

Human Subjects Research Training via CITI



You will first complete Dartmouth-Hitchcock Health's requirements. You will then complete a few additional modules to satisfy Dartmouth College's requirements. Upon completion of each organization's requirements, you will submit your Completion Certificates to Student Affairs (Geisel.Student.Research@dartmouth.edu).

Average time required to complete courses:

- Human Subjects Research (HSR): 4-6 hours
- Responsible Conduct of Research (RCR): 4-6 hours
- Good Clinical Practice (GCP) with FDA Focus: 4-6 hours
- Conflict of Interest (COI): 30 minutes

You do not have to complete the courses, or modules within a course, in one session. You may leave and come back to the site using your CITI username and password. A minimum aggregate score of 80% within each course is required to pass the course.

Your certification is valid for three years. At expiration, you will need to complete refresher modules in order to maintain certification.

Establish CITI Account and Affiliation

Go to <https://citiprogram.org>

If you are a new CITI user:

1. Click 'Register' in the upper right
2. Select an affiliation: begin typing 'Dartmouth' and select 'Dartmouth-Hitchcock Health' from the list

A screenshot of the CITI Program website's "Select Your Organization Affiliation" form. The form has a title bar "Select Your Organization Affiliation". Below the title bar, there is a red text instruction: "This option is for persons affiliated with a CITI Program subscriber organization." Below that, a grey text instruction says: "To find your organization, enter its name in the box below, then pick from the list of choices provided." There is a search input box containing the text "Dartmouth". Below the input box, a dropdown menu is open, showing four options: "Dartmouth College", "Dartmouth-Hitchcock Health", and "University of Massachusetts Dartmouth".

3. Agree to the terms and affirm that you are affiliated with D-HH
4. Click 'Create a CITI Program account'
5. Continue through the account creation steps

If you are an existing CITI user:

1. Log in to your account
2. In the upper right, click your username and choose 'Profiles' from the drop-down menu

3. In the 'Institutional Profiles' section, click the 'Add An Affiliation' button
4. On the 'Affiliate with an Institution' page, begin typing 'Dartmouth' and select 'Dartmouth-Hitchcock Health' from the list
5. Agree to the terms and affirm that you are affiliated with D-HH
6. Click 'Continue'
7. Fill in and submit the form

Enroll in and Complete Dartmouth-Hitchcock Health modules

When logged in and associated with D-HH, select your curriculum as follows (example screen shot below):

- Q1 – Human Subjects Research (HSR): “Biomedical Research Investigators”
- Q2 – Good Clinical Practice (GCP): “GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)”
- Q3 – Responsible Conduct of Research (RCR): “Biomedical Responsible Conduct of Research”
- Q4 – Conflicts of Interest (COI): “Yes”

CITI - Learner Registration - Dartmouth-Hitchcock Health

Steps : [1](#) [2](#) [3](#) [4](#) [5](#) [6](#) **7**

Select Curriculum

* indicates a required field.

You will be provided a series of enrollment questions. Your responses will determine the curriculum for the courses you are going to take. Please read the questions carefully. Please read the responses carefully to make the best choice.

Question 1

Human Subjects Research (HSR)

Please choose one learner group below based on your role and the type of human subjects activities you will conduct. You will be enrolled in the Basic Course for that group.

Choose one answer

Biomedical Research Investigators: Choose this group to satisfy CITI training requirements for Investigators and staff involved primarily in Biomedical research with human subjects.

Social & Behavioral Research Investigators: Choose this group to satisfy CITI training requirements for Investigators and staff involved primarily in Social and Behavioral research with human subjects.

Research with data or laboratory specimens- ONLY: No direct contact with human subjects.

IRB Members: This Basic Course is appropriate for IRB or Ethics Committee members.

Not at this time.

Complete all required modules within each of the four courses (see Appendix A for a detailed list).

Enroll in and Complete Dartmouth College modules

In this step you will complete only those DC-required modules that are not included in the D-HH requirements

Add Dartmouth College affiliation within your CITI profile:

1. In the upper right, click your user name and choose 'Profiles' from the drop-down menu.
2. In the 'Institutional Profiles' section, click the 'Add An Affiliation' button
3. On the 'Affiliate with an Institution' page, begin typing 'Dartmouth' and select 'Dartmouth College' from the list
4. Agree to the terms and affirm that you are affiliated with Dartmouth College
5. Click 'Continue'
6. Fill in and submit the form

Add your Dartmouth College courses:

On the 'Select Curriculum' pages, make the following selections:

- Q1 – Course Selection
 - Human Subjects Research – Basic Courses
 - Good Clinical Practice
 - Conflict of Interest
 - Responsible Conduct of Research
- Q3 – Human Subjects Research
 - Group 1 – Biomedical Research
- Q6 – Good Clinical Practice
 - Good Clinical Practice for MOST categories...
- Q8 – Conflict of Interest
 - The Basic Course
- Q9 – Responsible Conduct of Research
 - Responsible Conduct of Research (RCR-Basic)

Access the five modules required by Dartmouth College that are not included in the D-HH requirements (see Appendix B for detailed list):

1. Click on 'My Courses' in the top navigation bar
2. In the 'Institutional Courses' section, click on 'View Courses' next to 'Dartmouth College'
3. Modules you completed through your D-HH (and any other) affiliation should appear as complete within your Dartmouth College list
4. Navigate to the modules you still need to complete (see Appendix B)

Complete all required modules (see Appendix B for a detailed list).

Submit Completion Certificates to Geisel Student Affairs

1. Download the Completion Certificate for each required course (4 D-HH, 3 DC)
2. Email the PDFs to Student Affairs: Geisel.Student.Research@dartmouth.edu

Appendix A: Dartmouth-Hitchcock Health Required Modules

Dartmouth-Hitchcock Health Required Modules

(* indicates a module is required by D-HH but not required by DC)

Please note: If you have previously completed modules within CITI through another affiliation, any modules that match D-HH's requirements should appear as completed within the respective course(s) through your D-HH affiliation.

Human Subjects Research (HSR) – Biomedical Research Basic Course (also referred to as 'IRB Courses')

Required Modules

- Conflicts of Interest in Human Subjects Research (ID: 17464)
- Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)
- Informed Consent (ID: 3)
- Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)
- Records-Based Research (ID: 5)
- Genetic Research in Human Populations (ID: 6)
- FDA-Regulated Research (ID: 12)
- Research and HIPAA Privacy Protections (ID: 14)
- Vulnerable Subjects – Research Involving Workers/Employees (ID: 483)
- Research Involving Children (ID: 9)*
- History and Ethics of Human Subjects Research (ID: 498)
- Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777)
- Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)

Elective Modules (1 Required; user's choice)

- Avoiding Group Harms – U.S. Research Perspectives (ID: 14080)
- Avoiding Group Harms – International Research Perspectives (ID: 14081)

Biomedical Responsible Conduct of Research (RCR)

Required Modules

- Authorship (RCR-Basic) (ID: 16597)
- Collaborative Research (RCR-Basic) (ID: 16598)
- Conflicts of Interest (RCR-Basic) (ID: 16599)
- Data Management (RCR-Basic) (ID: 16600)
- Mentoring (RCR-Basic) (ID: 16602)
- Peer Review (RCR-Basic) (ID: 16603)
- Research Misconduct (RCR-Basic) (ID: 16604)
- Introduction to RCR (RCR-Basic) (ID: 17009)
- Research Involving Human Subjects (RCR-Basic) (ID: 13566)*
- Plagiarism (RCR-Basic) (ID: 15156)

Conflict of Interest (COI)

Required Modules

- Financial Conflicts of Interest: Overview, Investigator Responsibilities, and COI Rules (COI-Basic) (ID: 15070)
- Institutional Responsibilities as They Affect Investigators (COI-Basic) (ID: 15072)

Good Clinical Practice (GCP) with FDA Focus*

Required Modules

- The CITI Good Clinical Practice Course for Clinical Trials Involving Drugs and Devices (ID: 1350)
- Overview of New Drug Development (ID: 1351)
- Overview of ICH GCP (ID: 1352)
- ICH – Comparison Between ICH GCP E6 and U.S. FDA Regulations (ID: 1354)
- Conducting Investigator-Initiated Studies According to FDA Regulations and GCP (ID: 1355)
- Investigator Obligations in FDA-Regulated Research (ID: 1356)
- Managing Investigational Agents According to GCP Requirements (ID: 1357)
- Overview of U.S. FDA Regulations for Medical Devices (ID: 1358)
- Informed Consent in Clinical Trials of Drugs, Biologics, and Devices (ID: 1359)
- Detecting and Evaluating Adverse Events (ID: 1360)
- Reporting Serious Adverse Events (ID: 1361)
- Monitoring of Clinical Trials by Industry Sponsors (ID: 1362)
- Audits and Inspections of Clinical Trials (ID: 1363)
- Completing the CITI GCP Course (ID: 1364)

Appendix B: Additional Dartmouth College Required Modules

Dartmouth College Required Modules that are not included in D-HH requirements

Human Subjects Research (HSR) – Biomedical Research Basic Course (also referred to as ‘IRB Courses’)

Required Modules

- Cultural Competence in Research (ID: 15166)
- Belmont Report and Its Principles (ID: 1127)
- Dartmouth College (ID: 567)

Elective Modules (2 Required; must complete the one you didn’t select in D-HH training)

- Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)
- Avoiding Group Harms - International Research Perspectives (ID: 14081)

Biomedical Responsible Conduct of Research (RCR)

Required Modules

- Reproducibility of Research Results (ID: 17756)