



Using CITI Program Content: Human Subjects Research (HSR)

CONTENT AUTHOR

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INTRODUCTION

The HSR series is CITI Program’s longest running curriculum, developed as a groundbreaking collaboration among ten institutions in order to meet the pressing need for human subjects protections training for researchers, staff, Institutional Review Boards (IRBs), and other members of organizational communities where research with human subjects occurs.

Like all CITI Program educational materials, the components of the HSR series can be customized to meet the specific needs of your organization’s learners. Taking advantage of this flexibility requires that you are familiar with the CITI Program’s HSR content offerings and with the capabilities of the CITI Program’s web platform to deliver them. This module addresses the components of the HSR series. For general information on the CITI Program’s instructional capabilities, see [Using CITI Program Content: An Introduction](#).

LEARNING OBJECTIVES

By the end of this module, you should be able to:

- Identify the structure of the CITI Program’s HSR series and how the series components can be customized to meet the needs of your organization’s learner groups.
- Determine how to access the HSR series based on organization-wide or individual needs.
- Determine if other CITI Program content, available from the Responsible Conduct of Research (RCR) series or Good Clinical Practice (GCP) series, is more suitable for some of your learner group(s) as an alternative or in addition to the HSR content.
- Specify the set up of suitable HSR content for your organization’s learner groups.
- Obtain additional information on the HSR series from the [HSR Catalog](#), Help Desk Staff, and Sales Group.

HSR SERIES OVERVIEW

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; Refresher Stage 2: 6 years after completion]).

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.

Basic Courses

- **Basic Biomedical (Biomed) Modules**

- Belmont Report and CITI Course Introduction
- History and Ethics of Human Subjects Research
- Basic Institutional Review Board (IRB) Regulations and Review Process
- Informed Consent
- Social and Behavioral Research (SBR) for Biomedical Researchers
- Records-Based Research
- Genetic Research in Human Populations
- Populations in Research Requiring Additional Considerations and/or Protections
- Vulnerable Subjects – Research Involving Prisoners
- Vulnerable Subjects – Research Involving Children
- Vulnerable Subjects – Research Involving Pregnant Women, Human Fetuses, and Neonates
- Avoiding Group Harms – U.S. Research Perspectives
- Avoiding Group Harms – International Research Perspectives
- FDA-Regulated Research
- Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research
- Research and HIPAA Privacy Protections

- **Basic Social-Behavioral-Educational (SBE) Modules**
 - Belmont Report and CITI Course Introduction
 - History and Ethical Principles – SBE
 - Defining Research with Human Subjects – SBE
 - The Federal Regulations – SBE
 - Assessing Risk – SBE
 - Informed Consent – SBE
 - Privacy and Confidentiality – SBE
 - Research with Prisoners – SBE
 - Research with Children – SBE
 - Research in Public Elementary and Secondary Schools – SBE
 - International Research – SBE
 - Internet-Based Research – SBE
 - Unanticipated Problems and Reporting Requirements in Social and Behavioral Research

- **Additional Modules of Interest**
 - Modules of Interest
 - Are You Thinking About Being in a Research Study?
 - Cultural Competence in Research
 - Conflicts of Interest in Research Involving Human Subjects
 - Hot Topics
 - Humanitarian Use Devices (HUDs)
 - International Studies
 - Clinical Trial Agreement (CTA) Modules
 - Overview of the Clinical Trial Agreement (CTA)
 - Understanding the Terms of the Clinical Trial Agreement (CTA)
 - Role of the Researcher and Site in Managing the Clinical Trial Agreement (CTA)
 - Clinical Trial Agreement (CTA) Negotiation for Researchers and Sites
 - Community-Engaged Research Modules
 - Introduction to Community-Engaged Research (CEnR)
 - Introduction to Community-Based Participatory Research (CBPR)
 - Ethical and Practical Considerations in Community-Engaged Research (CEnR)
 - Consent Modules
 - Consent and Biobanks and Associated Databases
 - Consent and Cultural Competence
 - Informed Consent and Incidental Findings in Research with Human Subjects
 - Consent and Subject Recruitment Challenges: Remuneration
 - Consent and Subject Recruitment Challenges: Therapeutic Misconception (TM)
 - Consent in the 21st Century
 - Consent Tools Used in Research
 - Consent with Subjects Who Do Not Speak English

- IRB-Focused Modules
 - External IRB Review
 - I Have Agreed to be an IRB Community Member. Now What?
 - The IRB Administrator’s Responsibilities
 - The IRB Member Module – “What Every New IRB Member Needs to Know”
- Phase I Research Modules
 - Phase I Research: Understanding Phase I Research
 - Phase I Research: Protecting Phase I Subjects
- Population-Specific Modules
 - Gender and Sexuality Diversity (GSD) in Human Research
 - Illegal Activities or Undocumented Status in Human Research
 - Research Involving Subjects at the End of Life
 - Research with Critically Ill Subjects
 - Research with Decisionally Impaired Subjects
 - Research with Older Adults
 - Research with Persons who are Socially or Economically Disadvantaged
 - Research with Subjects with Physical Disabilities & Impairments
 - Students in Research
 - Vulnerable Subjects – Research Involving Workers/Employees
- Stem Cell Research Modules
 - Stem Cell Research Oversight (Part I)
 - Stem Cell Research Oversight (Part II)

Refresher Courses (See the [HSR Catalog](#) for a detailed list of each set of refresher modules)

- Biomedical (Biomed) Refresher 1 Modules
- Biomedical (Biomed) Refresher 2 Modules
- Biomedical (Biomed) Refresher 3 Modules
- Social-Behavioral-Educational (SBE) Refresher 1 Modules
- Social-Behavioral-Educational (SBE) Refresher 2 Modules

Institutional/Signatory Official: Human Subject Research Course

- **Institutional/Signatory Official Modules**
 - Introduction to Being an Institutional Official (IO)
 - IO Knowledge Requirements: Human Subject Protections
 - Expectations of the IO
 - Challenges of Being an IO: Human Subject Protections

IRB Chair Course

- **IRB Chair Modules**
 - Role and Responsibilities of an IRB chair
 - IRB Chair Meeting Responsibilities
 - The IRB Chair's Role Outside of the IRB Meeting

SUBSCRIPTION OPTIONS

HSR series subscriptions are available to both organizations and independent learners. Review the information on the following page to help determine which option best meets your current needs. To discuss these options in further detail, please contact sales@citiprogram.org.

Organization Subscription

HSR series access is included within the CITI Program base subscription fee. Organization access allows for unlimited learner use (per site), designated administrative oversight, and the flexibility to use the courses in a number of different ways as discussed in the next section.

Independent Learner Subscription

The HSR series is available to independent learners for \$110/course. Independent learner access is intended for those not affiliated to an organization that subscribes to the CITI Program or whose organization does not offer the HSR series.

SELECTING MODULES FOR YOUR ORGANIZATION'S LEARNERS

For the HSR series, the CITI Program offers the following options on how modules are presented to learners.

- **Required:** A module that must be taken by the learner in order to earn a Completion Report.
- **Elective:** A module that is associated with a set of other **Elective** modules. Learners select and complete a specified minimum number of electives from the set in order to earn a Completion Report. For example, if a learner group is required to complete three **Elective** modules, and five choices are presented, then completing any three of the five modules will allow the learner to move forward.
- **Supplemental:** A module that becomes available to the learner after completing any applicable **Required** and **Elective** modules. A learner may review **Supplemental** modules on a voluntary basis.

The selection of **Required**, **Elective**, and **Supplemental** is entirely at the discretion of your organization. Although, there must be at least one **Required** module for each learner group.

It is important to note that organizations may also develop customized organization-specific content to supplement the training. Organizations then work with the CITI Program to develop modules that are included in learner groups for seamless delivery to learners.

Organizations may choose to create separate HSR learner groups containing only the HSR modules in any combination as noted above. Alternatively, organizations may add the HSR modules to existing learner groups. A combination of both a HSR-specific learner group and inclusion of HSR modules in existing learner groups is yet a third option for organizations.

In keeping with the options above, the CITI Program can assist administrators in creating courses (learner groups) that best meet their organizational needs, including utilizing modules from across the CITI Program. To discuss course recommendations that combine modules from different CITI Program offerings, please contact the Help Desk at support@citiprogram.org or (888) 529-5929.

LEARNER GROUPS

The creation of learner groups for your organization is a key part of the set up process. While the CITI Program affords organizations multiple ways of forming learner groups, it offers organizations the opportunity to select pre-determined learner groups or “set-ups.” For example, a basic course learner group for biomedical researchers might reflect the following set-up:

University of Great States – Biomedical Researchers Learner Group

Required Modules

- Belmont Report and CITI Course Introduction
- History and Ethics of Human Subjects Research
- Basic Institutional Review Board (IRB) Regulations and Review Process
- Informed Consent
- Social and Behavioral Research (SBR) for Biomedical Researchers
- Records-Based Research
- Genetic Research in Human Populations
- Populations in Research Requiring Additional Considerations and/or Protections
- Vulnerable Subjects – Research Involving Children
- FDA-Regulated Research
- Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research
- Research and HIPAA Privacy Protections
- Conflicts of Interest in Research Involving Human Subjects
- Vulnerable Subjects – Research Involving Workers/Employees

Elective Modules (Learner must complete at least one)

- Avoiding Groups Harms – U.S. Research Perspectives
- Avoiding Group Harms – International Research Perspectives

Supplemental Modules

- Modules of Interest
 - Are You Thinking About Being in a Research Study?
 - Cultural Competence in Research
 - Hot Topics
 - Humanitarian Use Devices (HUDs)
 - International Studies
- Clinical Trial Agreement (CTA) Modules
 - Overview of the Clinical Trial Agreement (CTA)
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 - Consent with Subjects Who Do Not Speak English
- IRB-Focused Modules
 - External IRB Review
- Phase I Research Modules
 - Phase I Research: Understanding Phase I Research
 - Phase I Research: Protecting Phase I Subjects
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 - Research with Subjects with Physical Disabilities & Impairments
 - Students in Research
 - Vulnerable Subjects – Research Involving Pregnant Women, Fetuses, and Neonates
 - Vulnerable Subjects – Research Involving Prisoners

- Stem Cell Research Modules
 - Stem Cell Research Oversight (Part I)
 - Stem Cell Research Oversight (Part II)

The CITI Program contains “set-ups” for other groups such as SBE researchers, Biomedical Data or Specimens Only Researchers, and IRB Members. To discuss course recommendations, please contact the CITI Program Help Desk at (888) 529-5929 or support@citiprogram.org.

INDEPENDENT LEARNERS

For a listing of HSR courses available to independent learners, see the [Independent Learner Course Guide](#).

RETRAINING FREQUENCY

There is not one uniform standard regarding how frequently HSR training should occur. However, it has been our experience that most organizations select a three-year period of retraining. CITI Program’s HSR refresher courses allow organizations an endless number of options when it comes to developing content to meet their retraining needs, including different timings between basic and refresher course stages depending on the learner group.

TRAINING METHODS

The CITI Program offers content in several different areas. A number of organizations have found it helpful to supplement their HSR training with modules from some of these series in order to meet organizational training objectives. For example, the RCR series focuses on research ethics across a number of different areas, which has meshed well with a more detailed discussion of ethics and regulations associated with human subjects research. For organizations with researchers who may also be involved in clinical trials of drugs, biologics, or devices, presenting the GCP modules as supplemental for an HSR learner group, has been helpful in meeting the needs of a select group of individuals within the organization’s community.

There is not a uniform standard regarding the methods and format used for HSR training. CITI Program content is designed to be a component of an overall foundation of training for an organization's affiliates. We recommend that organizations build frameworks of training that combine CITI Program content with face-to-face training, one-on-one mentoring, and other types of learning opportunities, as appropriate to the particular topics and their organizational cultures.

LANGUAGE AVAILABILITY

At the present time, the CITI Program’s entire HSR series is available in English. In addition, most of the modules are available in Spanish. A select number of modules are also available in French, Chinese, Portuguese, Korean, Khmer, Russian, Tamil, and Vietnamese. See the [HSR Catalog](#) for more details regarding language availability.

CONTINUING EDUCATION (CE) CREDITS

Detailed information regarding CMEs/CEUs is available in the [HSR Catalog](#) or on the [CITI Program website](#). For more information on how to ensure CE availability for your organization's learners contact support@citiprogram.org or (888) 529-5929.

SUMMARY

The HSR series is highly customizable and commonly used to help meet organizational training requirements, particularly when funding agencies also require evidence of human subjects training. Many organizational administrators have found it helpful to visit the CITI Program's website at least annually to review current course offerings and to consider these in light of the organization's previously selected options. The CITI Program's Help Desk is experienced with all of its curricular series, including HSR, and can assist you in configuring content for your learners. Contact the Help Desk at support@citiprogram.org or (888) 529-5929.

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