HUMAN SUBJECT RESEARCH (HSR)

Series Catalog

CITI Program's HSR series consists of modules from two basic tracks, *Biomedical (Biomed)* and *Social-Behavioral-Educational (SBE),* and a set of *Additional Modules of Interest*. Organizations may group these modules to form a basic *Biomed* or *SBE* course, or a course that combines the two tracks. The *Additional Modules of Interest* should be used in any course variation, if relevant.

The basic *Biomed* modules have three corresponding sets of refresher modules and the basic *SBE* modules have two corresponding sets of refresher modules. These refresher modules are intended to provide learners with a review of what was covered in the basic level modules. It is generally recommended that organizations select refresher module requirements that reflect their selections for the basic course(s). Refresher courses should be taken in a cycle at an interval specified by your organization (for example, Refresher Stage 1: 3 years after completion of basic course; Refresher Stage 2: 6 years after completion of basic course).

Two additional standalone courses are available: *Institutional/Signatory Official: Human Subject Research,* and *IRB Chair*. The *Institutional/Signatory Official: Human Subject Research* course provides a general introduction to the roles and responsibilities of the institutional official at an organization holding a Federalwide Assurance (FWA). The *IRB Chair* course provides detailed training for current and future IRB chairs.

This catalog provides a listing, description, and language availability for each module within the HSR series, as well as information on continuing education (CE) credits and how to access the series.

Subscription Information

The HSR series is available to subscribing organizations as part of the **base subscription fee**. Independent Learner registration is available for $110 USD/course. For more information on subscriptions, **click here**.

In order to meet the needs of subscribing organizations, the CITI Program can assist administrators in creating courses that best meet their organizational needs, including combining modules from across the CITI Program. To discuss course recommendations that combine modules from different CITI Program offerings, please contact the CITI Program Help Desk at **support@citiprogram.org** or (888) 529-5929.

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Basic Courses

For a basic course in the HSR series, organizations may select modules from the *Biomedical (Biomed)* track, *Social-Behavioral-Educational (SBE)* track, and set of *Additional Modules of Interest*. For recommendations on how to set up a basic course using HSR modules, see the **Using CITI Program Content: Human Subjects Research (HSR)** document.

Human Subjects Research – Biomedical (Biomed) Modules

These modules provide an introduction to biomedical research with a focus on the protection of human subjects. They offer historic and current information on regulatory and ethical issues important to the conduct of research involving human subjects.

Continuing Education (CE) Credits and Units

View **CE credits, credit designation periods, and fees** for this course.

Module Title	Recommended Use	ID (Language)
Belmont Report and CITI Course Introduction	Required	1127 (English) 16459 (Spanish) 15895 (Korean) 16303 (Russian) 16448 (French) 16273 (Khmer) 16241 (Vietnamese) 16384 (Tamil)
History and Ethics of Human Subjects Research	Required	498 (English) 1478 (Spanish) 1507 (Portuguese) 15924 (Korean)
Basic Institutional Review Board (IRB) Regulations and Review Process	Required	2 (English) 1479 (Spanish) 1508 (Portuguese) 15923 (Korean) 1588 (Chinese) 15546 (Khmer) 15884 (Vietnamese)
Informed Consent	Required	3 (English) 12194 (Spanish) 1509 (Portuguese) 15926 (Korean) 1589 (Chinese) 16248 (Khmer) 15885 (Vietnamese)

Social and Behavioral Research (SBR) for Biomedical Researchers	Required	4 (English) 1718 (Spanish) 15927 (Korean) 1590 (Chinese) 16250 (Khmer) 15886 (Vietnamese)
Records-Based Research	Required	5 (English) 1490 (Spanish) 15928 (Korean) 1591 (Chinese) 16329 (Khmer) 16242 (Vietnamese)
Genetic Research in Human Populations	Required	6 (English) 1672 (Spanish) 15929 (Korean) 1592 (Chinese) 16254 (Khmer) 15887 (Vietnamese)
Populations in Research Requiring Additional Considerations and/or Protections	Required	16680 (English) 1483 (Spanish) 15930 (Korean) 1593 (Chinese) 16447 (French) 16258 (Khmer) 15888 (Vietnamese)
Vulnerable Subjects - Research Involving Prisoners	Supplemental	8 (English) 1482 (Spanish) 15931 (Korean) 1594 (Chinese) 16550 (Vietnamese)
Vulnerable Subjects - Research Involving Children	Required	9 (English) 1498 (Spanish) 12822 (Portuguese) 15932 (Korean) 1595 (Chinese) 16551 (Vietnamese)
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates	Supplemental	10 (English) 1499 (Spanish) 12821 (Portuguese) 15933 (Korean) 1598 (Chinese) 16552 (Vietnamese)

Avoiding Group Harms - U.S. Research Perspectives	Elective	14080 (English) 1719 (Spanish) 15934 (Korean) 1599 (Chinese) 16269 (Khmer) 16118 (Vietnamese)
Avoiding Group Harms - International Research Perspectives	Elective	14081 (English) 15935 (Korean) 16554 (Vietnamese)
FDA-Regulated Research	Required	12 (English) 1493 (Spanish) 15936 (Korean) 1600 (Chinese) 16260 (Khmer) 15889 (Vietnamese)
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research	Required	14777 (English) 15939 (Korean) 16555 (Vietnamese
Research and HIPAA Privacy Protections	Required	14 (English) 15942 (Korean) 1725 (Vietnamese)

Belmont Report and CITI Course Introduction

This module provides a link to the Belmont Report. It also offers additional information regarding the CITI Program's website and the availability of the *Belmont Report* in English, Chinese, Spanish, and French.

History and Ethics of Human Subjects Research

This module 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.

Basic Institutional Review Board (IRB) Regulations and Review Process

IRBs are a standard within the area of human subjects research. This module provides basic information about the human subject protection regulations and IRBs, including the role, authority, and composition of the IRB. The information presented is based on the Common Rule as codified by the U.S. Department of Health and Human Services (HHS) at 45 CFR 46. The different types of IRB review processes are discussed, providing the learner with an overview of the essential issues associated with exempt, expedited, and full (convened) IRB reviews. This module concludes with a discussion of the other regulations and requirements (such as the U.S. Food and Drug Administration [FDA] and the International Conference on Harmonisation [ICH]) and regulatory groups (for example, the National Institutes of Health [NIH] and the Department of Education [DOE]) that require compliance based on certain types of research.

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Informed Consent

The process and documentation of informed consent are fundamental tenets of human subjects research. It is important for researchers to understand these concepts. To that end, this module provides the learner with the framework for informed consent found within the Common Rule. Some of the special challenges associated with informed consent are also discussed, including informed consent as it relates to vulnerable populations. The module concludes with a review of the requirements for waiver of informed consent as well as the differences between U.S. Food and Drug Administration (FDA) and U.S. Department of Health and Human Services (HHS) regulations.

Social and Behavioral Research (SBR) for Biomedical Researchers

Because biomedical researchers employ a variety of SBR techniques within the framework of biomedical research, it is important to understand the nature, risks, and benefits associated with these techniques. This module discusses the types of studies that utilize SBR techniques, along with the kinds of data collected. A review of some of the risks and benefits that are unique to SBR completes the course.

Records-Based Research

Researchers may make important advances in the fields of education, medicine, psychology, and public policy by using previously collected information that does not involve prospective interaction with human subjects. 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. As a compliment to that review, this module also provides learners with an overview of the types of review processes required for records-based research. This overview includes the questions that must be addressed in order to make the appropriate determinations with respect to review.

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 module begins with an introduction to the types and complexity of genetic research. The learner is then provided with a review of ethical, legal, and regulatory issues associated with genetic research. A discussion of the issues surrounding the use of stored biological samples concludes this module.

Populations in Research Requiring Additional Considerations and/or Protections

This module 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. The module also discusses the impact on autonomy, beneficence, and justice that may arise due to research on or with vulnerable individuals or groups.

Vulnerable Subjects - Research Involving Prisoners

This module 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. This module also includes a discussion of each of the permitted categories for research involving prisoners and the required IRB considerations and determinations. The module concludes with the topic of what happens if an enrolled subject becomes a prisoner.

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Vulnerable Subjects - Research Involving Children

This module describes the major historical events that influenced how research with children can be conducted. It describes problems with this type of research that may violate ethical standards. It reviews the assent and informed consent requirements, and the current efforts by the U.S. Food and Drug Administration (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 is provided, including examples.

Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates

This module describes 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 involving the 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.

Avoiding Group Harms - U. S. Research Perspectives

This module is designed for U.S. research perspectives and describes some distinct groups or communities of people who are vulnerable to group harms. 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.

Avoiding Group Harms - International Research Perspectives

This module is designed for international research perspectives and describes some distinct groups or communities of people who are vulnerable to group harms. 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.

FDA-Regulated Research

This module addresses U.S. Food and Drug Administration (FDA)-regulated clinical research and the responsibilities of researchers, Institutional Review Boards (IRBs), and sponsors when an U.S. FDA-regulated product is utilized in a study. In particular, this module includes information on when an Investigational New Drug (IND) application is necessary and the requirements of the FDA Form 1572. A sub-module discusses the International Conference on Harmonisation (ICH) guidelines.

Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research

The U.S. Food and Drug Administration (FDA) and the U.S. Department of Health and Human Services (HHS) 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 Institutional Review Board (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. The purpose of this module is to provide guidance to researchers on complying with HHS and FDA 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. As a part of the discussion, this module includes a discussion on how to detect UPs and how to report them.

Research and HIPAA Privacy Protections

This module 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 FDA requirements. Situations where full HIPAA privacy protections are required and those that can qualify for waivers, alterations or exemptions with more limited requirements are discussed. This module also includes a discussion of the responsibilities of researchers and institutions for meeting HIPAA privacy requirements and for appropriate data security protections that are necessary to protect privacy.

Human Subjects Research – Social-Behavioral-Educational (SBE) Modules

These basic modules provide an introduction to issues that arise in the context of SBE research involving human subjects.

Continuing Education (CE) Credits and Units

View **CE credits, certification, designation periods, and fees** for this course.

Module Title	Recommended Use	ID (Language)
Belmont Report and CITI Course Introduction	Required	1127 (English) 16459 (Spanish) 15895 (Korean) 16303 (Russian) 16448 (French) 16273 (Khmer) 16241 (Vietnamese) 16384 (Tamil)
History and Ethical Principles – SBE	Required	490 (English) 16460 (Spanish) 15896 (Korean) 16299 (Russian) 16449 (French) 16377 (Tamil)
Defining Research with Human Subjects – SBE	Required	491 (English) 16461 (Spanish) 15897 (Korean) 16294 (Russian) 16450 (French) 15548 (Khmer) 16111 (Vietnamese) 16378 (Tamil)
The Federal Regulations – SBE	Required	502 (English) 16462 (Spanish) 15898 (Korean) 16298 (Russian) 16451 (French) 16379 (Tamil)

Assessing Risk - SBE	Required	503 (English) 16463 (Spanish) 15899 (Korean) 16295 (Russian) 16452 (French) 16330 (Khmer) 16112 (Vietnamese) 16380 (Tamil)
Informed Consent - SBE	Required	504 (English) 16464 (Spanish) 15900 (Korean) 16297 (Russian) 16453 (French) 16381 (Khmer)
Privacy and Confidentiality - SBE	Required	505 (English) 16465 (Spanish) 15901 (Korean) 16296 (Russian) 16454 (French) 15545 (Khmer) 16113 (Vietnamese) 16382 (Tamil)
Research with Prisoners – SBE	Supplemental	506 (English) 15902 (Korean)
Research with Children – SBE	Supplemental	507 (English) 16466 (Spanish) 15903 (Korean) 16455 (French)
Research in Public Elementary and Secondary Schools – SBE	Supplemental	508 (English) 15904 (Korean)
International Research – SBE	Supplemental	509 (English) 16467 (Spanish) 15905 (Korean) 16456 (French)
Internet-Based Research - SBE	Supplemental	510 (English) 16468 (Spanish) 15907 (Korean) 16457 (French) 16331 (Khmer) 16114 (Vietnamese)
Unanticipated Problems and Reporting Requirements in Social and Behavioral Research	Required	14928 (English) 16469 (Spanish) 15906 (Korean) 16300 (Russian) 16458 (French) 16383 (Tamil)

Belmont Report and CITI Course Introduction

This module provides a link to the Belmont Report. It also offers additional information regarding the CITI Program's website and the availability of the *Belmont Report* in English, Chinese, Spanish, and French.

History and Ethical Principles - SBE

This module 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 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.

Defining Research with Human Subjects – SBE

This module discusses an interpretation of definitions of the terms "human subject" and "research" with an emphasis on the interpretation for human subjects research in the social and 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.

The Federal Regulations – SBE

This module provides an overview of the federal regulations and their basic provisions. A close reading of the regulations includes research methods and topics of inquiry relevant for researchers in the social and behavioral sciences and the humanities. Methods include surveys, interviews, focus groups, oral history, participant observation, observations of public behavior, and the analysis of existing data. This module provides specific examples of the ways in which the federal regulations are particularly pertinent to social and behavioral science researchers and the methodologies noted. In addition, regulatory information pertinent to social and behavioral researchers is covered, including the criteria for expedited and full board review and the authority of the Institutional Review Board (IRB).

Assessing Risk - SBE

This module discusses 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.

Informed Consent - SBE

This module 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 regulations. 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. This module also includes information related to recruitment, consent comprehension, timing of consent, and exculpatory language, topics that are important to the overall concept of informed consent.

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Privacy and Confidentiality – SBE

This module defines privacy and confidentiality. It 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.

Research with Prisoners – SBE

This module describes the requirements for conducting research with prisoners. Included in the discussion is a review of the regulatory definition of a "prisoner," the permitted categories of research involving prisoners and Institutional Review Board (IRB) review considerations. Importantly, this module contains a discussion on essential elements related to designing prisoner research, including consent issues and the assessment of risk. This module concludes with information related to accessing prisoner populations.

Research with Children – SBE

This module describes regulations that apply to research with children. It 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. Included in the discussion is a review of the criteria for waiver of parental permission and/or child assent.

Research in Public Elementary and Secondary Schools – SBE

This module 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 Subpart D at 45 CFR 46: Additional Safeguards for Children. Examples of activities that may qualify for exemption are discussed. This module 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.

International Research – SBE

Social and behavioral scientists conduct research around the globe. This module includes a discussion of applicable regulations and guidelines and the importance of the local context. Because international research may also include collaborating institutions, this module 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

The Internet, with an estimated 2.3 billion users worldwide, has much to offer researchers, both as a research tool and as the object of study. This module presents the problems associated with obtaining consent online and explains why privacy and confidentiality may be of particular concern for Internet research. In addition, several problems with assessing risks of harm associated are included as it may often be difficult for researchers to assess these risks if they do not have previous experience with web-based research.

Unanticipated Problems and Reporting Requirements in Social and Behavioral Research

This module 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.

Human Subjects Research – Additional Modules of Interest

These modules may be added to either HSR – Biomedical or SBE courses.

Continuing Education (CE) Credits and Units

View **CE credits, credit designation periods, and fees** for this course.

Module Title		Recommended Use	ID (Language)
Are You Thinking About Being in a Research Study?		Supplemental	14562 (English)
Cultural Competence in Research		Supplemental	15166 (English) 16304 (Russian) 16385 (Tamil)
Conflicts of Interest in Research Involving Human Subjects		Required	488 (English) 1669 (Spanish) 15943 (Korean) 1728 (Chinese) 16301 (Russian) 16262 (Khmer) 16110 (Vietnamese) 16375 (Tamil)
Hot Topics		Supplemental	487 (English) 15954 (Korean) 16261 (Khmer) 16109 (Vietnamese)
Humanitarian Use Devices (HUDs)		Supplemental	16306 (English)
International Studies		Supplemental	971 (English) 1481 (Spanish) 1510 (Portuguese) 15940 (Korean) 1601 (Chinese) 16302 (Russian) 16376 (Tamil)
Clinical Trial Agreement (CTA) Modules	Overview of the Clinical Trial Agreement (CTA)	Supplemental	17356 (English)
	Understanding the Terms of the Clinical Trial Agreement (CTA)	Supplemental	17357 (English)
	Role of the Researcher and Site in Managing the Clinical Trial Agreement (CTA)	Supplemental	17358 (English)
	Clinical Trial Agreement (CTA) Negotiation for Researchers and Sites	Supplemental	17359 (English)
Community-Engaged Research (CEnR) Modules	Introduction To Community-Engaged Research (CEnR)	Supplemental	16994 (English)
	Introduction to Community-Based Participatory Research (CBPR)	Supplemental	16995 (English)

	Ethical and Practical Considerations in Community-Engaged Research (CEnR)	Supplemental	16996 (English)
Consent Modules	Consent and Biobanks and Associated Databases	Supplemental	17254 (English)
	Consent and Cultural Competence	Supplemental	17263 (English)
	Informed Consent and Incidental Findings in Research with Human Subjects	Supplemental	17342 (English)
	Consent and Subject Recruitment Challenges: Remuneration	Supplemental	16881 (English)
	Consent and Subject Recruitment Challenges: Therapeutic Misconception	Supplemental	17259 (English)
	Consent in the 21st Century	Supplemental	17060 (English)
	Consent Tools Used in Research	Supplemental	16944 (English)
	Consent with Subjects Who Do Not Speak English	Supplemental	17260 (English)
IRB-Focused Modules	External IRB Review	Supplemental	16711 (English)
	I Have Agreed to be an IRB Community Member. Now What?	Supplemental	13018 (English) 15947 (Korean)
	The IRB Administrator's Responsibilities	Supplemental	13813 (English) 15949 (Korean)
	The IRB Member Module - "What Every New IRB Member Needs to Know"	Supplemental	816 (English) 15946 (Korean)
Phase I Research Modules	Phase I Research: Understanding Phase I Research	Supplemental.	16873 (English)
	Phase I Research: Protecting Phase I Subjects	Supplemental	16874 (English)
Population-Specific Modules	Gender and Sexuality Diversity (GSD) in Human Research	Supplemental	16556 (English)
	Illegal Activities or Undocumented Status in Human Research	Supplemental	16656 (English)
	Research Involving Subjects at the End of Life	Supplemental	16658 (English)
	Research with Critically Ill Subjects	Supplemental	16592 (English)
	Research with Decisionally Impaired Subjects	Supplemental	16610 (English)
	Research with Older Adults	Supplemental	16502 (English)
	Research with Persons who are Socially or Economically Disadvantaged	Supplemental	16539 (English)

	Research with Subjects with Physical Disabilities & Impairments	Supplemental	16657 (English)
	Students in Research	Supplemental	1321 (English)
	Vulnerable Subjects - Research Involving Workers/Employees	Supplemental	483 (English) 1720 (Spanish) 15944 (Korean) 1726 (Chinese)
Stem Cell Research Modules	Stem Cell Research Oversight (Part I)	Supplemental	13882 (English) 15937 (Korean)
	Stem Cell Research Oversight (Part II)	Supplemental	14584 (English) 15938 (Korean)

Are You Thinking About Being in a Research Study?

This module aims to help subjects (and their family members) learn more about participating in research. This module defines research and common terms, provides questions to think about, and reviews the overall steps of a research study from the perspective of a subject. The module is written in lay language and is designed to be used by subjects and their family members.

Cultural Competence in Research

This module provides learners with an overview of the essentials of practicing cultural competence in research. It reviews its definition and the importance of understanding the demographics, historical contexts, communication styles, customs, values, and beliefs of study populations involved in research. The module continues with a discussion of how Institutional Review Boards (IRBs) and researchers can operate to support this work.

Conflicts of Interest in Research Involving Human Subjects

This module describes conflicts of interest, which are frequently debated and defined by varying regulatory requirements. It includes a general discussion of conflicts of interest with an emphasis on financial conflicts of interest and the ethical concerns that arise in human subjects research. This is followed by a review of the current reporting and disclosure requirements for researchers, including the 2011 Public Health Service (PHS) amendment and the U.S. Food and Drug Administration (FDA) regulations. The role of Institutional Review Boards (IRBs) and the primary strategies for eliminating, reducing, and managing conflicts of interest completes this module.

Hot Topics

This optional module is designed to provide learners with current information on recent developments in the Institutional Review Board (IRB) universe. It is updated annually, with previous content archived and accessible to learners.

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Humanitarian Use Devices (HUDs)

This module provides a basic overview of the FDA regulations and responsibilities regarding HUDs. It describes the Humanitarian Use Device (HUD) program and Humanitarian Device Exemption (HDE) regulatory process, and explains the applicable requirements and differences between 1) a "clinical use" of a HUD to treat or diagnose patients or 2) a "HUD investigation." This module also categorizes the FDA regulations and IRB review requirements for HUD investigations within and outside of the HDE approved indications, and identifies additional federal rules or institutional requirements that may apply to the clinical use of a HUD or HUD investigations.

International Studies

This module provides information for U.S. researchers and collaborating international researcher who receive funding from the U.S. federal government sources and who plan to conduct human subject research outside the U.S. This module is focused on international research ethics, U.S. government, and international guidelines. It includes a list of ethical review hyperlinks for countries and regions of the world. It is intended to help researchers and their staff members identify ethical requirements of their global research partners.

Clinical Trial Agreement (CTA) Modules

Overview of the Clinical Trial Agreement (CTA)

Discusses the general purpose of a CTA, roles and responsibilities of parties to the CTA, and how the CTA fits into the research enterprise. The module also compares and contrasts clinical trials involving drugs, biologics, and devices from a CTA perspective.

Understanding the Terms of the Clinical Trial Agreement (CTA)

Provides an overview of the context behind certain CTA terms and sections, types of language used for CTA sections, and some key elements of each section. The module also outlines what should be addressed in the key sections of the CTA and the aim for each section.

Role of the Researcher and Site in Managing the Clinical Trial Agreement (CTA)

Discusses key roles of the researcher and site in managing the CTA, including initial assessment, review, and implementation. The module also describes how the CTA is linked to site policies, the protocol, and the informed consent form, and identifies key sections of the CTA that could present risk to the site.

Clinical Trial Agreement (CTA) Negotiation for Researchers and Sites

Addresses strategies and preparation for CTA and study budget negotiations. The module also identifies terminology and alternative wording options to ensure a fair and balanced CTA.

Community-Engaged Research (CEnR) Modules

Introduction to Community-Engaged Research (CEnR)

This module discusses the meaning of the term "community," the disciplines and social movements that contributed to the development of CEnR, and the principles that guide CEnR. It also identifies the differences between a traditional research approach and the CEnR approach.

Introduction to Community-Based Particapatory Research (CBPR)

The module discusses the historical context for CBPR's framework and philosophical foundation, strategies for effectively using CBPR, and the ways a CBPR approach benefits and otherwise impacts communities, as well as academic researchers and their organizations. It also identifies the ways CBPR differs from traditional approaches to research.

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Ethical and Practical Considerations in to Community-Engaged Research (CEnR)

This module identifies the ethical and practical considerations particular to the design, review, and conduct of CEnR. It also demonstrates how to apply ethical risk-benefit assessments for CEnR, the varying impacts that risks and benefits may have on individual research participants as well as on communities and groups, and strategies for training and educating community members on a research team.

Consent Modules

Consent and Biobanks and Associated Databases

This module describes different consent approaches used for biobanks and associated databases, with reference to pertinent legal and ethical documents and regulatory requirements. Additionally, learners will review examples of key consent clauses (for example, linkage, return of research results and incidental findings, storage for future use, and access by researchers).

Consent and Cultural Competence

Cultural competence, as it applies to developing consent processes, obtaining consent, and evaluating the appropriateness of the consent processes is a focus of this module. The module describes strategies for enhancing understanding of research among diverse populations and communities during the consent process.

Informed Consent and Incidental Findings in Research with Human Subjects

This module defines incidental findings (IFs) in human subjects research and covers how IFs should be managed in the informed consent process. It provides an overview of Institutional Review Board (IRB) and researcher responsibilities, as well as strategies for managing IFs in the consent process, including review of the research plan, IF management plan, and consent form language.

Consent and Subject Recruitment Challenges: Remuneration

This module explores the types of remuneration in research, regulatory requirements regarding remuneration to research subjects, how to distinguish between remuneration and reimbursement, and strategies to reduce the potential for undue influence. It also identifies ways of disclosing remuneration plans in consent and advertising materials.

Consent and Subject Recruitment Challenges: Therapeutic Misconception

This module discusses therapeutic misconception and identifies potential strategies researchers and IRB members can use for reducing therapeutic misconception in the consent process. Also discussed are the related phenomena of therapeutic misestimation and therapeutic optimism.

Consent in the 21st Century

This module explores how technology has impacted the informed consent process in the 21st Century, especially electronic informed consent (eIC). This module covers technology and tools used in the recruitment and consent process, describes alternatives to paper-based informed consent forms, and explores confidentiality issues. This module reviews federal guidance concerning multimedia tools and eIC.

Consent Tools Used by Researchers

This module provides an overview of the potential barriers to informed consent and discusses strategies and tools that may be used to enhance and ensure research subjects' understanding of study information, including subject capacity assessments, the teach-back approach, tools for child assent, use of framing and graphics, and video and multimedia presentations. This module discusses ways to present research information to subjects in several simple, practical, and inexpensive ways.

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Consent with Subjects Who Do Not Speak English

This module focuses on the role that language plays in developing consent processes and obtaining consent in study populations that do not speak English. This module also covers challenges and strategies that researchers can use in the consent process, including the role of interpreters and the use of translations in obtaining consent and during the conduct of the study. The module concludes with a discussion of the federal regulations and guidance covering recruitment and consent for subjects who do not speak English with particular attention to the role of the IRB and the responsibilities of researchers.

IRB-Focused Modules

External IRB Review

This module reviews the history and developments of external IRB review, the variety of relationships between institutions and IRBs, and the agreements and obligations involved in those relationships. It covers major arguments for and against institutional acceptance of an external IRB, defines several types of relationships between research institutions and external IRBs, describes differences in operations of internal and external IRBs and their organizations, describes different types of agreements between institutions and external IRBs, and discusses the factors that contribute to the increasing use of centralized IRB review.

I Have Agreed to Be an IRB Community Member. Now What?

This module is designed for new Institutional Review Board (IRB) community members, but may be useful to anyone involved with human subjects research. It provides the basic information and tools related to IRBs, including an overview of definitions and the regulations, and provides strategies for a community member to become a well-informed IRB member. This module offers an overview of various aspects of the IRB review processes as they relate to specific types of protocols.

The IRB Administrator's Responsibilities

This module is intended for Institutional Review Board (IRB) administrators and directors; however, all individuals within an IRB office might benefit from the information presented in this module. An overview of the basic policies and procedures that institutions should have with regard to the human subjects protection program, including the IRB, provides the foundation for the IRB administrators'/directors' responsibilities.

The IRB Member Module – "What Every New IRB Member Needs to Know"

This module is designed as an overview and resource for individuals joining an Institutional Review Board (IRB). It includes discussions on time commitment, liability, the role of the IRB chair, and the levels of review. An overview of IRB tools, including the content of new submissions as well as what is often seen during committee review provides a foundation for new IRB members and is complimented by a discussion of how an IRB member can review protocols. This module concludes with information related to the IRB meeting, including the importance of quorum, the types of IRB decisions, and the review of minutes. This module is designed for new scientific and non-scientific members, but may also be useful for any IRB member who continues to serve on an IRB.

Phase I Research Modules

Phase I Research: Understanding Phase I Research

This module increases awareness of phase I research as it relates to regulatory requirements, Institutional Review Board (IRB) review, and safeguards for protecting human research subjects.

Phase I Research: Protecting Phase I Subjects

This module identifies ways in which researchers and staff involved in phase I research can apply the necessary safeguards to protect subjects involved in phase I research.

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Population-Specific Modules

Gender and Sexuality Diversity (GSD) in Human Research

This module provides a starting point to develop cultural competency for human subject researchers and research team members, who will come in contact with subjects or prospective subjects of a variety of sexuality and/or gender identities. It is also meant to be a resource for IRB members and administrative staff. The module begins with a short overview of the constituent parts of the GSD community from a broad perspective, continues with a summary of the legal and social/cultural vulnerabilities faced by members of these groups and describes research considerations for members of these communities, and concludes with a discussion on what IRBs and researchers should do with respect to these populations.

Illegal Activities or Undocumented Status in Human Research

This module provides training and insight to researchers, administrators, and IRBs regarding added risks and challenges of conducting research with individuals who are engaged in illegal activities or who have undocumented status. It presents examples of vulnerable groups and identifies ethical considerations when including them in research. The module also describes research design issues, recruitment methods, informed consent issues, and additional safeguards specific to research with groups of individuals involved in illegal activities or who have undocumented status.

Research Involving Subjects at the End of Life

Persons at the end of life may be vulnerable for numerous reasons, including cognitive and physical impairments, which may progress as death approaches. This module describes the ethical challenges of research with subjects at the end of life, including voluntariness and withdrawal from research. It also describes how cognitive impairment may impact vulnerability in end of life research and identifies strategies to overcome this challenge. Barriers to subject recruitment and special challenges for researchers and IRBs in assessing risk of harm and potential benefits in end of life research are also examined.

Research with Critically Ill Subjects

Well-designed and implemented basic science and interventional trials have the potential for reducing morbidity and mortality of patients with critical illness, as well as decreasing the cost and burden of care. However, critically ill patients represent a particularly vulnerable population in research and may have limitations in their ability to give informed consent, or may be at risk of exploitation. This module discusses ethical considerations and additional safeguards for critically ill subjects participating in research.

Research with Decisionally Impaired Subjects

This module provides an overview of the nature and sources of decisional impairment. It also discusses the obligations imposed on IRBs and researchers to ensure that appropriate protections are in place when research involves adult subjects who are or may be decisionally impaired and may have impaired consent capacity.

Research with Older Adults

This module provides education and training regarding the conduct of research with older adults. It discusses information for both researchers and IRBs in order to begin the process of addressing underrepresentation of older adults in research, while at the same time providing critical information to consider when conducting research with this group. The module also covers the demographic and social issues concerning the exclusion of older adults in research, barriers to inclusion, and research design considerations to enhance inclusion and protect this potentially vulnerable population.

Research with Persons who are Socially or Economically Disadvantaged

This module provides education and training regarding the conduct of research with individuals who are socially or economically disadvantaged. It describes the ethical and regulatory mandates for the inclusion of these populations in research, as well as the additional protections that may be used to minimize risk. The module also describes considerations for IRBs and researchers when planning, reviewing, or conducting research with socially or economically disadvantaged persons.

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Research with Subjects with Physical Disabilities & Impairments

This module provides an overview of physical disabilities and impairments, and the obligations imposed on IRBs and researchers to ensure that appropriate research protections are in place when research involves subjects who are physically disabled and may require additional tailored protections. Additional barriers, vulnerabilities, and challenges that individuals with physical disabilities face when participating in research are identified. The module also discusses safeguards and additional protections that IRBs and researchers can implement to protect this potentially vulnerable population, as well as ways to make research studies more accessible to individuals with physical disabilities.

Students in Research

This module is designed as a "one-stop shop" for students who may be involved in human subjects research as a researcher and/or a subject. Degree requirements in undergraduate, masters, or doctoral degree programs often require students to conduct or assist in research projects that include human subjects. In addition, students may be asked or be "required" to participate as subjects in research projects. A review of the history and principles of ethics for research involving human subjects, including a definition of research and categories of review; students as researchers; the role and operations of Institutional Review Boards (IRBs); and the issues related to students as subjects are provided, as well as a resource section.

Vulnerable Subjects – Research Involving Workers/Employees

This module describes why workers may be a vulnerable population when they participate in research, and the potential risks and benefits associated with research involving workers/employees. This module also discusses protections that need to be afforded to workers/employees. It proposes that while workers may serve as study subjects for political as well as scientific reasons, adequacy of the science and adherence to the Common Rule are paramount.

Stem Cell Research Modules

Stem Cell Research Oversight (Part I)

This module is the first of a pair of modules on human stem cells and it introduces the learner to the nature and characteristics of both adult and embryonic stem cells. Learners are provided with a review of the requirements of the federal regulations associated with stem cell research and the role of both state and local requirements.

Stem Cell Research Oversight (Part II)

This module builds on the content presented in *Part 1* and provides a framework for institutional review of stem cell research, national guidelines as well as current federal law and policy. This module provides an overview of the National Academy of Sciences (NAS), International Society for Stem Cell Research (ISSCR), and National Institutes of Health (NIH) guidelines related to human stem cell research and research involving human subjects. Consideration is given to U.S. Department of Health and Human Services (HHS) and U.S. Food and Drug Administration (FDA) regulatory requirements, Stem Cell Research Oversight (SCRO) committee composition and responsibilities, categories of research, and a comprehensive definition of provenance as it applies to human stem cell research. A detailed overview of the recommendations of the NAS, ISSCR, and NIH Guidelines as well as information related to the procurement, banking, and use of human stem cell lines are provided via the hyperlinks that follow the module.

Refresher Courses

Refresher courses in the HSR series should be completed after a basic course and in sequential order within each track. For recommendations on how to use a refresher course, see the **Using CITI Program Content: Human Subjects Research (HSR)** document.

Human Subjects Research – Biomedical (Biomed) Refresher 1

This course provides summaries of the important concepts for each module in the *Human Subjects Research – Biomedical (Biomed)* track. It is to be completed after the basic *Human Subjects Research - Biomed* modules. In order to receive credit for the course, a learner must complete all of the modules listed below.

Continuing Education (CE) Credits and Units

View **CE credits, credit designation periods, and fees** for this course.

Module Title	Recommended Use	ID (Language)
Biomed Refresher 1 – History and Ethical Principles	Required	975 (English) 15953 (Korean)
Biomed Refresher 1 – Regulations and Process	Required	981 (English) 15954 (Korean)
Biomed Refresher 1 – Informed Consent	Required	980 (English) 15955 (Korean)
Biomed Refresher 1 – SBR Methodologies in Biomedical Research	Required	982 (English) 15956 (Korean)
Biomed Refresher 1 – Records-Based Research	Required	983 (English) 15957 (Korean)
Biomed Refresher 1 – Genetics Research	Required	984 (English) 15958 (Korean)
Biomed Refresher 1 – Research Involving Vulnerable Subjects	Required	985 (English) 15959 (Korean)
Biomed Refresher 1 – Vulnerable Subjects - Prisoners	Required	973(English) 15960 (Korean)
Biomed Refresher 1 – Vulnerable Subjects - Children	Required	974 (English) 15961 (Korean)
Biomed Refresher 1 – Vulnerable Subjects – Pregnant Women, Human Fetuses, and Neonates	Required	986 (English) 15962 (Korean)
Biomed Refresher 1 – FDA-Regulated Research	Required	987 (English) 15963 (Korean)
Biomed Refresher 1 – Research and HIPAA Privacy Protections	Required	17261 (English)

Biomed Refresher 1 – History and Ethical Principles

This module is a Biomedical refresher for *History and Ethical Principles*.

Biomed Refresher 1 – Regulations and Process

This module is a Biomedical refresher for *Regulations and Process*.

Biomed Refresher 1 – Informed Consent

This module is a Biomedical refresher for *Informed Consent*.

Biomed Refresher 1 – SBR Methodologies in Biomedical Research

This module is a Biomedical refresher for *SBR Methodologies in Biomedical Research.*

Biomed Refresher 1 – Records-Based Research

This module is a Biomedical refresher for *Records-Based Research*.

Biomed Refresher 1 – Genetics Research

This module is a Biomedical refresher for *Genetics Research*.

Biomed Refresher 1 – Populations in Research Requiring Additional Considerations and/or Protections

This module is a Biomedical refresher for *Populations in Research Requiring Additional Considerations and/or Protections*.

Biomed Refresher 1 – Vulnerable Subjects – Prisoners

This module is a Biomedical refresher for Vulnerable Subjects – Prisoners.

Biomed Refresher 1 – Vulnerable Subjects – Children

This module is a Biomedical refresher for *Vulnerable Subjects – Children*.

Biomed Refresher 1 – Vulnerable Subjects – Pregnant Women, Human Fetuses, and Neonates

This module is a Biomedical refresher for *Vulnerable Subjects – Pregnant Women, Human Fetuses, and Neonates*.

Biomed Refresher 1 – FDA-Regulated Research

This module is a Biomedical refresher for *FDA-Regulated Research*.

Biomed Refresher 1 – Research and HIPAA Privacy Protections

This module is a Biomedical refresher for *Research and HIPAA Privacy Protections.*

Human Subjects Research – Biomedical (Biomed) Refresher 2

This course provides summaries of the important concepts for each module in the *Human Subjects Research - Biomedical (Biomed)* track. This refresher course is to be completed after the *Biomed Refresher 1* course. In order to receive credit for the course, a learner must complete all of the modules listed below.

Continuing Education (CE) Credits and Units

View **CE credits, credit designation periods, and fees** for this course.

Module Title	Recommended Use	ID (Language)
Biomed Refresher 2 – History and Ethical Principles	Required	511 (English)
Biomed Refresher 2 – Regulations and Process	Required	512 (English)
Biomed Refresher 2 – SBR Methodologies in Biomedical Research	Required	515 (English)
Biomed Refresher 2 – Records-Based Research	Required	516 (English)
Biomed Refresher 2 – Genetics Research	Required	518 (English)
Biomed Refresher 2 – Research Involving Vulnerable Subjects	Required	519 (English)
Biomed Refresher 2 – Vulnerable Subjects - Prisoners	Required	520 (English)
Biomed Refresher 2 – Vulnerable Subjects - Children	Required	521(English)
Biomed Refresher 2 – Vulnerable Subjects – Pregnant Women, Human Fetuses, and Neonates	Required	522 (English)
Biomed Refresher 2 – Informed Consent	Required	514 (English)
Biomed Refresher 2 – FDA-Regulated Research	Required	524 (English)
Biomed Refresher 2 – Research and HIPAA Privacy Protections	Required	526 (English)
Biomed Refresher 2 – Conflicts of Interest in Research Involving Human Subjects	Required	681 (English)

Biomed Refresher 2 – History and Ethical Principles

This module is a Biomedical refresher for *History and Ethical Principles*.

Biomed Refresher 2 – Regulations and Process

This module is a Biomedical refresher for *Regulations and Process*.

Biomed Refresher 2 – SBR Methodologies in Biomedical Research

This module is a Biomedical refresher for *SBR Methodologies in Biomedical Research*.

Biomed Refresher 2 – Records-Based Research

This module is a Biomedical refresher for *Records-Based Research*.

Biomed Refresher 2 – Genetics Research

This module is a Biomedical refresher for *Genetics Research*.

Biomed Refresher 2– Populations in Research Requiring Additional Considerations and/or Protections

This module is a Biomedical refresher for *Populations in Research Requiring Additional Considerations and/or Protections*.

Biomed Refresher 2 – Vulnerable Subjects – Prisoners

This module is a Biomedical refresher for *Vulnerable Subjects – Prisoners*.

Biomed Refresher 2 – Vulnerable Subjects – Children

This module is a Biomedical refresher for *Vulnerable Subjects – Children*.

Biomed Refresher 2 – Vulnerable Subjects – Pregnant Women, Human Fetuses, and Neonates

This module is a Biomedical refresher for *Vulnerable Subjects – Pregnant Women, Human Fetuses, and Neonates*.

Biomed Refresher 2 – Informed Consent

This module is a Biomedical refresher for *Informed Consent*.

Biomed Refresher 2 – FDA-Regulated Research

This module is a Biomedical refresher for *FDA-Regulated Research*.

Biomed Refresher 2 – Research and HIPAA Privacy Protections

This module is a Biomedical refresher for *Research and HIPAA Privacy Protections*.

Biomed Refresher 2 – Conflicts of Interest in Research Involving Human Subjects

This module is a Biomedical refresher for *Conflicts of Interest in Research Involving Human Subjects*.

Human Subjects Research – Biomedical (Biomed) Refresher 3

This course provides of summaries of the important concepts for each module in the *Human Subjects Research – Biomedical (Biomed)* track. This refresher course is to be completed after the *Biomed Refresher 2* course. In order to receive credit for the course, a learner must complete all of the modules listed below.

Continuing Education (CE) Credits and Units

View **CE credits, certification, designation periods, and fees** for this course.

Module Title	Recommended Use	ID (Language)
Biomed Refresher 3 – History and Ethical Principles – Research vs. Practice	Required	993 (English)
Biomed Refresher 3 – History and Ethical Principles – Belmont Principles	Required	12640 (English)
Biomed Refresher 3 – Regulations and Process – IRB Authority and Composition	Required	12644 (English)
Biomed Refresher 3 – Regulations and Process – IRB Responsibilities	Required	12645 (English)
Biomed Refresher 3 – Informed Consent	Required	1003 (English)
Biomed Refresher 3 – Genetics Research	Required	12633 (English)
Biomed Refresher 3 – SBR Methodologies in Biomedical Research	Required	1004 (English)
Biomed Refresher 3 – Research Involving Vulnerable Subjects	Required	12643 (English)
Biomed Refresher 3 – Vulnerable Subjects - Prisoners	Required	12647 (English)
Biomed Refresher 3 – Vulnerable Subjects - Children	Required	12648 (English)
Biomed Refresher 3 – Vulnerable Subjects – Pregnant Women, Human Fetuses, and Neonates	Required	12649 (English)
Biomed Refresher 3 - Research and HIPAA Privacy Protections	Required	17265 (English)

Biomed Refresher 3 – History and Ethical Principles – Research vs. Practice

This module is a Biomedical refresher examines *History and Ethical Principles – Research vs. Practice*.

Biomed Refresher 3 – History and Ethical Principles – Belmont Principles

This module is a Biomedical refresher focuses on History and Ethical Principles – Belmont Principles.

Biomed Refresher 3 – Regulations and Process – IRB Authority and Composition

This module is a Biomedical refresher on Regulations and Process – IRB Authority and Composition.

Biomed Refresher 3 – Regulations and Process – IRB Responsibilities

This module is a Biomedical refresher on *Informed Consent.*

Biomed Refresher 3 – Informed Consent

This module is a Biomedical refresher for *Informed Consent*.

Biomed Refresher 3 – Genetics Research

This module is a Biomedical refresher for *Genetics Research*.

Biomed Refresher 3 – SBR Methodologies in Biomedical Research

This module is a Biomedical refresher for *SBR Methodologies in Biomedical Research*.

Biomed Refresher 3 – Populations in Research Requiring Additional Considerations and/or Protections

This module is a Biomedical refresher for *Populations in Research Requiring Additional Considerations and/or Protections*.

Biomed Refresher 3 – Vulnerable Subjects - Prisoners

This module is a Biomedical refresher for *Vulnerable Subjects – Prisoners.*

Biomed Refresher 3 – Vulnerable Subjects - Children

This module is a Biomedical refresher for *Vulnerable Subjects – Children.*

Biomed Refresher 3 – Vulnerable Subjects – Pregnant Women, Human Fetuses, and Neonates

This module is a Biomedical refresher for *Vulnerable Subjects – Pregnant Women, Human Fetuses, and Neonates*.

Biomed Refresher 3 - Research and HIPAA Privacy Protections

This module is a Biomedical refresher for *Biomed Refresher 3 - Research and HIPAA Privacy Protections*.

Human Subjects Research – Social-Behavioral-Educational (SBE) Refresher 1

This course provides of summaries of the important concepts for each module in the *Human Subjects Research – Social-Behavioral-Educational (SBE)* track. It is to be completed after the basic *Human Subjects Research - SBE* modules. In order to receive credit for the course, a learner must complete all of the modules listed below.

Continuing Education (CE) Credits and Units

View **CE credits, credit designation periods, and fees** for this course.

Module Title	Recommended Use	ID (Language)
SBE Refresher 1 – History and Ethical Principles	Required	936 (English)
SBE Refresher 1 – Federal Regulations for Protecting Research Subjects	Required	937 (English)
SBE Refresher 1 – Defining Research with Human Subjects	Required	15029 (English)
SBE Refresher 1 – Informed Consent	Required	938 (English)
SBE Refresher 1 – Assessing Risk	Required	15034 (English)
SBE Refresher 1 – Privacy and Confidentiality	Required	15035 (English)
SBE Refresher 1 – Research with Prisoners	Required	939 (English)
SBE Refresher 1 – Research with Children	Required	15036 (English)
SBE Refresher 1 – Research in Educational Settings	Required	940 (English)
SBE Refresher 1 – International Research	Required	15028 (English)

SBE Refresher 1 – History and Ethical Principles

This module is a SBE refresher for *History and Ethical Principles*.

SBE Refresher 1 – Federal Regulations for Protecting Research Subjects

This module is a SBE refresher on *Federal Regulations for Protecting Research Subjects*.

SBE Refresher 1 – Defining Research with Human Subjects

This module is a SBE refresher for *Defining Research with Human Subjects*.

SBE Refresher 1 – Informed Consent

This module is a Biomedical refresher on *Informed Consent*.

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SBE Refresher 1 – Assessing Risk

This module is a Biomedical refresher for *Assessing Risk*.

SBE Refresher 1 – Privacy and Confidentiality

This module is a Biomedical refresher on *Privacy and Confidentiality.*

SBE Refresher 1 – Research with Prisoners

This module is a Biomedical refresher on *Research with Prisoners.*

SBE Refresher 1 – Research with Children

This module is a Biomedical refresher on *Research with Children.*

SBE Refresher 1 – Research in Educational Settings

This module is a Biomedical refresher for *Research in Educational Settings*.

SBE Refresher 1 – International Research

This module is a Biomedical refresher for *International Research.*

Human Subjects Research – Social-Behavioral-Educational (SBE) Refresher 2

This course provides of summaries of the important concepts for each module in the *Human Subjects Research – Social-Behavioral-Educational (SBE)* track. It is to be completed after the *SBE Refresher 1* course. In order to receive credit for the course, a learner must complete all of the modules listed below.

Continuing Education (CE) Credits and Units

View **CE credits, credit designation periods, and fees** for this course.

Module Title	Recommended Use	ID (Language)
SBE Refresher 2 – History and Ethical Principles	Required	12702 (English)
SBE Refresher 2 – Federal Regulations for Protecting Research Subjects	Required	15040 (English)
SBE Refresher 2 – Defining Research with Human Subjects	Required	15038 (English)
SBE Refresher 2 – Informed Consent	Required	12620 (English)
SBE Refresher 2 – Assessing Risk	Required	12624 (English)
SBE Refresher 2 – Privacy and Confidentiality	Required	12622 (English)
SBE Refresher 2 – Research with Prisoners	Required	12627 (English)
SBE Refresher 2 – Research with Children	Required	15043 (English)
SBE Refresher 2 – Research in the Public Schools	Required	15042 (English)
SBE Refresher 2 – International Research	Required	15045 (English)

SBE Refresher 2– History and Ethical Principles

This module is a SBE refresher for *History and Ethical Principles*.

SBE Refresher 2 – Federal Regulations for Protecting Research Subjects

This module is a SBE refresher on *Federal Regulations for Protecting Research Subjects*.

SBE Refresher 2 – Defining Research with Human Subjects

This module is a SBE refresher for *Defining Research with Human Subjects*.

SBE Refresher 2 – Informed Consent

This module is a Biomedical refresher on *Informed Consent*.

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SBE Refresher 2 – Assessing Risk

This module is a Biomedical refresher for *Assessing Risk*.

SBE Refresher 2 – Privacy and Confidentiality

This module is a Biomedical refresher on *Privacy and Confidentiality.*

SBE Refresher 2 – Research with Prisoners

This module is a Biomedical refresher on *Research with Prisoners*.

SBE Refresher 2 – Research with Children

This module is a Biomedical refresher on *Research with Children*.

SBE Refresher 2 – Research in Educational Settings

This module is a Biomedical refresher for *Research in Educational Settings*.

SBE Refresher 2 – International Research

This module is a Biomedical refresher for *International Research*.

Additional Courses

Institutional/Signatory Official: HSR Course

This course provides a general introduction for institutional officials (IOs) in a variety of organizations – biomedical, behavioral, social sciences, and others, as well as a variety of organizational structures – academic medical centers, colleges and universities, independent IRBs, research sites, and others. It introduces the learner to the roles and responsibilities of the IO, including the regulatory role and expectations, obligations imposed on the organization by the Federalwide Assurance (FWA), and functions that are part of the human research protections program (HRPP). For recommendations on how to use this course, see the **Using CITI Program Content: Human Subjects Research (HSR)** document.

Module Title	Recommended Use	ID (Language)
Introduction to Being an Institutional Official (IO)	Required	16640 (English)
IO Knowledge Requirements: Human Subject Protections	Required	16641 (English)
Expectations of the IO	Required	16642 (English)
Challenges of Being an IO: Human Subject Protections	Required	16643 (English)

Introduction to Being an Institutional Official (IO)

This module focuses on general administrative topics that are defined/controlled by each organization. These administrative topics include: who in the organization has the authority to appoint/name the IO, functions that are part of the HRPP, and typical IO duties. This module also covers IO leadership topics including: communication, evaluation, resource allocation, delegating authority, and succession planning.

IO Knowledge Requirements: Human Subject Protections

This module focuses on the federal regulations for human subject research, the ethical principles relevant to research, and the current model for structuring portions of an organization that play a role in research involving human subjects. It contains some specific "need-to-know" areas for the institutional official including functions that are part of the HRPP, the role of the IRB, the major ethical principles for human subjects research, and the regulatory expectations for research organizations.

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Expectations of the IO

This module focuses on the role of the IO and what federal regulators expect to be within the scope of those duties. It presents some techniques that have been successfully used by others and ways the IO can promote an organizational culture of respect, commitment, caring, and compliance. The required communications with the federal officials are also examined, as well as the processes that are part of the FDA's Human Subject Protection/Bioresearch Monitoring (HSP/BIMO) Initiative. Finally, the role of an internal quality improvement (QI) program and how it fits into the HRPP is explained.

Challenges of Being an IO: Human Subject Protections

This module focuses on the IO as the designated leader of the HRPP. It examines the executive role of the IO in the HRPP, provides some effective techniques and strategies for fostering organizational communication and improving its effectiveness, and describes ways in which the IO can assist the function of key parts of the HRPP. The IO's role is examined in promoting an organizational culture of respect, commitment, caring, and compliance, and seeking to continually improve the quality of services the organization delivers while protecting subjects of research.

IRB Chair Course

This course is intended for current and future chairs of Institutional Review Boards (IRBs). It provides detailed training in regards to their role and responsibilities, meeting responsibilities, and role outside of the IRB meeting. For recommendations on how to use this course, see the **Using CITI Program Content: Human Subjects Research (HSR)** document.

Continuing Education (CE) Credits and Units

View **CE credits, credit designation periods, and fees** for this course.

Module Title	Recommended Use	ID (Language)
Role and Responsibilities of an IRB Chair	Required	15386 (English)
IRB Chair Meeting Responsibilities	Required	15387 (English)
The IRB Chair's Role Outside of the IRB Meeting	Required	15388 (English)

Role and Responsibilities of an IRB Chair

This module describes the qualifications of an IRB chair, expectations, and time commitments often associated with being an IRB chair, and the relationship between the IRB chair and IRB administrator. It also presents the ethical principles, regulations, and policies and procedures that affect the IRB and the role of its chair.

IRB Chair Meeting Responsibilities

This module details the critical areas related to preparation for the IRB meeting, the responsibilities associated with running an IRB meeting, and the activities and procedures that occur after a convened meeting.

The IRB Chair's Role Outside of the IRB Meeting

This module explains the additional duties required of an IRB chair outside of the convened meeting, the role of a chair in making expedited reviewer designations, unanticipated problems and the role of an IRB chair, and suspensions and terminations of approved research.