National Institutes of Health (NIH) GCP Training Requirements

Effective January 1, 2017, NIH requires all funded investigators and staff who are involved in the conduct, oversight or management of clinical trials be trained in Good Clinical Practice (see NIH Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials). This policy applies to all currently funded as well as future clinical trials. Investigators are not required to retake GCP training during their study (unless required by local regulation or by their sponsor).

NIH defines a clinical trial as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. See https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html.

The individual responsible for the conduct of the clinical trial at a trial site is the investigator. If a clinical trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

Individuals, identified by the investigator, who are responsible for study coordination, data collection, and data management, are clinical trial staff. Clinical trial staff manage participant recruitment and enrollment, maintain consistent study implementation, data management, and ensure integrity and compliance with regulatory and reporting requirements. These individuals may also seek informed consent from prospective participants, enroll and meet with research participants, and collect and record information from research participants. Clinical trial staff may also be called the research coordinator, study coordinator, research nurse, study nurse or sub-investigator.

GCP training is available for investigators and clinical trial staff through NYU’s CITI program. NIDA’s National Drug Abuse Clinical Trials Network also provides good clinical practice training here: https://gcp.nihtraining.com/ as does the National Institute of Allergy and Infectious Diseases: https://gcplearningcenter.niaid.nih.gov/Pages/default.aspx

Investigators who choose to take the NIDA or NIAID course will be required to maintain their certification.

If you have any questions about registering for CITI or completing this training, please contact Alison Dewhurst at 212 998-2116 or by email at ad105@nyu.edu.
HOW TO REGISTER AND TAKE THE NYU CITI GCP COURSE

1. Log into your CITI account
2. At the Main Menu, choose New York University Courses
3. Scroll down to “My Learner Tools for New York University,” and click on “Add a course.”
4. Under “Select Curriculum,” answer the questions in this manner:

   Question 1: No

   ![Image of Question 1]

   **Conflicts of Interest**
   Would you like to take the Conflicts of Interest course?
   Choose one answer
   - Yes
   - No

   Question 2: Not at this time

   ![Image of Question 2]

   **Human Subjects Research**
   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.
   - IRB Members: This Basic Course is appropriate for IRB or Ethics Committee members.
   - Not at this time.
Question 3: Not at this time

Question 3

CITI US Export Control Regulations course
Please make your selection below to receive the CITI US Export Control Regulations course.
Choose one answer

- CITI Export Controls
- Not at this time.

Question 4: Not at this time

Question 4

Responsible Conduct of Research
Please make your selection below to receive one of the courses in the Responsible Conduct of Research.
Choose one answer

- Short Supplmental Course
- Full International Course
- Neuroscience Research at CNS
- Administrators Course
- Not at this time.

Question 5: Please do NOT check anything in this section

Question 5

Laboratory Animal Research
Do you conduct studies that use Lab animals?

1. If YES, then you must complete the Basic course and the appropriate species specific modules.

2. If you are an IACUC Member you should complete the "Essentials for IACUC Members".

3. Choose the appropriate species specific electives according to your research interests.

Choose all that apply
Question 6: Choose GCP for Clinical Trials with Investigational Drugs/Medical Devices (US FDA Focus) and then Click the SUBMIT button

The GCP Course should show under your New York University Courses. Click on the course title to begin.

You will then see the course requirements. You will need to click on “Complete the Integrity Assurance Statement” before you will be allowed to take the course.
You will need to complete these modules:

### Required Modules

<table>
<thead>
<tr>
<th>Module</th>
<th>Date Completed</th>
<th>Score</th>
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<tbody>
<tr>
<td>The CITI Good Clinical Practice Course for Clinical Trials Involving Drugs and Devices (ID: 1350)</td>
<td>Incomplete</td>
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<tr>
<td>Investigator Obligations in FDA-Regulated Research (ID: 1356)</td>
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<tr>
<td>Informed Consent in Clinical Trials of Drugs, Biologics, and Devices (ID: 1359)</td>
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<td>0/0 (0%)</td>
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<tr>
<td>Overview of New Drug Development (ID: 1351)</td>
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<td>0/0 (0%)</td>
</tr>
<tr>
<td>Overview of ICH GCP (ID: 1352)</td>
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<td>0/0 (0%)</td>
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<tr>
<td>ICH - Comparison Between ICH GCP E6 and U.S. FDA Regulations (ID: 1354)</td>
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<td>0/0 (0%)</td>
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<tr>
<td>Conducting Investigator-Initiated Studies According to FDA Regulations and GCP (ID: 1355)</td>
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<td>0/0 (0%)</td>
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<tr>
<td>Managing Investigational Agents According to GCP Requirements (ID: 1357)</td>
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<td>0/0 (0%)</td>
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<tr>
<td>Overview of U.S. FDA Regulations for Medical Devices (ID: 1358)</td>
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<tr>
<td>Detecting and Evaluating Adverse Events (ID: 1360)</td>
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<tr>
<td>Reporting Serious Adverse Events (ID: 1361)</td>
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<tr>
<td>Audits and Inspections of Clinical Trials (ID: 1363)</td>
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<tr>
<td>Monitoring of Clinical Trials by Industry Sponsors (ID: 1362)</td>
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<tr>
<td>Completing the CITI GCP Course (ID: 1364)</td>
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</table>

There are also supplemental modules. These are optional:

### Supplemental Modules

<table>
<thead>
<tr>
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<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Humanitarian Use Devices (HUE) (ID: 16306)</td>
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<td>0/0 (0%)</td>
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<tr>
<td>Phase I Research: Understanding Phase I Research (ID: 16873)</td>
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<td>0/0 (0%)</td>
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<tr>
<td>Phase I Research: Protecting Phase I Subjects (ID: 16874)</td>
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<td>Overview of the Clinical Trial Agreement (CTA) (ID: 17356)</td>
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<tr>
<td>Understanding the Terms of the Clinical Trial Agreement (CTA) (ID: 17357)</td>
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<td>Role of the Researcher and Site in Managing the Clinical Trial Agreement (CTA) (ID: 17358)</td>
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<td>0/0 (0%)</td>
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<tr>
<td>Clinical Trial Agreement (CTA) Negotiation for Researchers and Sites (ID: 17359)</td>
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<td>0/0 (0%)</td>
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</table>

NOTE: Supplemental modules are provided for general interest only. You DO NOT receive credit for completing these modules.

Once you have completed the course, you can obtain a copy of your course completion certificate. The NYU Administrator also has access to it.