CITI Policy

Brenau University is a Collaborative Institutional Training Initiative (CITI) affiliated participating organization. All Brenau University Institutional Review Board (IRB) Members, faculty conducting and/or supervising research, and students conducting human subjects' research must complete designated CITI modules in order to supervise or conduct human subjects' research at Brenau University.

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CITI Training Requirements for Brenau University

Prior to participating in human subjects' research, the Brenau University Institutional Review Board (IRB) requires all faculty, students, and investigators to complete and maintain the research training provided by the Collaborative Institutional Training Initiative (CITI). Instructions for accessing the CITI site and completing the Training can be found in the next section.

1. All Brenau University faculty members and students who conduct human subjects' research (HSR) are required to obtain CITI certification. If any outside investigators, professionals, collaborators, etc., are involved in conducting human subjects' research with a Brenau University faculty member, he or she must also obtain CITI certification.

2. The type of CITI certification required will depend on the type of research being conducted. It is the responsibility of the Principal Investigator or Faculty Research Advisor to select what CITI research track best fits his/her intended research. CITI has two HSR courses: (1) Biomedical Research Basic Course and (2) Social-Behavioral-Education (SBE) Research Basic Course. Please refer to page 6 of this document for a description of these two tracks to help you decide what track you and your students should complete. If additional help is needed on helping you decide on a CITI research track, please contact the Brenau University IRB.

3. For the HSR Biomedical Research Basic Course, you MUST complete 15 required modules AND one elective module - Avoiding Group Harms - U.S. Research Perspectives. A complete list of the Biomedical Research Basic Course modules is provided in Appendix A.

4. For the HSR SBE Research Basic Course, you must complete 14 required modules. A complete list of the SBE Research Basic Course modules is provided in Appendix B.

5. For all faculty and students who conduct human subject research, it is **OPTIONAL** to complete the Responsible Conduct of Research modules for the Biomedical or Social and Behavioral Education tracks in addition to the Biomedical or SBE research track courses.

6. Students may also be required to complete additional CITI modules at the discretion of their Principal Investigator/Faculty Research Advisor.

7. All **IRB Committee members** must take the HSR modules under the **HSR-Biomedical** track and the **IRB Member module - "What Every New IRB Member Needs to Know"**. IRB committee members must provide confirmation of completion of these modules within one month of accepting a position on the IRB committee.

8. All IRB Chairs and Co-Chairs must take the same courses as required of all committee members as well as the recommended modules for IRB Chairs.

9. All researchers involved in submitting a research proposal to Brenau's IRB MUST upload their completed CITI Certification to their profile on IRBNet and link it to the submitted proposal. No

submissions will be reviewed unless the CITI certifications for ALL researchers have been linked to the project.

CITI Access and Training Instructions

The training courses required by Brenau University's IRB can be accessed through the CITI site (https://www.citiprogram.org/). The Basic Research Course modules may take approximately 4-6 hours to complete. The Refresher Research Course modules may take approximately 2-3 hours to complete. Please follow the steps below to register with CITI and complete the training.

1) Go to: https://www.citiprogram.org/
2) Click on *Register* at the top right of the CITI home page
3) Under *Select your Organization Affiliation, type in* "Brenau University", then check the 'I agree to the Terms of Service' box
4) Scroll to bottom of the page and click on *Continue to Step 2*
5) Fill in your personal information then click on *Continue to Step 3*
6) Create a username and password, and select a security question and type in your answer, and then click on *Continue to Step 4*
7) Type in the name of your country of residence, and then click on *Continue to Step 5*
8) Indicate preferences for continuing education unit (CEU) credit and for receiving marketing information—you are not required to purchase the CEU credit—then click on *Continue to Step 6*
9) For *Institutional Email Address*, type in your Brenau email address; then type in your *Department/School,* and then click on the drop down menu and select your primary '*Role in Research'* (e.g., Principal Investigator, Student Researcher), and then click on *Continue to Step 7*
10) For *Question 1-Human Subjects Research*, select either *'Social & Behavioral Research Investigators',* OR *'Biomedical Research Investigators'*. (IRB members – you will need to either come back to this page or go to 'Add a Course' in order to add the IRB Member Course module).
11) Omit questions 2, 3 & 4; scroll to bottom of the page and click on *Complete Registration*
12) You will be given the opportunity to register with another institution (e.g., the local VA or the institution of a collaborator); if not, select *Finalize Registration*
13) Now, select *Brenau University Courses* and you are ready to complete your CITI HSR Course module. You may take each module quiz as many times as you wish. Before you can begin, you must click on the box to select '*Complete the Integrity Assurance Statement'* before beginning the modules.
14) All modules must be passed with a minimum score of 80%.
15) There are many other CITI courses available on their website. You can elect to register and complete any additional course(s) if it is an available option under the Brenau University agreement with the CITI program. There is no need to submit your certification of completion to the IRB for completing these additional courses/modules.
16) If you have completed the required HSR Biomedical Research Basic Course and/or the SBE Research Basic Course at another institution and the certification(s) is within the last three years, you may transfer your completed coursework to your Brenau University profile. You will need to follow the instructions on the 'Main Menu' under 'Affiliate with Another Institution'.

Certification Period and Renewals

If you are conducting research, Brenau University requires that you renew your CITI Certification every three (3) years.

1. CITI will automatically notify you 180 days, then 90 days, then 30 days prior to the expiration of any CITI certification(s) via the email listed in your CITI profile. CITI will also automatically upload the specific Refresher Course(s) you will need to complete to your online CITI account under the 'Main Menu' tab. If this does not occur, you can manually add the required Refresher Course(s) by clicking on 'Add a Course' under the 'Main Menu' and then go to 'My Learner Tools for Brenau University'. If you do not receive an automatic email notification from CITI and/or the course does not automatically load to your account, you are still responsible for the timely renewal of any required CITI certification(s).
2. A list of the Refresher Courses for the **HSR-Biomedical track** can be found in Appendix C and a list of the Refresher Courses for the **HSR-Social and Behavioral Education** can be found in Appendix D.
    a. The Biomedical Research Refresher Courses begin with Refresher Course 1, which you will complete three years after your initial certification. You will then proceed to sequentially complete every three years, Refresher Course 2 and Refresher Course 3, respectively. After completion of the Biomedical Research Refresher Course 3, you must restart the series and complete the Human Subjects Research (HSR) – Biomedical Research Basic Course.
    b. The Social and Behavioral Education Research Refresher Courses begin with Refresher Course 1, which you will complete three years after your initial certification. Three years later you will then proceed to complete, Refresher Course 2. After completion of Refresher Course 2, you must restart the series and complete the Human Subjects Research (HSR) – Social and Behavioral Education Research Basic Course.

Distinctions between Biomedical Research and Social Behavioral Research

UCLA Office of Research Administration. (2017, June 13). For and about the IRB: IRB Descriptions. Retrieved from http://ora.research.ucla.edu/OHRPP/Pages/IRBDescriptions.aspx.

Biomedical Research: Biomedical research refers to the study of specific diseases and conditions (mental or physical), including detection, cause, prophylaxis, treatment and rehabilitation of persons; the design of methods, drugs and devices used to diagnose, support and maintain the individual during and after treatment for specific diseases or conditions; and/or the scientific investigation required to understand the underlying life processes which affect disease and human well-being, including such areas as cellular and molecular bases of diseases, genetics, immunology. This research is typically quantitative and not qualitative. Biomedical research is often patient-oriented and the research involves:

- Studies of mechanisms of human disease
- Studies of therapies or interventions for disease
- Clinical trials
- Studies to develop new technology related to disease

Social Behavioral Research: Social-behavioral research refers broadly to research that deals with human attitudes, beliefs, and behaviors and is often characterized by data collection methods such as questionnaires, interviews, focus groups, direct or participant observation, and non-invasive physical measurements. The research may be qualitative or quantitative. Social-behavioral research also includes epidemiological or outcomes research and health services research:

- **Epidemiological and behavioral studies:** These types of studies examine the distribution of disease, the factors that affect health, and how people make health-related decisions.
- **Outcomes and health services research:** These studies seek to identify the most effective and most efficient interventions, treatments, and services.

Appendix A: CITI Biomedical Research Basic Course Modules

16 REQUIRED MODULES: Biomedical Courses	OPTIONAL MODULES: Biomedical Responsible Conduct of Research
Basic Institutional Review Board (IRB) Regulations and Review Process: Provides foundational information about the human subject protection regulations and IRBs, including the role, authority, and composition of the IRB. It discusses different types of IRB review processes, including an overview of the essential issues associated with exempt, expedited, and full (convened) IRB reviews. The information presented is based on the Common Rule as codified by the U.S. Department of Health and Human Services at 45 CFR 46, Subpart A. It concludes with a discussion of additional regulations and requirements (including the U.S. Food and Drug Administration and the International Council for Harmonisation), as well as others (for example, the National Institutes of Health and the U.S. Department of Education) that require compliance based on certain types of research.	**Using Animal Subjects in Research (RCR-Basic):** NA
Informed Consent: Presents the framework for informed consent found within the Common Rule (45 CFR 46, Subpart A), including the process and documentation of informed consent. Some of the special challenges associated with informed consent in research are also discussed, including informed consent as it relates to vulnerable populations, the requirements for waiver of informed consent, as well as the differences between U.S. Food and Drug Administration and U.S. Department of Health and Human Services regulations.	**Research Involving Human Subjects (RCR-Basic):** Provides an introduction to ethical and regulatory issues relating to the participation of human beings in research. It includes a description of the informed consent process and the Common Rule—a set of regulations adopted by a number of U.S. federal agencies.
Social and Behavioral Research (SBR) for Biomedical Researchers: Discusses SBR techniques within the framework of biomedical research and the nature, risks, and benefits associated with these techniques.	**Authorship (RCR-Basic):** Provides an overview of the ethical responsibilities of authors. It also discusses the criteria used to determine authorship, the range of

Included in this discussion are the types of biomedical studies that utilize SBR techniques, along with the kinds of data collected. It concludes with the risks and benefits that are unique to SBR	acceptable authorship practices, circumstances where acknowledgement is appropriate, and challenging and problematic authorship practices.
Records-Based Research: Records-based research has its own risks, and researchers who propose to conduct such research must have an understanding of those risks and how to minimize them. Learners will be presented with an overview of the risks associated with and the types of review required for records-based research. They will also learn about privacy and confidentiality, certificates of confidentiality, and the federal privacy law.	**Collaborative Research (RCR-Basic):** Discusses the ethical issues relating to collaborative research partnerships. It also includes a discussion of issues related to collaborating with researchers from other disciplines and with industry.
Genetic Research in Human Populations: Although continued advancements in genetic research present exciting opportunities in biomedicine, they also present some of the most difficult challenges with respect to the protection of human subjects. This content begins with an introduction to the types and complexity of genetic research. Next it provides a review of ethical, legal, and regulatory issues associated with genetic research. Finally, it offers a discussion of the issues surrounding the use of stored biological samples.	**Conflicts of Interest (RCR-Basic):** Describes the different types of conflicts of interest, conflicts of commitment, reasons why conflicts of interest and commitment can be problematic, and strategies that may mitigate or eliminate the impact of conflicts of interest.
Vulnerable Subjects - Research Involving Prisoners: Describes the special requirements for conducting research with prisoners. The learner is provided with a review of why incarcerated individuals need special protection, as well as the regulatory definition of what constitutes a prisoner. It also includes a discussion of each of the permitted categories for research involving prisoners and the required IRB considerations and determinations pursuant to 45 CFR 46, Subpart C. It concludes with the topic of what happens if an enrolled subject becomes a prisoner.	**Data Management (RCR-Basic):** Discusses the ethical issues associated with data, including data collection, management, sharing, ownership, and protection.
Vulnerable Subjects - Research Involving Children: Describes the major historical events that influenced how research with children can be conducted today. Compares differences between U.S. Department of Health and Human Services regulations (45 CFR 46,	**Mentoring (RCR-Basic):** Discusses the ethical responsibilities of mentors and trainees. Specifically covered are the roles of an advisor, supervisor, and mentor, as well as

Subpart D) and the U.S. Food and Drug Administration regulations (21 CFR 50, Subpart D) for the inclusion of children in research. Reviews the assent and informed consent requirements, and the current efforts by the FDA to ensure the inclusion of children in studies on the safety and efficacy of new drugs. An overview of the categories of research involving children pursuant to 45 CFR 46, Subpart D is provided, including examples.	strategies for managing conflicts between mentors and trainees.
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates: Discusses the historical exclusion of women of childbearing potential and the special requirements for conducting research involving pregnant women and fetuses. It includes a discussion of each of the permitted categories for research pursuant to 45 CFR 46, Subpart B, involving pregnant women, human fetuses, and neonates, as well as Institutional Review Board (IRB) review requirements and determinations. Informed consent requirements associated with the different categories of research permitted with pregnant women and human fetuses are also discussed.	**Peer Review (RCR-Basic):** Focuses on the ethical responsibilities of authors, editors, and reviewers of manuscripts, as well as a discussion of the grant proposal review process.
FDA-Regulated Research: Addresses U.S. Food and Drug Administration-regulated clinical research and the responsibilities of researchers, IRBs, and sponsors when an FDA-regulated product is utilized in a study. In particular, it includes information on when an Investigational New Drug (IND) application is necessary and the requirements of Form FDA 1572. Medical devices research, including defining a medical device, classifying risk, and when an investigational device exemption (IDE) is needed are also presented. Lastly, it addresses FDA regulations about informed consent, emergency use, and 21 CFR Part 11 and electronic records and signatures.	**Research Misconduct (RCR-Basic):** Describes the three practices (fabrication, falsification, and plagiarism) that constitute research misconduct and the steps that can be taken to handle allegations of research misconduct.
Research and HIPAA Privacy Protections: Discusses the requirements of the Health Insurance Portability and Accountability Act (HIPAA) and how they supplement the U.S. Department of Health and Human Services (HHS) and U.S. FDA requirements. It	

also describes situations where full HIPAA privacy protections are required and those that can qualify for waivers, alterations or exemptions with more limited requirements. In addition, it reviews the responsibilities of researchers and institutions for meeting HIPAA privacy requirements and for appropriate data security protections that are necessary to protect privacy.	
Vulnerable Subjects - Research Involving Workers/Employees: Describes why workers/employees may be a vulnerable population when they participate in research, and the potential risks and benefits associated with research involving workers/employees. It also discusses protections that need to be afforded to workers/employees. It proposes that while workers/employees may serve as study subjects for political as well as scientific reasons, adequacy of the science and adherence to the Common Rule (45 CFR 46, Subpart A), are paramount.	
Conflicts of Interest in Research Involving Human Subjects: Provides an overview of COIs in human subjects research by identifying when an interest or relationship may result in a COI, differentiating types of COIs and when they should be reported, and discussing challenges and strategies to manage both individual and institutional COIs. This module also reviews federal regulations that govern disclosure and management of individual COIs.	
History and Ethics of Human Subjects Research: Discusses ethical principles for the conduct of research involving human subjects. It provides an overview of the historical events that influenced the development of the current regulatory requirements, a review of the Belmont Principles, and a discussion of the contemporary ethical standards that guide research today.	
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research: The U.S. Food and Drug Administration and the U.S. Department of Health and Human Services human subject protection regulations require	

institutions to have policies and procedures to ensure prompt reporting of unanticipated problems (UPs) involving risk to subjects or others to the IRB, regulatory agencies, and appropriate institutional officials. In addition, FDA regulations require researchers to promptly report to the IRB all UPs involving risk to subjects or others and unanticipated adverse device effects. This content is intended to provide guidance to researchers on complying with reporting requirements by providing an overview of UPs, unanticipated adverse device effects, and the relationship between adverse events and UPs involving risk to subjects or others. It includes a discussion on how to detect UPs and how to report them.	
Populations in Research Requiring Additional Considerations and/or Protections: Provides an introduction to potentially vulnerable populations or those requiring additional protections and/or considerations in research. It describes different sources of vulnerability and distinguishes between populations in research who are specifically protected in the federal regulations and those who are not. It also includes the impact on autonomy, beneficence, and justice that may arise due to research on or with vulnerable individuals or groups.	
Elective Module - Required:	
Avoiding Group Harms - U.S. Research Perspectives: Describes some distinct groups or communities of people who are vulnerable to group harms and is intended for individuals conducting research in the U.S. In addition, learners are presented with examples of research that has caused group harms. This module concludes with strategies that researchers can take to reduce the risk of group harms.	

Appendix B: CITI Social-Behavioral-Education Research Basic Course Modules

15 REQUIRED MODULES: Social and Behavioral	OPTIONAL MODULES: Social and Behavioral Responsible Conduct of Research
Conflicts of Interest in Research Involving Human Subjects: Provides an overview of COIs in human subjects research by identifying when an interest or relationship may result in a COI, differentiating types of COIs and when they should be reported, and discussing challenges and strategies to manage both individual and institutional COIs. This module also reviews federal regulations that govern disclosure and management of individual COIs.	**Using Animal Subjects in Research (RCR-Basic):** NA
History and Ethical Principles – SBE: Discusses the evolution of the ethical principles in the U.S. that guide research design as well as the development of the federal regulations that govern the conduct of research relevant to researchers in the social and behavioral sciences. It reviews why ethics are necessary when conducting research involving human subjects including major historical events that have influenced how human subjects' research is conducted. It also describes problems with past studies that have violated ethical standards or have raised ethical concerns that have contributed to the national dialog related to the protection of human subjects. The Belmont Report principles are discussed as the basis for the ethical standards for research that guide us today.	**Research Involving Human Subjects (RCR-Basic):** Provides an introduction to ethical and regulatory issues relating to the participation of human beings in research. It includes a description of the informed consent process and the Common Rule—a set of regulations adopted by a number of U.S. federal agencies.
Defining Research with Human Subjects – SBE: Defines the terms "human subject" and "research" with an emphasis on the interpretation for human subjects research in the social and	**Authorship (RCR-Basic):** Provides an overview of the ethical responsibilities of authors. It also discusses the criteria used to determine authorship, the range of acceptable authorship practices, circumstances where

behavioral sciences. Also included is a discussion as to the differences between private and public information and behavior, a critical aspect of many types of social and behavioral research.	acknowledgement is appropriate, and challenging and problematic authorship practices.
The Federal Regulations – SBE: Describes the federal regulations and their basic provisions for human subjects research. It provides specific examples of the ways in which the federal regulations are particularly pertinent to social and behavioral science researchers and methodologies. It also discusses the criteria for exemption from the federal regulations, describes criteria for the use of expedited review procedures and institutional review board (IRB) review, summarizes the authority and scope of an IRB, and describes the kinds of additional IRB review that approved research may need. In addition, it reviews regulatory information pertinent to social and behavioral research including the criteria for expedited and full board review and the authority of the IRB	**Collaborative Research (RCR-Basic):** Discusses the ethical issues relating to collaborative research partnerships. It also includes a discussion of issues related to collaborating with researchers from other disciplines and with industry.
Assessing Risk – SBE: Presents the challenges in identifying and evaluating risks associated with participation in social and behavioral sciences research. Unlike biomedical clinical trials, risks associated with social and behavioral science research are often elusive and less predictable. Topics include assessing risks, balancing risks and potential benefits, minimizing and managing risks, certificates of confidentiality, and ways to address risks in the informed consent document and process.	**Conflicts of Interest (RCR-Basic):** Describes the different types of conflicts of interest, conflicts of commitment, reasons why conflicts of interest and commitment can be problematic, and strategies that may mitigate or eliminate the impact of conflicts of interest.
Informed Consent – SBE: Discusses the process and documentation of informed consent, including informed consent guidelines as well as the required and additional elements of informed consent as described by the federal regulations 45	**Data Management (RCR-Basic):** Discusses the ethical issues associated with data, including data collection, management, sharing, ownership, and protection.

CFR 46.There is also a discussion of the circumstances under which an Institutional Review Board (IRB) may waive the requirements for informed consent with examples of how this is commonly applied in social and behavioral sciences research. Includes information related to recruitment, ensuring consent comprehension, timing of consent, documentation of consent, safeguards for vulnerable subjects during consent, and exculpatory language.	
Privacy and Confidentiality – SBE: Distinguishes between privacy and confidentiality and identifies privacy risks associated with social behavioral study designs. Includes a discussion on protecting privacy in research and guidelines for designing confidentiality procedures. Topics include private versus public behavior, controlling access to private information, privacy and exempt research, privacy and research methods, confidentiality, privacy and reporting laws, and certificates of confidentiality. The discussion focuses on how these concepts apply to social and behavioral science research.	**Mentoring (RCR-Basic):** Discusses the ethical responsibilities of mentors and trainees. Specifically covered are the roles of an advisor, supervisor, and mentor, as well as strategies for managing conflicts between mentors and trainees.
Research with Prisoners – SBE: Examines the regulatory definition of "prisoner" and describes the requirements for conducting research with prisoners pursuant to 45 CFR 46 Subpart C. Reviews the permitted categories of research involving prisoners and Institutional Review Board (IRB) review considerations. Importantly, it contains a discussion on essential elements related to designing prisoner research, including consent issues, free choice, use of incentives, limits to confidentiality, when an enrolled subject becomes a prisoner, and the assessment of risk. It concludes with information related to accessing prisoner populations.	**Peer Review (RCR-Basic):** Focuses on the ethical responsibilities of authors, editors, and reviewers of manuscripts, as well as a discussion of the grant proposal review process.

Research with Children – SBE: Identifies regulations that apply to research with children. Defines "children" and discusses examples of research that meet the criteria of exempt research and expedited review and issues involved in obtaining and documenting parental permission and child assent. Discusses the four risk level categories according to 45 CFR 46 Subpart D. Included in the discussion is a review of the criteria for waiver of parental permission and/or child assent.	**Research Misconduct (RCR-Basic):** Describes the three practices (fabrication, falsification, and plagiarism) that constitute research misconduct and the steps that can be taken to handle allegations of research misconduct.
Research in Public Elementary and Secondary Schools – SBE: Provides an overview of the types of public school research and the regulations that apply to research in these settings. Individual sections discuss the Family Educational Rights and Privacy Act (FERPA), the Protection of Pupil Rights Amendment (PPRA), and at 45 CFR 46 Subpart D (Additional Safeguards for Children). Examples of activities that may qualify for exemption are discussed. It concludes with a discussion of parental permission and child assent issues, as well as research-related harms to children and requirements for reporting observed child abuse and neglect.	**Research and HIPAA Privacy Protections:** Discusses the requirements of the Health Insurance Portability and Accountability Act (HIPAA) and how they supplement the U.S. Department of Health and Human Services (HHS) and U.S. FDA requirements. It also describes situations where full HIPAA privacy protections are required and those that can qualify for waivers, alterations or exemptions with more limited requirements. In addition, it reviews the responsibilities of researchers and institutions for meeting HIPAA privacy requirements and for appropriate data security protections that are necessary to protect privacy.
International Research – SBE: Social and behavioral scientists conduct research around the globe. It includes a discussion of applicable regulations and guidelines and the importance of the local research context. Because international research may also include collaborating institutions, it provides information related to "engagement" in research. Additional topics include determining where research should be reviewed, exempt research, and informed consent considerations.	

Internet-Based Research – SBE: Identifies some of the ways in which social, behavioral, and educational researchers are using new Internet technologies. Discusses application of the federal definition of research with human subjects to Internet-based research and how ethical principles can be applied in the design, conduct, and review of Internet-based research. Presents issues associated with obtaining consent online and explains why privacy and confidentiality may be of particular concern for Internet-based research. Reviews challenges with assessing risks of harm in Internet-based research and issues that must be addressed.	
Vulnerable Subjects - Research Involving Workers/Employees: Describes why workers/employees may be a vulnerable population when they participate in research, and the potential risks and benefits associated with research involving workers/employees. It also discusses protections that need to be afforded to workers/employees. It proposes that while workers/employees may serve as study subjects for political as well as scientific reasons, adequacy of the science and adherence to the Common Rule (45 CFR 46, Subpart A), are paramount.	
Populations in Research Requiring Additional Considerations and/or Protections: Provides an introduction to potentially vulnerable populations or those requiring additional protections and/or considerations in research. It describes different sources of vulnerability and distinguishes between populations in research who are specifically protected in the federal regulations and those who are not. It also includes the impact on autonomy, beneficence, and justice that may arise due to	

research on or with vulnerable individuals or groups.	
Unanticipated Problems and Reporting Requirements in Social and Behavioral Research: Defines unanticipated problems, describes the reporting requirements associated with unanticipated problems, and identifies the types of actions an Institutional Review Board (IRB) may take in response to an unanticipated problem.	

Appendix C: CITI Biomedical Research Refresher Course Modules

Refresher Course 1 REQUIRED MODULES	Refresher Course 2 REQUIRED MODULES	Refresher Course 3 REQUIRED MODULES
Vulnerable Subjects – Children	History and Ethical Principles	History and Ethical Principles – Research vs. Practice
History and Ethical Principles	Regulations and Process	Informed Consent
Informed Consent	Informed Consent	SBR Methodologies in Biomedical Research
Regulations and Process	SBR Methodologies in Biomedical Research	Instructions
SBR Methodologies in Biomedical Research	Records-Based Research	Genetics Research
Records-Based Research	Genetics Research	History and Ethical Principles – Belmont Principles
Genetics Research	Populations in Research Requiring Additional Considerations and/or Protections	Populations in Research Requiring Additional Considerations and/or Protections
Populations in Research Requiring Additional Considerations and/or Protections	FDA-Regulated Research	Regulations and Process – IRB Authority and Composition
Instructions	HIPAA and Human Subjects Research	Regulations and Process – IRB Responsibilities
FDA-Regulated Research	Instructions	Vulnerable Subjects – Children
Research and HIPAA Privacy Protections	Conflicts of Interest in Human Subjects Research	Research and HIPAA Privacy Protections
Conflicts of Interest in Human Subjects Research	Vulnerable Subjects – Children	Conflicts of Interest in Human Subjects Research

Appendix D: CITI Social-Behavioral-Education Research Refresher Course Modules

Refresher Course 1 REQUIRED MODULES	Refresher Course 2 REQUIRED MODULES
History and Ethical Principles	History and Ethical Principles
Federal Regulations for Protecting Research Subjects	Federal Regulations for Protecting Research Subjects
Informed Consent	Informed Consent
Defining Research with Human Subjects	Defining Research with Human Subjects
Assessing Risk	Assessing Risk
Privacy and Confidentiality	Privacy and Confidentiality
Instructions	Instructions