

## OCHIN CITI Program

### Why CITI Program?

The Collaborative Institutional Training Initiative (CITI) Program is a leading provider of research education across the globe. In an effort to establish OCHIN as an independent research institution and to better align with compliance regulations, OCHIN has developed a training course with the help of CITI Program. This program offers users web-based trainings in three areas:

- **Conflicts of Interest (COI)** – This series covers the U.S. Public Health Service (PHS) regulations on financial conflicts of interest and an investigator’s responsibilities relating to the disclosure of “Significant Financial Interests.”
- **Human Subjects Research (HSR)** – This series covers the historical development of human subject’s protections, as well as current information on regulatory and ethical issues. It includes Biomedical and Social-Behavioral-Educational (SBE) tracks. *\*\*Completion of Human Subjects Research from CITI fulfills the NIH requirement.*
- **Responsible Conduct of Research (RCR)** – This series covers core norms, principles, regulations, and rules governing the practice of research.
- **Good Clinical Practice (GCP)** – This series consists of basic and refresher courses that provide essential good clinical practice training for research teams involved in clinical trials of drugs, biologics, and devices.

### Training Requirements

Users are asked to complete the *required* training courses in each module within 30 days of the initial request. A score of 80% is needed on all training courses to be considered passing. To assure that researchers and stakeholders receive regular training in these important areas, and in accordance with best practice standards at many institutions, all courses will expire after three years. OCHIN has designated two groups of learners to better align with role expectations:

- **All Researchers** – This includes anyone who has been named on a project as a Patient Investigator or Clinician Investigator, all OCHIN Research staff, and OCHIN research collaborators.
- **Research Stakeholder** – Patient and Clinician Stakeholders. This includes anyone who is partnering with OCHIN Research in a capacity not listed above (e.g., patient member). The Research Associate (RA) overseeing the proposal/project will select the trainings they need you to complete.

### Already completed CITI training?

If you have already completed CITI trainings for another institution or for an industry clinical trial sponsor, you’ll want to sync your OCHIN account with your other institutional account(s). This will allow you to receive credit for trainings already completed in the CITI Program system. If you are unable to sync your accounts online, please call CITI at 888-529-5929 to manually have the accounts merged. If you need to provide documentation for a completed training to an institution, you can log into your CITI account and click on the *My Reports* tab. OHSU IRB will allow the submission of completed OCHIN programs in lieu of completing OHSU’s programs for these areas.

### Creating and Managing Your Account

Please use the “Navigating CITI Program” guide to access CITI, create your personal account, and affiliate with other organizations.

CITI Modules	All Researchers – Training Courses	Research Stakeholders – Training Course
<p><b>Conflicts of Interest (COI)</b></p>	<p><b>Required:</b></p> <ul style="list-style-type: none"> <li>• Financial Conflicts of Interest</li> <li>• Institutional Responsibilities as They Affect Investigators</li> </ul> <p><b>Supplemental:</b></p> <ul style="list-style-type: none"> <li>• Conflicts of Commitment and Conscience</li> <li>• Institutional Conflicts of Interest</li> </ul>	<p><b>Required:</b></p> <ul style="list-style-type: none"> <li>• Institutional Conflicts of Interest</li> </ul> <p><b>Supplemental:</b></p> <ul style="list-style-type: none"> <li>• Conflicts of Commitment and Conscience</li> <li>• Financial Conflicts of Interest</li> <li>• Institutional Responsibilities as They Affect Investigators</li> </ul>
<p><b>Good Clinical Practice (GCP)</b></p>	<p><b>Required:</b></p> <ul style="list-style-type: none"> <li>• The CITI Good Clinical Practice Course for Clinical Trials Involving Drugs and Devices</li> <li>• Overview of New Drug Development</li> <li>• Overview of ICH GCP</li> <li>• ICH – Comparison Between ICH GCP E6 and U.S. FDA Regulations</li> <li>• Conducting Investigator-Initiated Studies According to FDA Regulations and GCP</li> <li>• Investigator Obligations in FDA-Regulated Research</li> <li>• Managing Investigational Agents According to GCP Requirements</li> <li>• Overview of U.S. FDA Regulations for Medical Devices</li> <li>• Informed Consent in Clinical Trials of Drugs, Biologics, and Devices</li> <li>• Detecting and Evaluating Adverse Events</li> <li>• Reporting Serious Adverse Events</li> <li>• Monitoring of Clinical Trials by Industry Sponsors</li> <li>• Audits and Inspections of Clinical Trials</li> <li>• Completing the CITI GCP Course</li> </ul>	<p><b>Required:</b></p> <ul style="list-style-type: none"> <li>• The CITI Good Clinical Practice Course for Clinical Trials Involving Drugs and Devices</li> </ul> <p><b>Supplemental:</b></p> <ul style="list-style-type: none"> <li>• Overview of New Drug Development</li> <li>• Overview of ICH GCP</li> <li>• ICH – Comparison Between ICH GCP E6 and U.S. FDA Regulations</li> <li>• Conducting Investigator-Initiated Studies According to FDA Regulations and GCP</li> <li>• Investigator Obligations in FDA-Regulated Research</li> <li>• Managing Investigational Agents According to GCP Requirements</li> <li>• Overview of U.S. FDA Regulations for Medical Devices</li> <li>• Informed Consent in Clinical Trials of Drugs, Biologics, and Devices</li> <li>• Detecting and Evaluating Adverse Events</li> <li>• Reporting Serious Adverse Events</li> <li>• Monitoring of Clinical Trials by Industry Sponsors</li> <li>• Audits and Inspections of Clinical Trials</li> <li>• Completing the CITI GCP Course</li> </ul>

CITI Modules	All Researchers – Training Courses	Research Stakeholders – Training Course
<b>Responsible Conduct of Research (RCR)</b>	<p><b>Required:</b></p> <ul style="list-style-type: none"> <li>• Introduction to RCR</li> </ul> <p><b>Supplemental:</b></p> <ul style="list-style-type: none"> <li>• Authorship</li> <li>• Collaborative Research</li> <li>• Conflicts of Interest</li> <li>• Data Management</li> <li>• Peer Review</li> <li>• Research Misconduct</li> <li>• Plagiarism</li> <li>• Research Involving Human Subjects</li> <li>• Research, Ethics, and Society</li> </ul>	<p><b>Required:</b></p> <ul style="list-style-type: none"> <li>• Research, Ethics, and Society</li> </ul> <p><b>Supplemental:</b></p> <ul style="list-style-type: none"> <li>• Introduction to RCR</li> <li>• Collaborative Research</li> <li>• Research Misconduct</li> <li>• Authorship</li> <li>• Data Management</li> <li>• Mentoring</li> <li>• Peer Review</li> <li>• Plagiarism</li> </ul>
<b>Human Subjects Research (HSR)</b>	<p><b>Required:</b></p> <ul style="list-style-type: none"> <li>• History and Ethics of Human Subjects Research</li> <li>• Basic Institutional Review Board (IRB) Regulations and Review Process</li> <li>• Research and HIPAA Privacy Protections</li> </ul> <p><b>Supplemental:</b></p> <ul style="list-style-type: none"> <li>• Assessing Risk</li> <li>• Avoiding Group Harms – International Research Perspectives</li> <li>• Avoiding Group Harms – US Research Perspectives</li> <li>• Consent and Biobanks and Associated Databases</li> <li>• Consent and Subject Recruitment Challenges: Remuneration</li> <li>• Consent in the 21<sup>st</sup> Century</li> <li>• Consent Tools Used in Research</li> <li>• Consent with Subjects Who Do Not Speak English</li> <li>• Cultural Competence in Research</li> <li>• Ethical and Practical Considerations in Community-Engaged Research (CEnR)</li> <li>• FDA-Regulated Research</li> </ul>	<p><b>Required:</b></p> <ul style="list-style-type: none"> <li>• Defining Research with Human Subjects – SBE</li> </ul> <p><b>Supplemental:</b></p> <ul style="list-style-type: none"> <li>• Informed Consent</li> <li>• Avoiding Group Harms – International Research Perspectives</li> <li>• Avoiding Group Harms – US Research Perspectives</li> <li>• Basic Institutional Review Board (IRB) Regulations and Review Process</li> <li>• Consent in the 21<sup>st</sup> Century</li> <li>• Cultural Competence in Research</li> <li>• Ethical and Practical Considerations in Community-Engaged Research (CEnR)</li> <li>• FDA-Regulated Research</li> <li>• Gender and Sexuality Diversity (GSD) in Human Research</li> <li>• Genetic Research in Human Populations</li> <li>• History and Ethics of Human Subjects of Research</li> <li>• Internet-Based Research</li> <li>• Introduction to Community-Based Participatory Research (CBPR)</li> </ul>

<p><b>Human Subjects Research (HSR) Cont'd.</b></p>	<ul style="list-style-type: none"> <li>• Gender and Sexuality Diversity (GSD) in Human Research</li> <li>• Genetic Research in Human Populations</li> <li>• Illegal Activities or Undocumented Status in Human Research</li> <li>• Informed Consent</li> <li>• Internet-Based Research</li> <li>• Introduction to Community-Based Participatory Research (CBPR)</li> <li>• Introduction to Community-Engaged Research</li> <li>• Populations in Research Requiring Additional Considerations and/or Protections</li> <li>• Privacy and Confidentiality (SBE)</li> <li>• Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research</li> <li>• Records-Based Research</li> <li>• Research in Public Elementary and Secondary Schools (SBE)</li> <li>• Research Involving Subjects at the End of Life</li> <li>• Research with Critically Ill Subjects</li> <li>• Research with Older Adults</li> <li>• Research with Subjects with Physical Disabilities and Impairments</li> <li>• Social and Behavioral Research (SBR) for Biomedical Researchers</li> <li>• The Federal Regulations</li> <li>• Unanticipated Problems and Reporting Requirements in Social and Behavioral Research</li> <li>• Vulnerable Subjects – Research Involving Children</li> <li>• Vulnerable Subjects – Research Involving Pregnant Women, Human Fetuses, and Neonates</li> <li>• Vulnerable Subjects – Research Involving Prisoners</li> </ul>	<ul style="list-style-type: none"> <li>• Introduction to Community-Engaged Research</li> <li>• Populations in Research Requiring Additional Considerations and/or Protections</li> <li>• Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research</li> <li>• Records-Based Research</li> <li>• Research and HIPAA Privacy Protections</li> <li>• Research with Decisionally Impaired Subjects</li> <li>• Research with Persons who are Socially or Economically Disadvantaged</li> <li>• Research with Subjects with Physical Disabilities and Impairments</li> <li>• Social and Behavioral Research (SBR) for Biomedical Researchers</li> <li>• Unanticipated Problems and Reporting Requirements in Social and Behavioral Research</li> <li>• Vulnerable Subjects – Research Involving Children</li> <li>• Vulnerable Subjects – Research Involving Pregnant Women, Human Fetuses, and Neonates</li> <li>• Vulnerable Subjects – Research Involving Prisoners</li> </ul>
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*\*Supplemental - These modules are provided for general interest only. You are not required to complete these modules.*