

The Advanced course is designed for senior-level IRB administrators and directors who have taken the foundations course or those with two or more years of experience as an IRB administrator. It complements the foundational course and may be used for professional development.

Course Content: HRPP/IRB Policies and Procedures, Reporting to Federal Agencies, communicating with subjects, internal quality assurance and quality improvement of the HRPP, external oversight of the HRPP/RIB: monitoring and inspections, leading and managing an IRB, strategic planning, operational management, working with ancillary committees, navigating reliance agreements and IRB Review, Developing an education and training program.

Total length of course: 5-6 hours