



Using CITI Program Content: Conflicts of Interest (COI)

CONTENT AUTHOR

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INTRODUCTION

Like all CITI Program educational materials, the components of the COI 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 COI series and with the capabilities of the CITI Program's web platform to deliver it. This module addresses the components of the COI 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 COI series and how it can be customized to meet the needs of your organization's learners.
- Determine if other CITI Program COI content, available from the *Human Subjects Research* (HSR) series or the *Responsible Conduct of Research* (RCR) series, is more suitable for some of your learners as an alternative to the COI series.
- Determine how to access the COI series based on organization-wide or individual needs.
- Specify the set up of a suitable COI curriculum for the learner groups at your organization.
- Obtain additional information on the COI series from the [COI Catalog](#), Help Desk staff and Sales Group.

COI BASIC COURSE OVERVIEW

The *COI Basic* course contains five modules:

- **Basic Module 1:** Financial Conflicts of Interest: Overview, Investigator Responsibilities, and COI Rules
- **Basic Module 2:** Institutional Responsibilities as They Affect Investigators
- **Basic Module 3:** Organization-Specific Policies*
- **Basic Module 4:** Conflicts of Commitment and Conscience
- **Basic Module 5:** Institutional Conflicts of Interest**

The *COI Basic* course is specifically designed to help learners satisfy the training requirements associated with the U.S. Public Health Service (PHS) regulations on financial conflicts of interest.

* As a part of the *COI Basic* course, your organization has the option of creating **Basic Module 3**, which will provide learners with information about your organization's internal COI policies. If you wish to include this module, a representative from your organization will need to fill out the **COI Basic Custom Module Form**. The form will help populate the module with your organization-specific content. A fee applies for the creation of this customized module.

** The Institutional Conflicts of Interest module is primarily designed for administrators.

COI REFRESHER COURSE OVERVIEW

The *COI Refresher* course includes five modules:

- **Refresher Module 1:** Conflicts of Interest and the PHS Regulations
- **Refresher Module 2:** Significant Financial Interests
- **Refresher Module 3:** Institutional Obligations as They Affect Investigators
- **Refresher Module 4:** COI Management and Noncompliance
- **Refresher Module 5:** Organization-Specific Module*

The *COI Refresher* course is specifically designed for learners who need retraining on key concepts and rules related to the U.S. PHS regulations on financial conflicts of interest. The course is primarily tailored to investigators who receive funding from a PHS agency or who are required by their organization to be familiar with PHS regulations.

* As a part of the *COI Refresher course*, your organization has the option of creating **Refresher Module 5**, which can help to retrain learners about your organization's internal COI policies. If you wish to include this module, a representative from your organization will need to fill out the **COI Refresher Custom Module Form**. The form will help populate the module with your organization-specific content. A fee applies for the creation of this customized module. Alternatively, if your organization already has a basic level Organization-Specific Module and prefers to use it for the *COI Refresher* course as well, then setting up a new module is not needed.

SUBSCRIPTION OPTIONS

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

Organization Subscription

COI 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

COI courses are 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 COI series.

SELECTING MODULES FOR YOUR ORGANIZATION'S LEARNERS

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

- **Required:** A **Required** 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 Supplemental module becomes available to the learner after completing any applicable **Required** and **Elective** modules. A learner may review **Supplemental** modules on a voluntary basis.

Organizations can select which modules are **Required**, **Elective**, or **Supplemental**. However, 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 COI learner groups containing only the COI modules in any combination as noted above. Alternatively, organizations may add the COI modules to existing learner groups. A combination of both a COI-specific learner group and inclusion of COI modules in existing learner groups is another option for organizations.

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.

COI Basic Course Recommendation

The standard recommendation is to designate **COI Basic Course Modules 1, 2, and 3 (if applicable)** as being **Required** and to make **Basic Modules 4 and 5 Supplemental**. Basic Module 5 is primarily designed for organizational administrators.

COI Refresher Course Recommendation

The standard recommendation is to designate **COI Refresher Course Modules 1, 2, 3, and 4** as being **Required** and to make **Basic Module 5 Supplemental**.

INDEPENDENT LEARNERS

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

RETRAINING FREQUENCY

There is not one uniform standard regarding how frequently COI training should occur. However, NIH-funded investigators have specific COI training requirements. Regarding the PHS regulations on financial conflicts of interest, investigators “must complete training prior to engaging in NIH-funded research and at least every four years, and immediately under the designated circumstances” (NIH 2015).

OTHER CITI PROGRAM COI CONTENT

CITI Program offers content on COI in its HSR series and in its RCR series. The *COI Basic* course described in this document is the recommended training content for individuals who are subject to the PHS regulations. However, organizations may also wish to require COI training for researchers who do not have NIH funding.

COI content in the HSR series may be more suitable for researchers who work with human subjects but are not necessarily subject to training requirements contained within the PHS regulations. COI content in the RCR series may be more suitable for beginning researchers or those who are not conducting human subjects research. For more information, refer to the [HSR Catalog](#) and/or [RCR Catalog](#).

TRAINING METHODS

There is not a uniform standard regarding the methods and format used for COI 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

English.

CONTINUING EDUCATION (CE) CREDITS

Detailed information regarding CMEs/CEUs is available in the [COI 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 COI series is highly customizable and commonly used to help meet the COI training requirements of funding agencies such as the NIH. CITI Program's Help Desk is experienced with all of its curricular series, including COI, and can assist you in configuring content for your learners. Contact the Help Desk at support@citiprogram.org or (888) 529-5929.

REFERENCES

National Institutes of Health (NIH). 2015. "[Frequently Asked Questions: Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought \(42 CFR Part 50 Subpart F\) applicable to grants and cooperative agreements \(2011 Revised Regulations\)](#)." Accessed March 2, 2016.

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