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Clinical Research Coordinator Orientation Manual

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CLINICAL RESEARCH COORDINATOR ORIENTATION MANUAL

INSTRUCTIONS

1. This manual is a guide for orienting/training clinical research coordinators in human subjects research and may be altered to meet specific needs. Optional sign-off columns and evaluation points may also be added or removed along with any additional information that may need to be obtained or added.
    a. Hyperlinks may be accessed by moving the cursor over the link and pressing "Ctrl"+ double right click on the mouse.

2. Training is ideally done under the direction of a trainer within the department, division, or area.

3. If done alone and additional assistance is needed, you are welcome to contact any of the following individuals/areas:

Office/Area	Name	Contact Information
Allergy/Immunology	Tarisa Mantia	tmantia@wustl.edu (314-996-8339)
Cardiology	Kaitlin Moore	Kaitlin.m.moore@wustl.edu (314-273-0830)
Cardiology	Jean Flanagan	jflanaga@wustl.eduail (314-454-7451)
General Surgery	Kristin Geile	geile@wustl.edu (314-286-1506)
Human Research Quality Assurance/Quality Improvement	Andrea Morris	morrisam@wustl.edu (314-747-5525)
Human Research Protection Office	Sarah Fowler-Dixon	sfowler-dixon@wustl.edu (314-747-6861)

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OVERVIEW OF WASHINGTON UNIVERSITY

❑ **Start Date and Shift Times**

Obtain start date to report to work and shift start and end times.

Start date: _____

Start time: _____ End time: _____

❑ **Time Reporting**

Submit time using the WorkDay system accessible with your WUSTL Key: https://one.wustl.edu/. Select Worday Login and click Launch Task. For assistance contact 314-935-WDAYor go to https://myday.wustl.edu.

❑ **Parking**

Obtain a parking pass from Parking Services: https://facilities.med.wustl.edu/services/transportation-parking/

❑ **Wash U Badge(s)**

Obtain a badge from WU Protective Services located in Olin Residence Hall.

❑ **Washington University School of Medicine (WUSM) Handbook**

Review the WUSM Employee Handbook: http://hr.wustl.edu/policies/Pages/default.aspx

Select "Cancel" once site is accessed and the information should pull up.

❑ **WUSTL Key**

This is your unique user ID and password for most WU electronic systems. Call 314-933-3333 for set-up or assistance.

❑ **Human Resources New Employee Orientation**

Attend a New Employee Orientation.

Date Scheduled: _____

❑ **Emergency Response**

Learn the Emergency Response system at WU: 314-362-4357 on medical school campus or 911 on West County, South County, or St. Peters campus

❑ **10-Digit Dialing – Medical Campus**

All 10 digits (area code + number) must be dialed when calling from the Medical School campus.

The above activities were completed.

Trainer's Signature:	Date:
Trainee's Signature:	Date:

GENERAL OFFICE INFORMATION

- ❑ **Orient to Office**

  Office space, furniture, computer, phone, printer(s), fax machine, office supplies, ordering office supplies, restroom, cafeteria, vending machines, physician offices

- ❑ **Assign Mentor and Introduce Co-Workers**

  My mentor is: _____

- ❑ **Provide Keys**
- ❑ **Review Department Organizational Charts**
- ❑ **Review Department Policies**

  Dress code, attendance, reporting illness, absences, scheduling vacation time, computer use, passwords, personal email and internet usage

- ❑ **Orient to Computer and Obtain Appropriate Accesses**

  Email Address: _____
  Computer Name: _____
  Printer Name(s): _____
  Copy Code(s): _____
  Shared Drive(s): _____
  Folder(s): _____
  EMR(s): _____
  Calendar(s): _____
  Other: _____
  _____

- ❑ **Review Phone and Voicemail Instructions**
- ❑ **Obtain Department Specific Username and Password**

  Example: PCF Username and Password for Pediatrics

- ❑ **Review Departmental Standard Operating Procedures (SOPs) (if applicable)**
- ❑ **Order Business Cards and Lab Coat(s)**

  Who to Contact: _____

- ❑ **Scrubs Access and SIS**

  Contact BJH Perioperative Services at 314-362-5584 or email scrubaccess@bjc.org to set this up.

- ❑ **Tour Operating Rooms, Patient Floors, Clinic Areas**
- ❑ **Setup VPN and Remote Access**

  Who to Contact: _____

The above activities were completed.

Trainer's Signature:	Date:
Trainee's Signature:	Date:

REQUIRED EMPLOYEE COMPLIANCE TRAINING

All training is completed through Learn@Work.
You can access Learn@Work by going to https://learnatwork.wustl.edu/.

❑ **Complete the Compliance Profile**

This will provide you with specific trainings based on your role and the research in which you will be involved. If your role changes in the future, you can go back and update the questions by going to My Compliance Profile Summary and retaking the Compliance Profile survey.

Required University Trainings:

- ❑ HIPAA 101
  For more information on HIPAA training visit: https://hipaa.wustl.edu/training/.
- ❑ HIPAA - Appropriate Use of Clinical Systems
  The HIPAA Privacy Office has added a brief module to Learn@Work on Appropriate Use of Clinical Systems. The module takes around 11 minutes to complete and is strongly encouraged for all non-physicians with access to Epic.
  Some departments choose to make this course mandatory.
  The HIPAA Privacy Office can assist in manually assigning the course. If interested, have send the employee's name and employee ID to hipaa@wustl.edu.
- ❑ OPBC – Billing Compliance 101 Initial Training
  For more information on billing compliance education visit: https://sites.wustl.edu/opbc/compliance-education/.
  For more information on billing compliance visit: http://opbc.wustl.edu.
  You will need to complete OPBC – FY(XX*) Annual Billing Compliance Education (*based on current fiscal year) each following year.
- ❑ UCO – YYYY* Code of Conduct Certification (*based on current year)
  For more information on Code of Conduct visit: https://universitycompliance.wustl.edu/code-of-conduct/.
- ❑ EHS – Initial Clinical Safety Training
  For more information on EHS training visit: https://ehs.wustl.edu/trainings/.
- ❑ HR – Diversity & Inclusion 1.0, 2.0, 3.0 and 4.0
  For more information on Diversity and Inclusion training visit: https://diversity.med.wustl.edu/training/.
- ❑ Return to Campus Guidelines – COVID-19
  For more information on COVID-19 and campus policies visit: https://hr.wustl.edu/returntocampus/.
  For daily employee screening visit: https://screening.wustl.edu.
- ❑ Workday Training
  This training is dependent upon your role within the university. You can find more information at https://myday.wustl.edu/get-ready/training/workday-elearnings/. By

searching the following terms in Learn@Work, you can register for the appropriate training for your role, which will include all courses required for that role:
WD – Employee Self-Service in Workday Training
WD – Manager Self-Service in Workday Training

Required Initial Human Subjects Education through CITI, GCP Trainings, and Coordinator Education:

Follow instructions in Addendum 1 for accessing CITI trainings and/or linking previously completed trainings.

- ❑ HRPO – Human Subjects Initial Education taken through the CITI system (also known as CITI)
- ❑ GCP – Good Clinical Practice Training (required every 3 years)
  There are 3 training options: (1) complete CITI GCP course online, (2) Complete NIH GCP course online, or (3) Attend a WUSTL-sponsored instructor-led GCP training course. For more information visit the GCP policy at https://research.wustl.edu/good-clinical-practices/
- ❑ Elective Education for Clinical Research Coordinators, done after initial HSR and GCP training

Required Epic Trainings:

The required epic trainings assigned to you will be based on the epic role assigned to you by your supervisor. You can access these trainings through Learn@Work by clicking Epic Training in the left-hand menu under your profile. Next, click the epic button to log in a view your required trainings.

Additional Role Specific Trainings:

Some of these may or may not apply depending on how the Compliance Profile is completed.

- ❑ EHS – Shipping Training
  Category A, B, Dry Ice, and GMO
  *categories required depends on role
- ❑ OST – OnCore Training
  View, Regulatory, Clinical Team, Financial
  *training(s) required depends on role
  For more information on OnCore training visit:
  https://clinicalstudies.wustl.edu/oncore/oncore-training/.
  For more information on OnCore visit: https://clinicalstudies.wustl.edu/oncore/.
  To access OnCore visit: https://wustl-oncore.forteresearchapps.com/forte-platform-web/login.

- ❑ OpenSpecimen Online Training (if applicable)
  Query, Projects, Biobanking, Bulk Export/Import
  For more information on OpenSpecimen visit:
  https://sites.wustl.edu/biobankhelp/training-and-documents/.
- ❑ MRI Training (includes CCIR location) (if applicable)

The training URL:
http://mirweb.mir.wustl.edu/sites/qs/training/SitePages/MRTraining.aspx

1. Log on: ACCOUNTS\WUSTL key username
   ACCOUNTS is the Domain
   Your password is your WUSTL key password
   Example: ACCOUNTS\lhood
2. Review the Training Material for the appropriate Level
3. When you fill in the Registration information be sure to select the appropriate access area\areas (i.e. Level I East Building or Level II East Building).
4. Fill in the Training screen information and proceed to the Quiz. After you successfully pass the Quiz, a MRI screening form will appear, fill in the screening form and submit. You will see a Final Completion page with instructions for receiving a yellow card and instructions for the I.D. Badge activation process if you are Level II.

Optional Research Trainings:

- ❑ Accelerating Clinical Coordinator Excellence (ACCE)
  Initial training for research coordinators. There is no cost associated with this class. For more information, visit https://acce.wustl.edu/.
- ❑ Necessary Elements in the Fundamentals of Human Subjects Research
  This course is intended for research coordinators who have been working in their role for approximately 6 months to a year and should be completed after ACCE. There is a cost associated with this class. For more information, visit https://hrpo.wustl.edu/education/conferences-series-workshops/necessary-elements-1/.

The above activities were completed.

Trainer's Signature:	Date:
Trainee's Signature:	Date:

REGULATORY DOCUMENTS

Save the following documents in the central binder and/or shared drive:

- ❑ **Signed and Dated Curriculum Vitae (CV)**
  This should include your current position at Washington University.
  This should be updated, signed/dated, and saved every 2 years.

- ❑ **Copy of License (as applicable)**

- ❑ **Copy of Human Subjects Education Training Certificate, Completion Record, and/or Courses**
  Washington University currently only requires this once but funders, sponsors, etc. may require updated training anywhere from every 1 – 3 years. If requested, updated training is necessary.

- ❑ **Copy of Good Clinical Practice (GCP) Certificate**
  This should be renewed and saved every 3 years.

- ❑ **Copy of Shipping Training Certificate (as applicable)**
  This should be renewed and saved every 2 years.

The above activities were completed.

Trainer's Signature:	Date:
Trainee's Signature:	Date:

GENERAL STUDY TRAINING

- ❑ **Review the Research Group's Open and Enrolling Studies**

- ❑ **Review the Research Group's Organizational Chart**

- ❑ **Review the Research Group's Policies**

- ❑ **Review the Research Group's Standard Operating Procedures (SOPs)**

- ❑ **Obtain CTEP ID and Access RCR for ECOG-ACRIN Studies (if applicable)**

  See Appendix B for instructions on setting this up.
  For additional information, contact Jason Atkinson (jason.atkinson@wustl.edu).

- ❑ **Meet Regularly with Mentor/Supervisor to Ask Questions and Review Progress**

- ❑ **Establish Performance Goals for the Year**

- ❑ **Complete Feasibility Assessment to Conduct the Study**

  Applicable for experienced personnel or individuals solely responsible for all study aspects.

- ❑ **Set Up myIRB Profile**

  Visit https://myirb.wusm.wustl.edu/

- ❑ **Schedule myIRB Training**

  Visit https://hrpo.wustl.edu/education/hrpo-education-programs/myirb-training/

- ❑ **Review HRPO's Research Guides** https://hrpo.wustl.edu/research-toolkit/research-guide/

- ❑ **Overview of Consent, Re-Consent Process, and E-Consent (if applicable)**

- ❑ **Overview of Use of Legally Authorized Representatives (LARs)**

- ❑ **Overview of Correct Documentation Procedures and Error Correcting**

- ❑ **Overview of Study Set-Ups**
  - Other departments/disciplines/vendors (i.e. lab, pharmacy, radiology, equipment vendors, central reading centers, etc.) – Logistics, credentials, etc.
  - Equipment – calibration and maintenance records
  - Trial Master File (Regulatory Binder, Essential Documents) & update during trial
  - Data Collection Tools for protocol adherence (source doc worksheets, logs, etc.)
  - Trainings

❑ **Overview of Investigational Product Management**

- Records: receipt, inventory, storage, dispensing, accountability, return/destroy
- Randomization codes/Emergency codes
- Compliance calculations

❑ **Overview of Monitoring Plans/Oversight**

- Reptrax for monitor and access to pharmacy
- Investigator Meeting
- Visits: PSSV, SIV, IMV, COV
- Visit Reports
- Audits

❑ **Review Management of Study Supplies**

Who to Contact: _____

❑ **Overview of Typical Data Review Procedures**

Timely review of study data (lab/test/radiology results) and communications with Investigator.

❑ **Overview of Adverse Event Reporting including Serious Adverse Events (SAEs)**

❑ **Overview of Procedures for Responding to Data Queries**

❑ **Overview of Financial and Contracting Procedures**

- ❑ SPA vs. CCS
- ❑ Budget Preparation
- ❑ Contracting

❑ **Overview of Communications, Notes to File, Record Retention**

❑ **Review HRPO Reporting Requirements**

https://hrpo.wustl.edu/wp-content/uploads/2020/05/Reportable-Events-How-to-Report-in-myIRB-When-the-IRB-of-Record-is-the-WU-IRB-or-the-NCI-CIRB.pdf

https://hrpo.wustl.edu/wp-content/uploads/2020/03/Reportable-Events-How-to-Report-in-myIRB-When-the-IRB-of-Record-is-NOT-the-WU-IRB-or-the-NCI-CIRB-2020-03-18.pdf

https://hrpo.wustl.edu/wp-content/uploads/2019/06/Deviations-in-approved-research-%E2%80%93-what-should-be-reported-when-and-how.pdf

❑ **Review Additional Medical Record Systems (as applicable)**

EPIC, Clindesk, Touchworks/Allscripts, IDX, Compass, OTTR, KIDDOS, Wellsoft, HMED, Aria, HILT, HALT etc.

❑ **Review Research Record Systems Related to Research Participant Records (as applicable)**

CIDER, ClinPortal, REDCap, Oncore

❑ **Overview of REDCap (as applicable)**

https://redcap.wustl.edu/

For version 7, you will need to request a username and password. For version ≥ 8, you will use your WUSTL key to login.

Review pre-recorded training videos: https://becker.wustl.edu/services/data-management-and-sharing/redcap-workshop-recordings/

❑ **Overview of PRMC Procedures (as applicable)**

The above activities were completed.

Trainer's Signature:	Date:
Trainee's Signature:	Date:

STUDY SPECIFIC TRAINING

Review this section with your trainer or other member of the research team. Complete this section for each research study.

Study Name: _____

- ❑ **Ensure You are Added as a Study Team Member to myIRB**

- ❑ **Ensure the Sponsor/Coordinating Center is Notified that You are a New Study Team Member**

  Provide sponsor/coordinating center with contact information for new study team member. Setup any trainings they may require and gain access to any databases necessary for study conduct.

- ❑ **Review Study Documents**
  - ❑ Protocol
  - ❑ ICF
  - ❑ Manual of Operating Procedures/Standard Operating Procedures
  - ❑ Contract
  - ❑ Budget
  - ❑ myIRB Application (pay close attention to questions specific to study conduct, such as approved consenting methods)

- ❑ **Review Study Specific Files/Folders**

  Review computer shared drives and how to access research files/folders stored on these drives. Review where and how hard copy files are stored.

- ❑ **Complete Study Training Requirements**

- ❑ **Ensure You are Added to the Delegation of Authority and Review Assigned Roles and Responsibilities**

- ❑ **Review Protocol Deviations and Reportable Events**

- ❑ **Review Study Specific Monitoring Plan/Oversight**

- ❑ **Review Study Specific Trial Master File**

- ❑ **Review Study Specific CRFs/eCRFs**

- ❑ **Review Participant Procedures**
  - ❑ Recruitment Strategies
  - ❑ Scheduling Logistics
  - ❑ Informed Consent
  - ❑ Inclusion/Exclusion Criteria
  - ❑ Screening and Enrollment Logs
  - ❑ Subject Visits (day/time requirements, order of procedures, protocol instructions for procedures)

- ❑ **Review Study Specific Data Review Procedures**

  Timely review of study data (lab/test/radiology results) and communications with Investigator.

- ❑ **Review Study Specific Adverse Event Reporting including Serious Adverse Events (SAEs)**

- ❑ **Review Procedures for Responding to Data Queries**

- ❑ **Review Study Specific Financial Procedures**
  - ❑ Subject Payments (if applicable)
  - ❑ Internal Invoices (if applicable)
  - ❑ Sending Invoices (if applicable)

- ❑ **Review Study Specific Communications, Notes to File, Record Retention**

The above activities were completed.

Trainer's Signature:	Date:
Trainee's Signature:	Date:

ADDITIONAL RESOURCES FOR JOB FUNCTIONS

Topic	DIRECTIONS/LINKS
1. **Departmental Contact Information for Medical Records Issues**	Epic: _____ Allscripts: _____ ClinDesk: _____
2. **WUSTL One**	https://one.wustl.edu/
3. **Clinical Research at WUSTL** • Clinicaltrials.gov. – how to register a study • Forms Library – Case Report Form templates, Regulatory Binder Lists • Roles and Responsibilities document	http://research.wustl.edu
4. **myIRB information under FAQ**	http://HRPO.wustl.edu https://myirb.wusm.wustl.edu/
5. **HRPO Research Guide**	https://hrpo.wustl.edu/research-toolkit/research-guide/ http://online.fliphtml5.com/ikcz/ifub/#p=1
6. **Research Coordinator Brown Bag Session**	https://research.wustl.edu/brown-bag/
7. **Research Programs available WU University College**	http://ucollege.wustl.edu/students/prospective
8. **Subscribe to Research News**	To receive information on human subjects education, policy and development updates. http://researchnews.wustl.edu/
9. **Standard Operating Procedures (SOP) Examples**	https://research.wustl.edu/topic_subgrouping/sop-templates/
10. **Sponsored Projects Accounting Information**	https://financialservices.wustl.edu/wfin-topic/sponsored-projects-accounting/
11. **Financial Management Series classes**	Offered 2-3 times per year – listed on the Office of the Vice Chancellor of Research (OVCR) Education Calendar http://research.wustl.edu/events/Pages/UpcomingEvents.aspx
12. **Review Research Resource Forms Library**	http://research.wustl.edu/ComplianceAreas/clinical/Research_forms/Pages/default.aspx
13. **Recruitment Resource: Volunteers for Health**	https://sites.wustl.edu/wuvfh/
14. **Recruitment Resource: Institute of Clinical and Translational Services (ICTS)**	http://icts.wustl.edu/
15. **Recruitment Resource: WU PAARC**	http://icts.wustl.edu/icts-researchers/icts-cores/find-services/by-core-name/washington-university-pediatric-adolescent-ambulatory-research-consortium-wu-paarc
16. **CCS and CARs services**	https://ccs.wustl.edu/
17. **Contracts and CTA (required)**	https://ccs.wustl.edu/ and researchcontracts@email.wustl.edu
18. **OnCore Clinical Trial Management System**	https://oncore.wustl.edu/login/

19. OnCore Confluence	https://cbmiapps.wustl.edu/confluence/display/OSS/III.OnCore+Enterprise+Implementation
20. PRMC Forms	https://siteman.wustl.edu/research/clinical-research-resources/prmc-forms/
21. QASMC Forms	https://siteman.wustl.edu/research/clinical-research-resources/qasmc-forms/
22. RedCap – Research Electronic Data Capture	https://redcap.wustl.edu/redcap/srvrs/
23. Qualtrics	For instructions and use: https://it.wustl.edu/items/qualtrics/
24. Conflicts of Interest	Financial conflicts of interest need to be on file and disclosed for all engaged members of the study team. See the WUSTL Vice Chancellor for Research website at: http://research.wustl.edu/ComplianceAreas/COI/Pages/COI.aspx.
25. Sunshine Act and Open Payments Program Under the Sunshine Act, physicians' financial conflicts of interest with pharmaceutical companies are posted publicly on the Centers for Medicare and Medicaid (CMS) website. CMS is responsible for administering the Sunshine Act and named it the Open Payments Program.	For more information on the Sunshine Act See CMS website at: https://www.cms.gov/openpayments/ For a specific doctor's payment, see the CMS Open Payments website at: https://openpaymentsdata.cms.gov/
26. HR Develop and Learn	https://hr.wustl.edu/develop-and-learn/
27. Human Subjects Research	https://research.wustl.edu/topics/human-subjects-research/

The above activities were completed.

Trainer's Signature:	Date:
Trainee's Signature:	Date:

OVERVIEW OF RESEARCH AT WASHINGTON UNIVERSITY

Topic	DIRECTIONS/LINKS
1. WU Compliance Guide	www.ComplianceGuide.wustl.edu
2. Broad WU roles and responsibilities	http://www.wustl.edu/policies/
3. Large list of research policies at WU	http://research.wustl.edu/PoliciesGuidelines/Pages/WUSTLPoliciesGuidelines.aspx https://research.wustl.edu/category/policy-procedure-guideline/
4. CRC Self Assessment Tool	To be used 3-6 months in the role. https://research.wustl.edu/crc-self-assessment/
5. Research Toolkit	https://hrpo.wustl.edu/research-toolkit/
6. IRB Fees	https://hrpo.wustl.edu/research-toolkit/fees/
7. Cancer research: Siteman Cancer Center	https://siteman.wustl.edu/research/

The above activities were completed.

Trainer's Signature:	Date:
Trainee's Signature:	Date:

ADDITIONAL RESOURCES

This is just a listing of useful websites.

Topic	DIRECTIONS/LINKS
1. ACRP professional organization (certification/ membership)	http://www.acrpnet.org/
2. SOCRA professional organization	https://www.socra.org/
3. Belmont Report	http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html
4. Clinical Trials.gov	https://clinicaltrials.gov/
5. Code of Federal Regulations	http://www.ecfr.gov/
6. Declaration of Helsinki	http://www.wma.net/en/30publications/10policies/b3/
7. NIH GCP Training:	https://gcp.nihtraining.com/
8. Office of Research Integrity	http://ori.dhhs.gov/
9. The Food and Drug Administration (FDA)	https://www.fda.gov/
10. Title 21 FDA Regulations	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm
11. Health and Human Services (HHS)	https://www.hhs.gov/
12. Title 45 HHS Regulations	https://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title45/45tab_02.tpl

The above activities were completed.

Trainer's Signature:	Date:
Trainee's Signature:	Date:

ACRONYMS AND ABBREVIATIONS

A	
AAHRPP	Association for the Accreditation of Human Research Protections Programs
ACRP	Association of Clinical Research Professionals
ADR	Adverse Drug Reaction
AE	Adverse Event
ATTC	Addiction Technology Transfer Center
C	
CE	Covered Entity
CDA	Confidentiality Disclosure Agreement
CFR	Code of Federal Regulations
CIDER	Clinical Investigational Data Exploration Repository
CITI	Collaborative IRB Training Initiative (Human Subjects Education) U of Miami
COI	Conflict of Interest
COV	Close Out Visit
CPA	Cooperative Project Assurance
CR	Common Rule
CRA	Clinical Research Associate
CRF	Case Report Form
CRO	Clinical Research Organization/Contract Research Organization
CRC	Clinical Research Coordinator
CTA	Clinical Trial Agreement
CV	Curriculum Vitae (resume)
D	
DHEW	Department of Health, Education and Welfare (no longer exists)
DHHS	Department of Health and Human Services (replaced DHEW)
DIA	Drug Information Association
DMC	Data Monitoring Committee
DoD	Department of Defense
DoDD	Department of Defense Directive
DoE	Department of Education
DOE	Department of Energy
DOJ	Department of Justice
DRC	Disclosure Review Committee
DSMB	Data Safety Monitoring Board
E	
EC	Ethics Committee
ECOG	Eastern Co-operative Oncology Group
ED	Emergency Department
EH&S	Environmental Health & Safety
EPA	Environmental Protection Agency

F	
FD	Financial Disclosure
FDA	Food and Drug Administration
FERPA	Family Educational Rights and Privacy Act
FIS	Financial Information System
FWA	Federal Wide Assurance
G	
GCP	Good Clinical Practice
GOG	Gynecologic Oncology Group
GMP	Good Manufacturing Practice
H	
HDE	Humanitarian Device Exemption
HIPAA	Health Insurance Portability and Accountability Act
HMO	Health Maintenance Organization
HPA	Human Protections Administrator
HRP	Human Research Protections
HRPP	Human Research Protection Program
HRPO	Human Research Protection Office
HRMS	Human Resources Management System
HSR	Health Services Research
HUD	Humanitarian Use Device
I	
IAA	IRB Authorization Agreement
IACUC	Institutional Animal Care and Use Committee
IB	Investigator's Brochure
IBC	Institutional Biohazard Committee
ICF	Individual Consent Form or Institutional Consent Form
ICH	International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals
ICH-GCP	International Conference on Harmonization/Good Clinical Practice
ICTS	Institute of Clinical and Translation Sciences
IDE	Investigational Device Exemption
IEC	Institutional Ethics Committee/Independent Ethics Committee
IIA	Individual Investigator Agreement
IMV	Interim Monitoring Visit
IND	Investigational New Drug
IO	Institutional Official
IRB	Institutional Review Board
J	
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
JIT	Just in Time (procedure)
L	
LCME	Liaison Committee for Medical Education
Learn@Work	Learning Management System for Washington University
LTF	Subjects Lost to Follow-up

M	
ML	Medical License
MPA	Multiple Projects Assurance
MSO	Medical Staff Office
N	
NAIM	National Association of IRB Managers
NCPHSBBR	National Commission for the Protection of Human Subject of Biomedical and Behavioral Research
NBAC	National Bioethics Advisory Commission
NCQA	National Committee for Quality Assurance
NDA	New Drug Application
NHRPAC	National Human Research Protections Advisory Committee
NIA	Nonaffiliated Investigator Agreement
NIH	National Institute of Heath
NIJ	National Institute of Justice
NSF	National Science Foundation
NSR	Non-significant Risk
O	
OGC	Office of General Council
OHRP	Office of Human Research Protections (formerly OPRR)
OPRE	Office of Planning, Research & Evaluation
OPRR	Office of Protection from Research Risks
ORA	Office of Regulatory Affairs
ORCA	Office of Research Compliance and Assurance
ORI	Office of Research Integrity
OSHA	Occupational Safety and Health Administration
OVCR	Office of the Vice Chancellor of Research
P	
PARC	Protocol Adherence Review Committee
PI	Principal Investigator
PHI	Private Healthcare Information/Public Health Information/Protected Health Information
PHS	Public Health Service (USPHS United States Public Health Service)
PMA	Pre-Market Approval
POG	Pediatric Oncology Group
PRIMR	Public Responsibility in Medicine and Research
PRMC	Protocol Review and Monitoring Committee
Q	
QA	Quality Assurance
QI	Quality Improvement

R	
RAPS	Regulatory Affairs Professional Society
RCO	Regulatory Compliance Officer
RDRC	Radioactive Drug Research Committee
REB	Research Ethics Board
RCT	Randomized Control Trial
RCR	Responsible Conduct of Research
RTOG	Radiation Therapy Oncology Group
S	
SAE	Serious Adverse Event
SAR	Suspect Adverse Reaction
SIS	Student Information System
SIV	Site Initiation Visit
SMO	Site Management Organization
SoCRA	Society of Clinical Research Coordinators
SOP	Standard Operating Procedure
SPA	Single Project Assurance
SR	Safety Report and/or Significant Risk
SRO	Sponsored Research Office
SUSAR	Suspected Unexpected Serious Adverse Reaction
SWOG	South West Oncology Group
V	
VA	Department of Veteran's Affairs
VPR	Vice President for Research
W	
WMA	World Medication Association
WUSTL Key	Washington University in St. Louis unique userID and password system

CITATIONS:

Mantia, Tarisa; Striler, Kim; Bell, Jennifer; Geile, Kristin; Karbarski, Rachel; Desai, Ann; McNulty, Kate; Santos, Marta; Clarke, Mickey; and Fowler-Dixon, Sarah, "Human Research Protection Office clinical research coordinator training manual" (2017). *HRPO Publications*. Paper 8. https://digitalcommons.wustl.edu/hrpopubs/8

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APPENDIX A – CITI INSTRUCTIONS in the OVCR's Quick Guide at: https://research.wustl.edu/citi.

CITI Program Login and Course Enrollment

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CITI Program contains training modules that fulfil many different training requirements:

1. Initial Human Subjects Education (*required one time only*)
2. Good Clinical Practice (*required every three years*)
3. Human Subjects Education Refresher Training (*required by some sponsors*)
4. Elective Education for Clinical Research Coordinators (*required by some departments*)
5. Other trainings that may be elective or required for some groups

See the diagram on the differences between Human Subject Education and Good Clinical Practice training requirements in Box.

Support

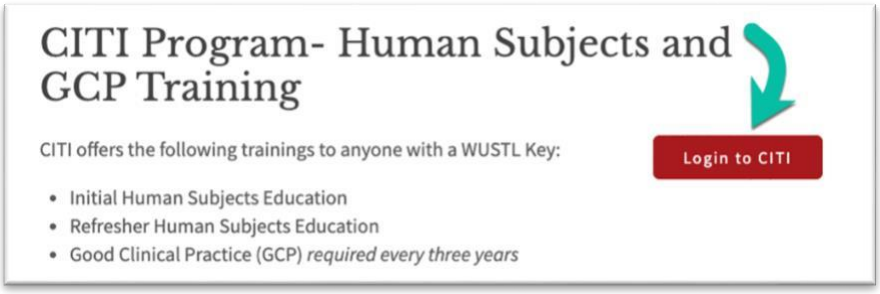
For help within the CITI program, contact the CITI helpdesk at 888.529.5929.

For Human Subjects Education assistance email hrpo@wustl.edu.

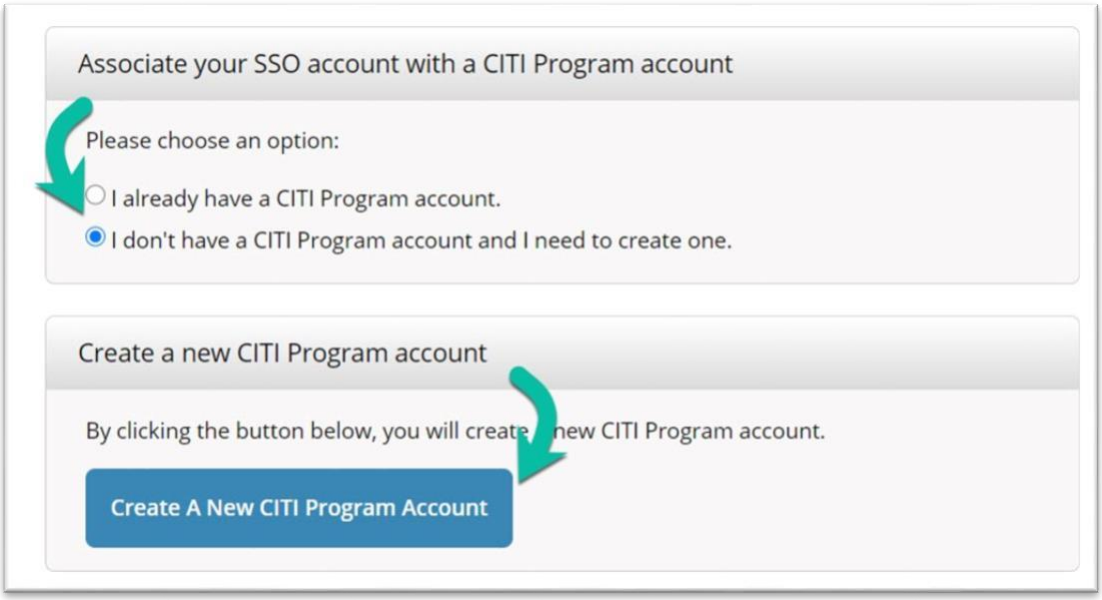
For GCP assistance email ovcrinfo@wustl.edu.

Creating an Account

1. First time users of Washington University's CITI program can login here using your WUSTL key.

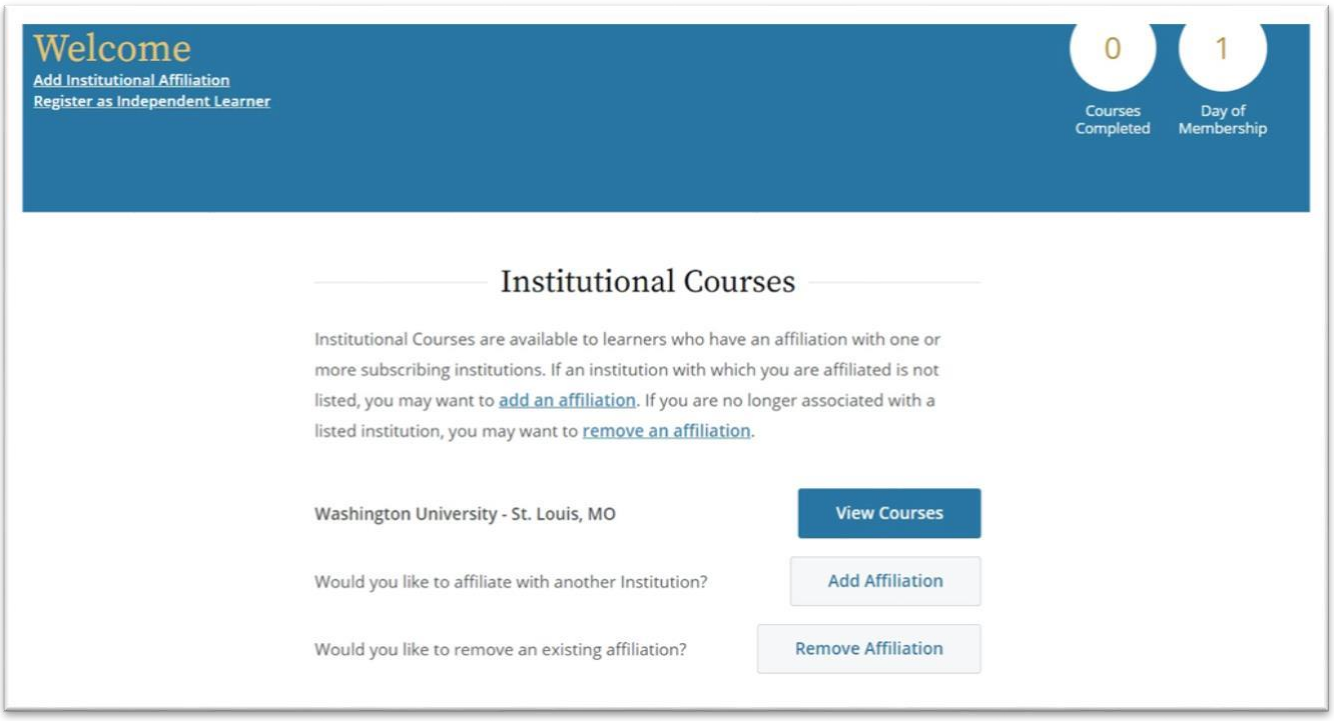


2. After logging in, select if you have an existing CITI account to link or if you need a new account.
    a. If you previously completed training through CITI at another institution, select "I already have a CITI Program account" then enter your username and password from the previous institution. See Transferring Courses for details.
    b. If you have never used CITI Program or are unsure, select "I don't have a CITI Program account and I need to create one."
3. Click the blue Create a New CITI Program Account.



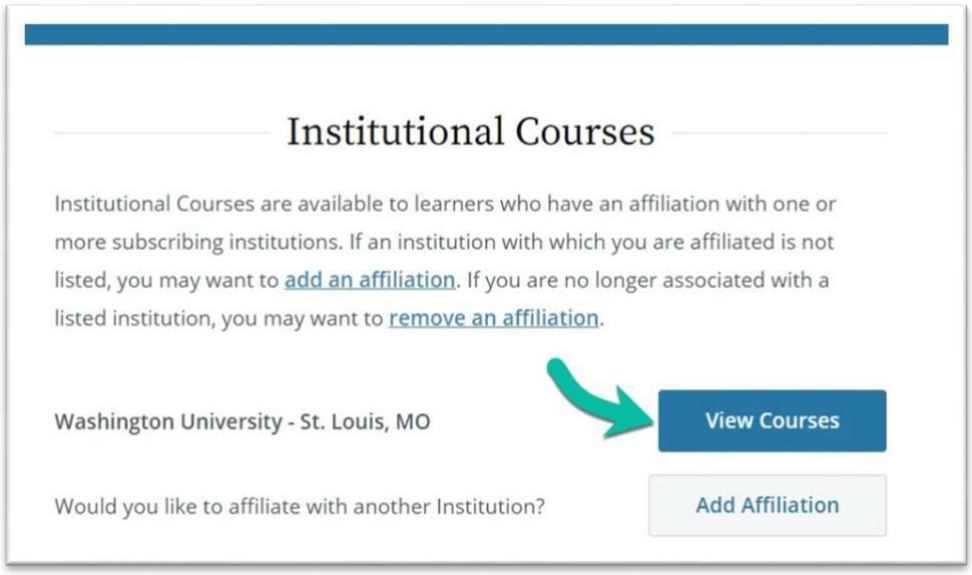
4. If you are prompted to complete a set of profile questions, see Editing your Profile.

5. Once your account is created or merged, you land on the CITI homepage:



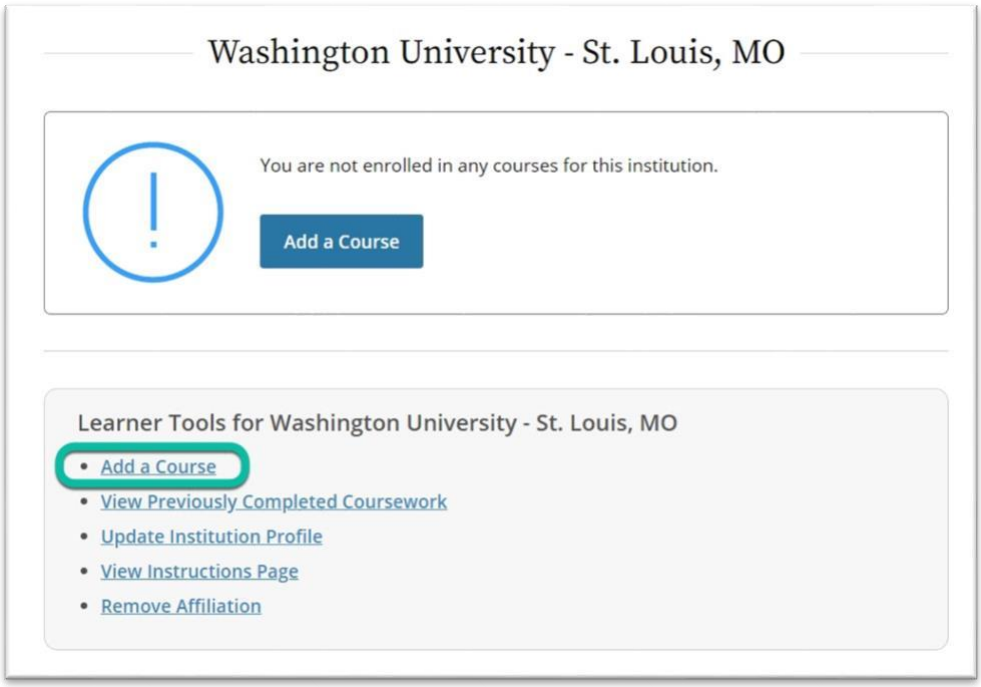
Taking a New Course

1. Login to CITI at research.wustl.edu/citi.
2. From the CITI homepage, click the blue View Courses button next to **Washington University – St. Louis, MO** in the middle of the page.
   Note: if you do not see this screen, skip to step 3.



3. This opens the WashU Homepage.
4. Scroll to the Learner Tools section at the bottom of the page.

5. Click **Add a Course**.

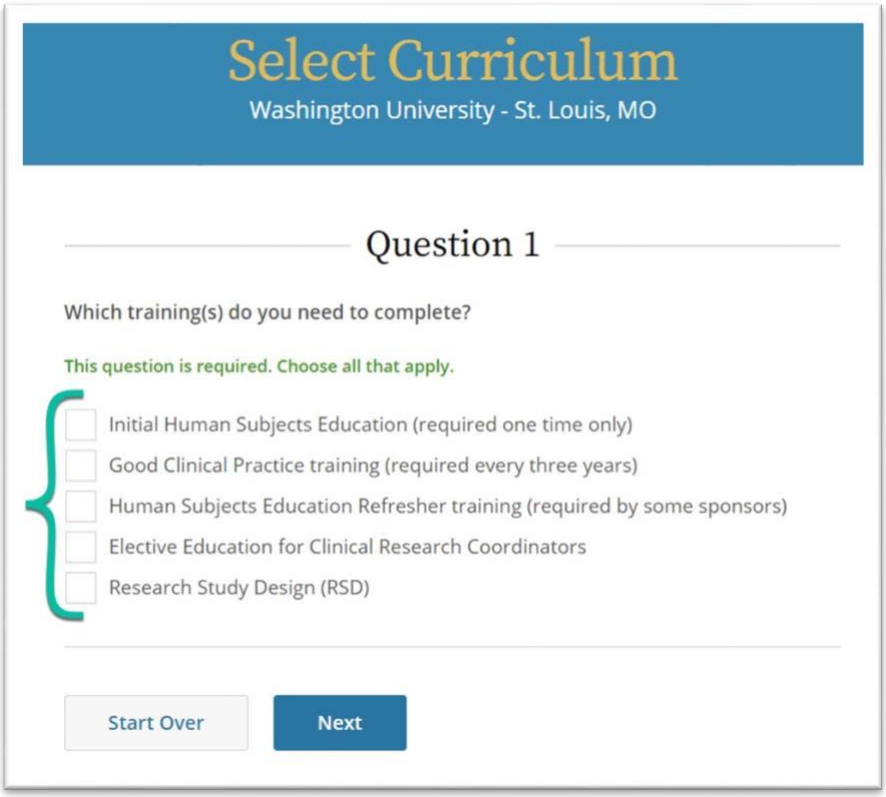


6. A new page opens with questions to enroll you in the necessary course(s).
7. Select the training(s) you need to complete

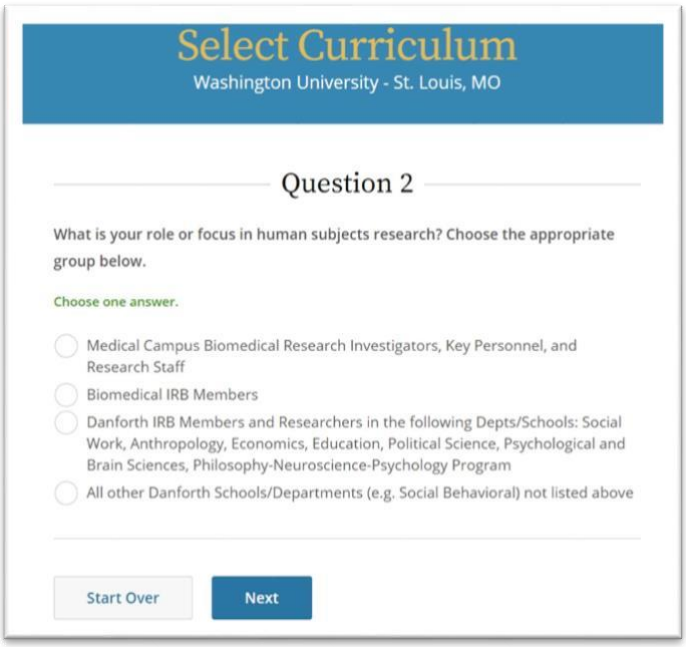
If you are unsure which training(s) you are required to complete, contact a compliance administrator in your department.

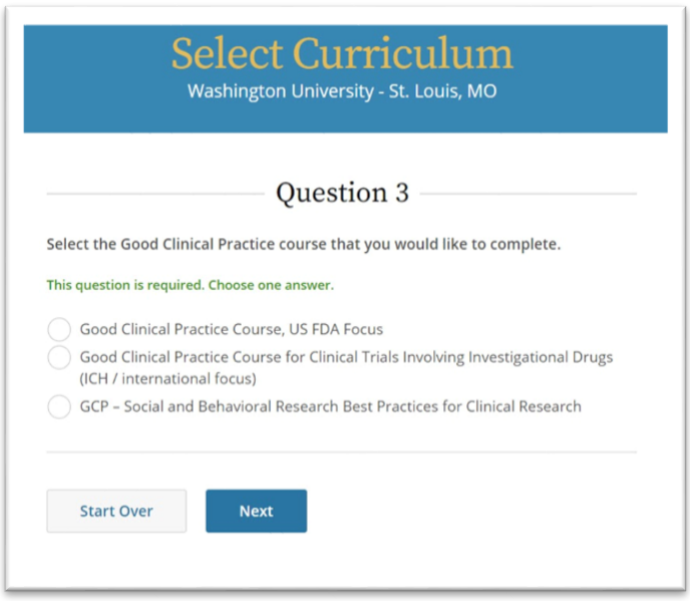
For Human Subjects Education course selection, contact HRPO.

For GCP course selection, choose the one that most represents your research.

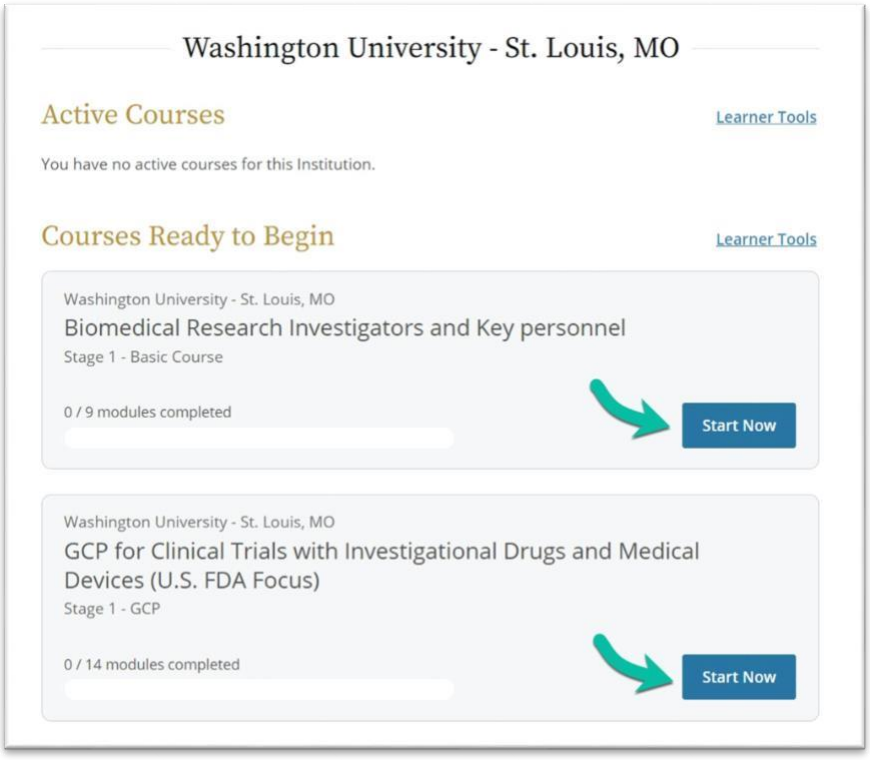


8. Based on your selections in Question 1, additional enrollment questions appear one at a time. Select a specific course for each question that appears.

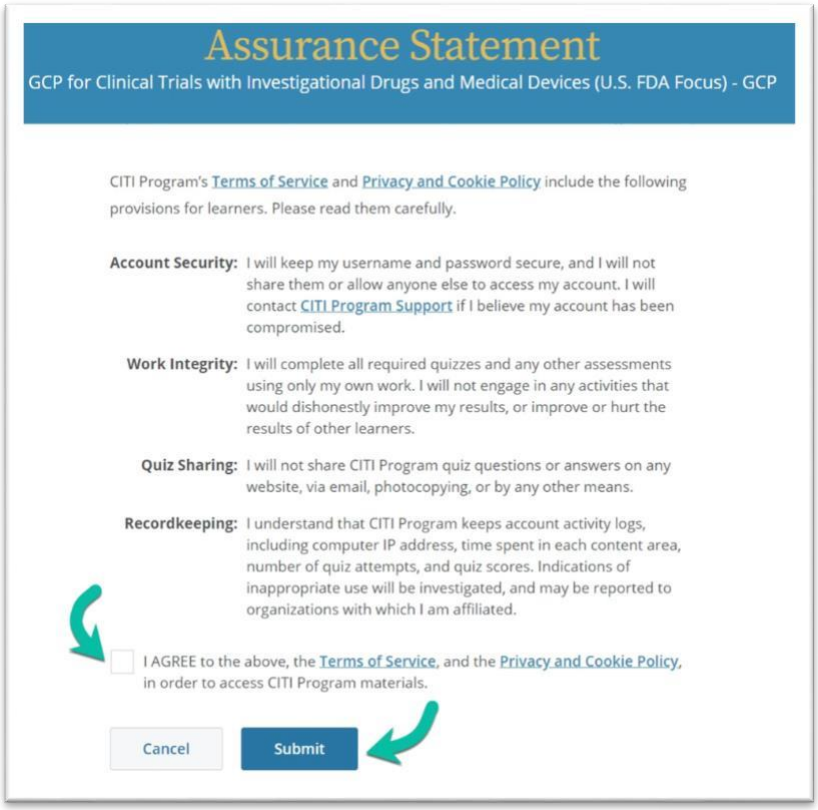




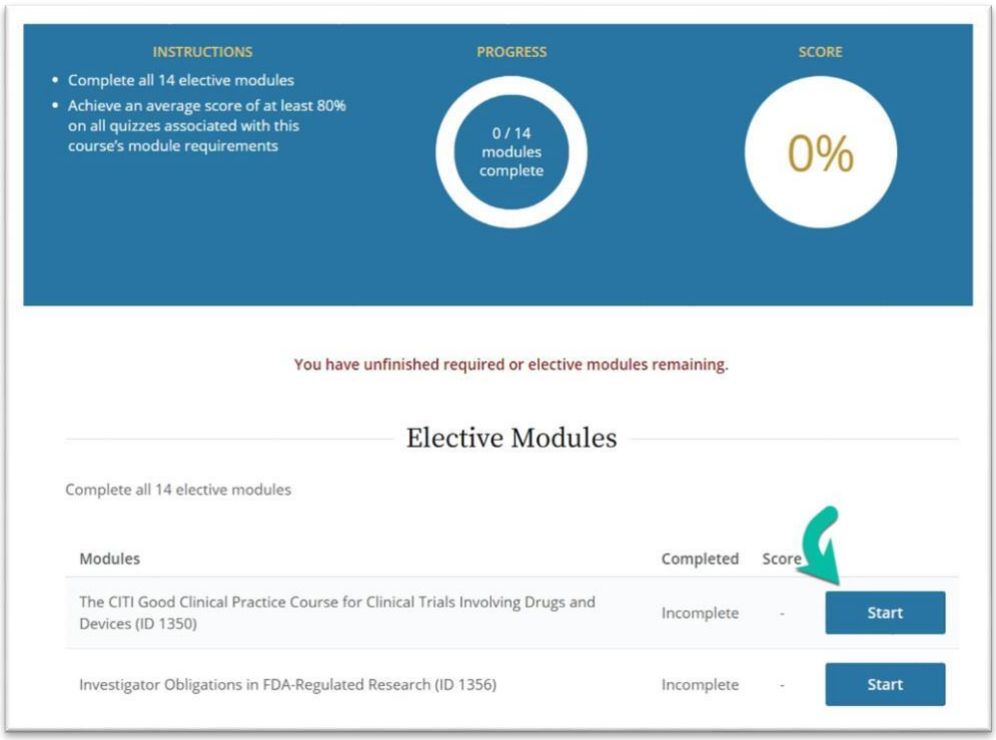
9. CITI has enrolled you for the course(s) based on your selection(s). New courses appear under Courses Ready to Begin.
10. Click **Start Now** to begin a course.



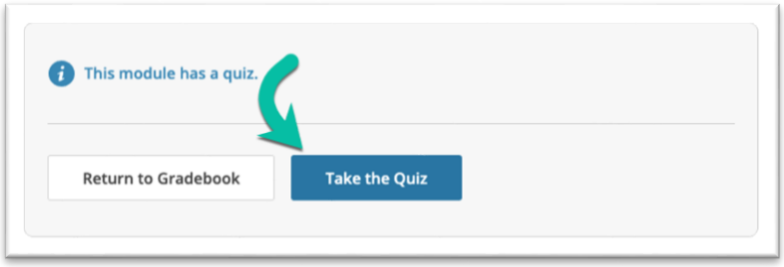
11. The Assurance Statement appears first. Read this information, select the checkbox next to I Agree, and click Submit.



12. The course homepage opens, displaying the number of modules and completion progress.
13. Click the blue Start button next to the first module.



14. Read each module's content, then complete the quiz.

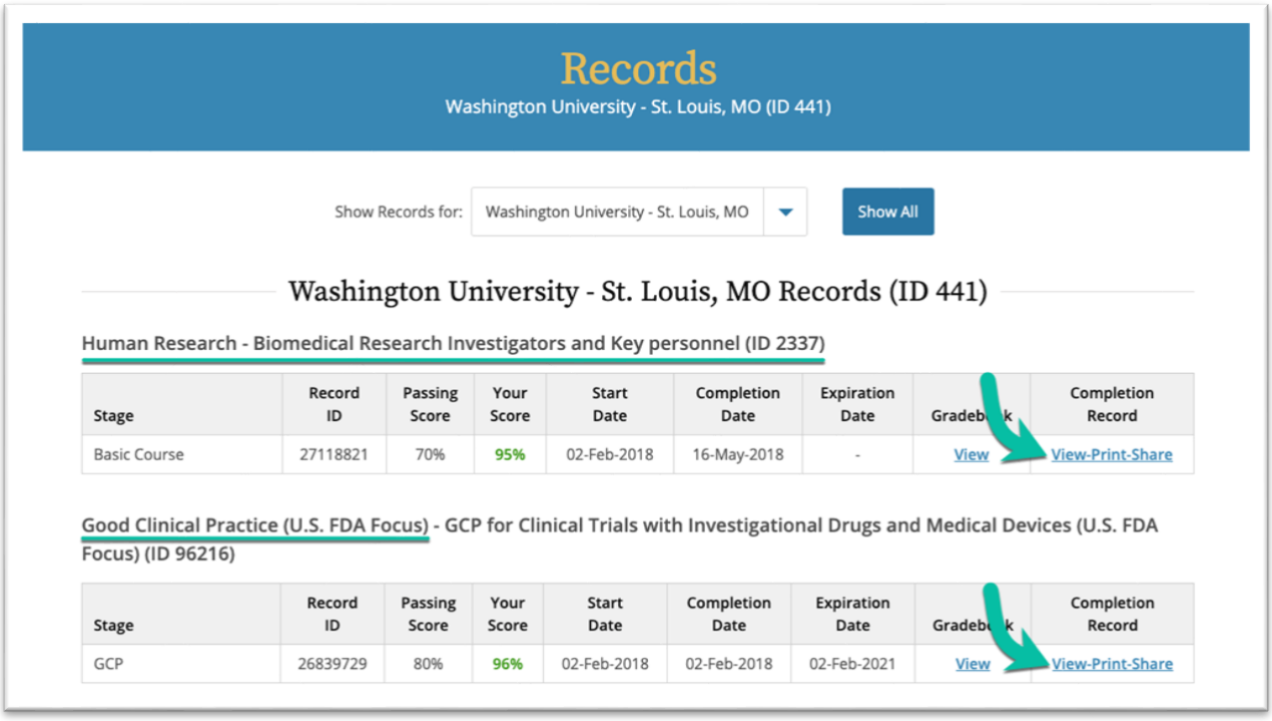


15. Complete all modules required for the course.
16. After the course is completed, CITI generates a certificate.
17. Completions are sent automatically to Learn@Work overnight.

Accessing Your Completion Records

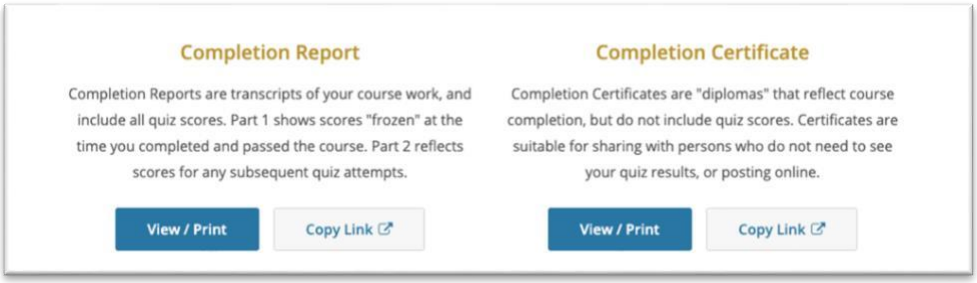
1. Login to CITI with your WUSTL key.
2. Click **Records** at the top of any CITI Page.

3. Locate the course for which you need the completion record or certificate.
4. In the Completion Record column for that course, click **View-Print-Share**.



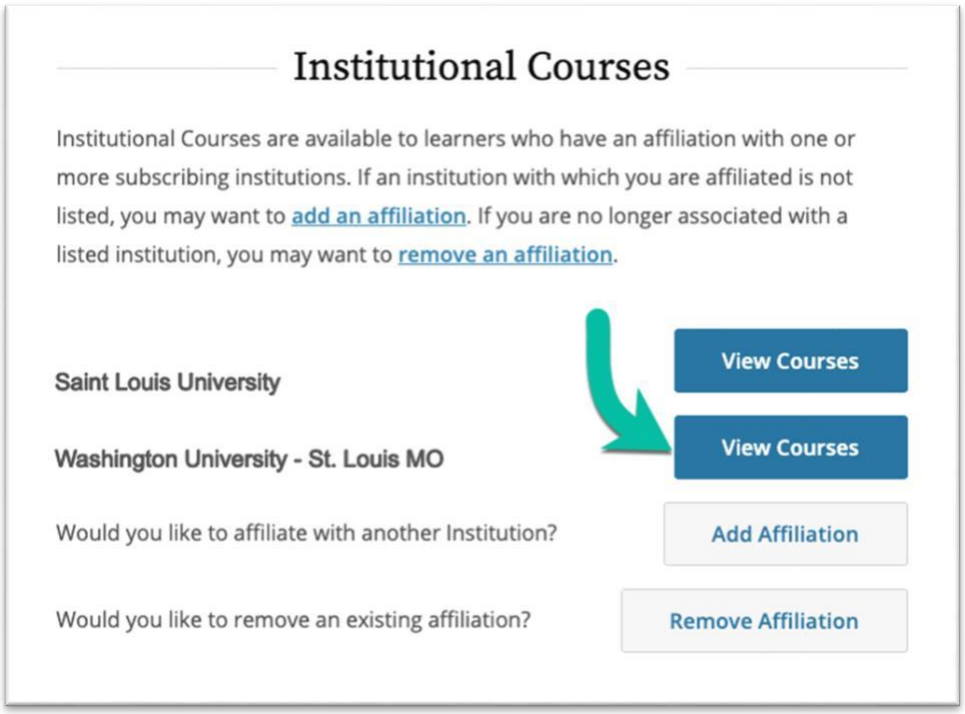
5. Click the links provided to access either your Completion Report (which contains quiz scores for all modules) or your Completion Certificate. Select copy link to generate a shareable link to your individual certificate or completion record.

If you are requesting HRPO to evaluate non-WashU CITI training for credit, you must supply the **Completion Report**.

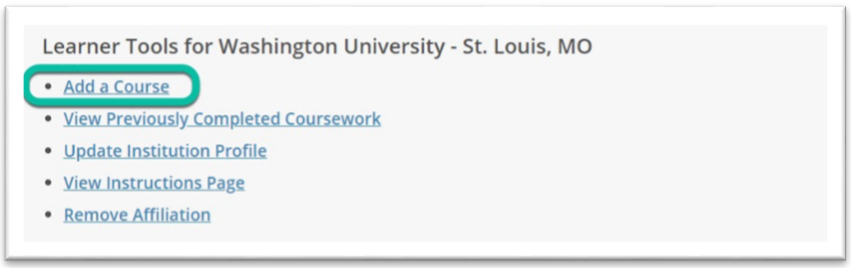


Transfer Courses from Another Institution

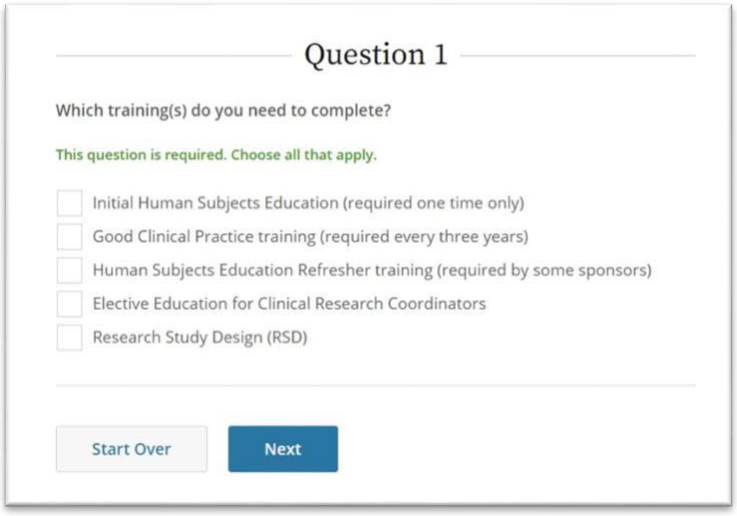
1. If your previous CITI account is already merged with your Washington University account you will see two institutions listed on the CITI Homepage. If your accounts are not merged:
   - Send your member IDs from **both** institutions to ovcrinfo@wustl.edu.
   - Your WashU Member ID can be found in the top right corner of CITI. Your member ID for the previous institution can be found on a completion record or certificate. If you cannot find your previous member ID, contact CITI at 888.529.5929.
   - You will be notified once your accounts are linked. Once linked, continue to step 2.
2. Click View Courses next to Washington University – St. Louis, MO.



3. Scroll to the Learner Tools section at the bottom of the page and click Add a Course.

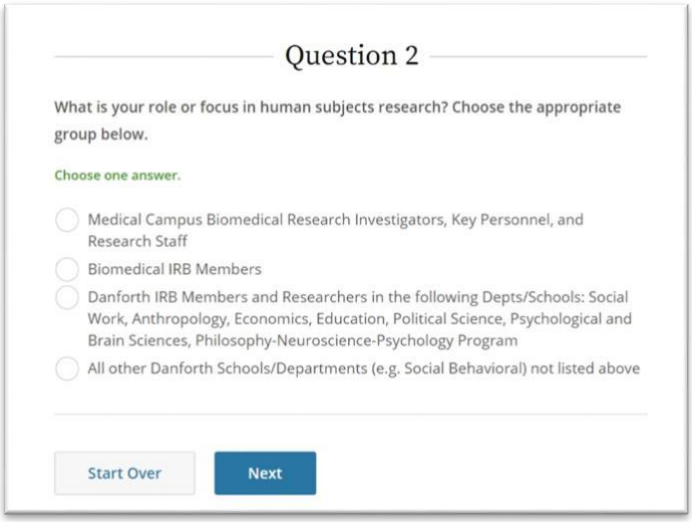


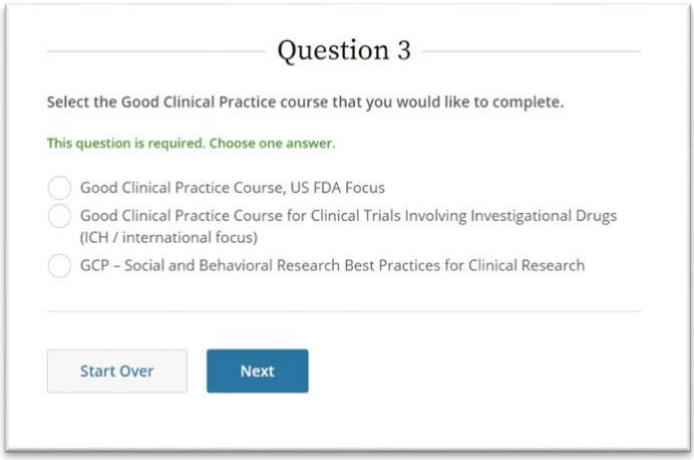
4. Complete the enrollment questions to enroll for the course that matches the existing completion from the previous institution.
    - **Question 1** – select the type of training to see specific course options.



    - **Questions 2 & 3** – Choose the specific course to transfer.

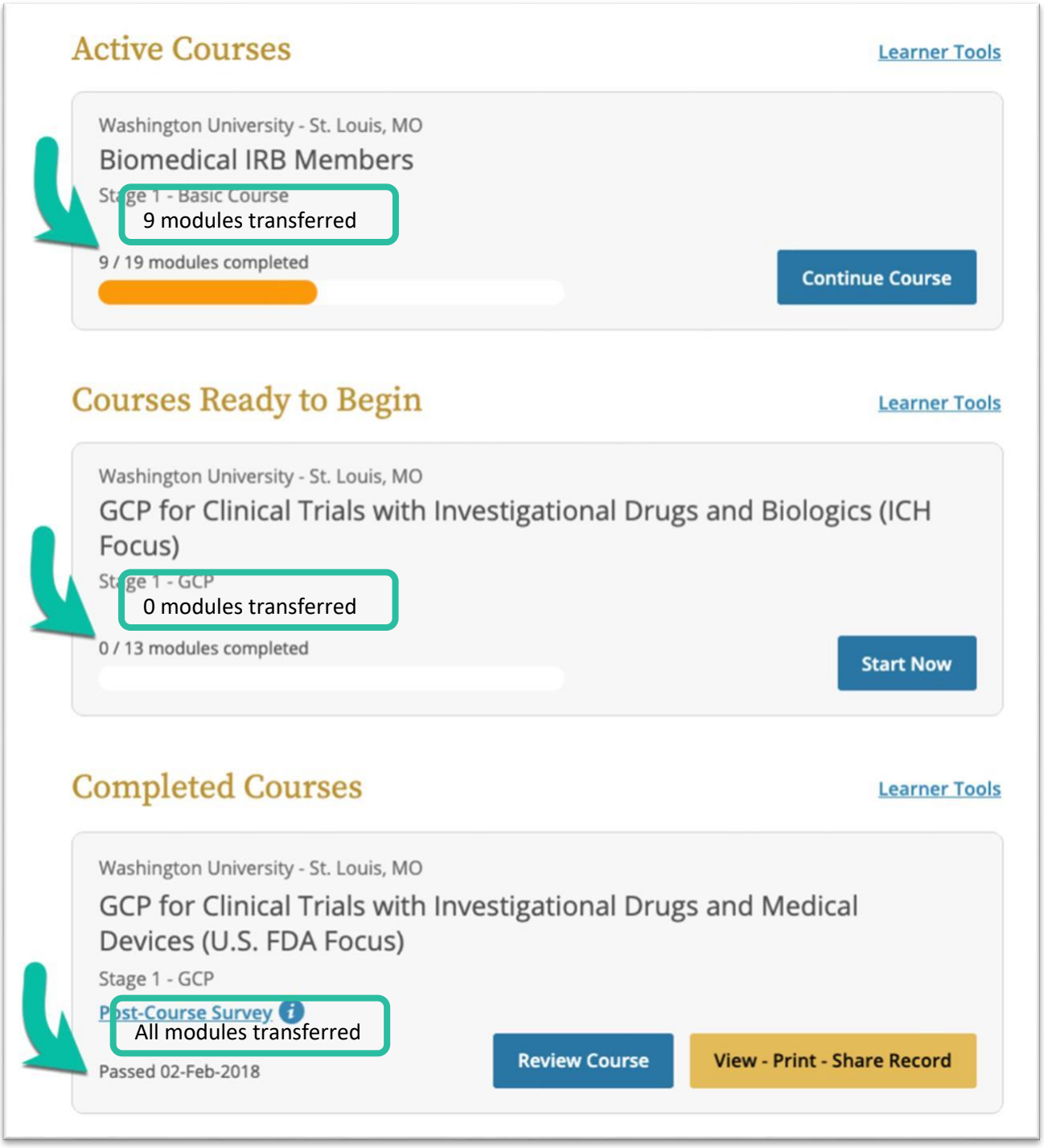
        i. If you are unsure which course matches the existing completion, you can enroll for all possible courses by completing the enrollment questions for all possible courses. Extraneous courses can be removed by clicking Remove a Course in Learner Tools at the bottom of the page.





5. After completing the enrollment questions, any matching modules will show as completed on your WashU homepage.

- Each course is made up of several modules with unique ID numbers. Module IDs must match exactly to be transferred.

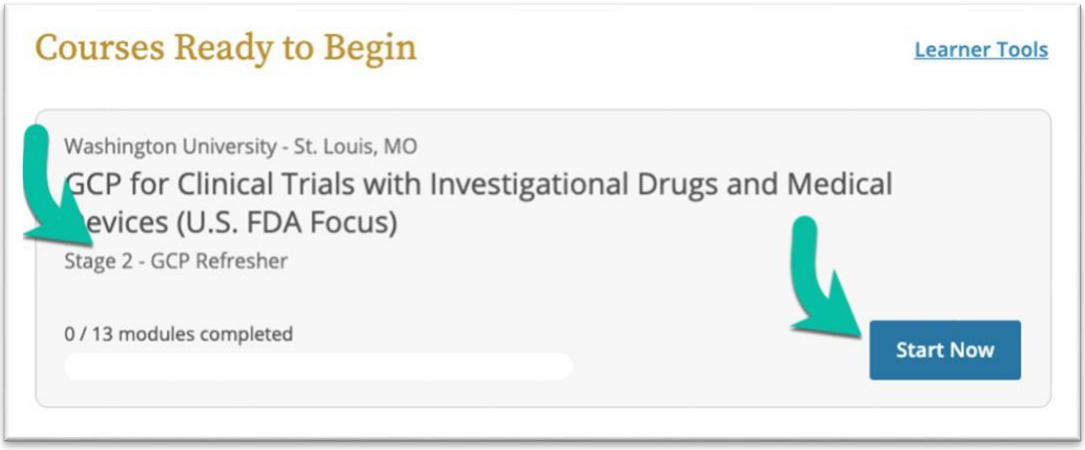


6. If all modules are complete, the course will appear under Completed Courses.
7. If some modules still must be completed, the course will appear under Active Courses with the number of already completed modules.
8. Once the course appears under Completed Courses you can generate a new certificate with Washington University as the institution. See Accessing your Completion Records.

If your previous Initial Human Subjects Education did not transfer automatically, you can request HRPO to manually evaluate the training for possible WashU credit. Email your completion report to hrpo@wustl.edu with a request to be evaluated for Human Subjects Education credit.

Retaking GCP Course(s)

All GCP courses in CITI are valid for three years. Three months before the course expires, CITI will email you notifying that the course is due for recertification. The course's refresher version will also appear under Courses Ready to Begin. Click Start Now to begin the course.



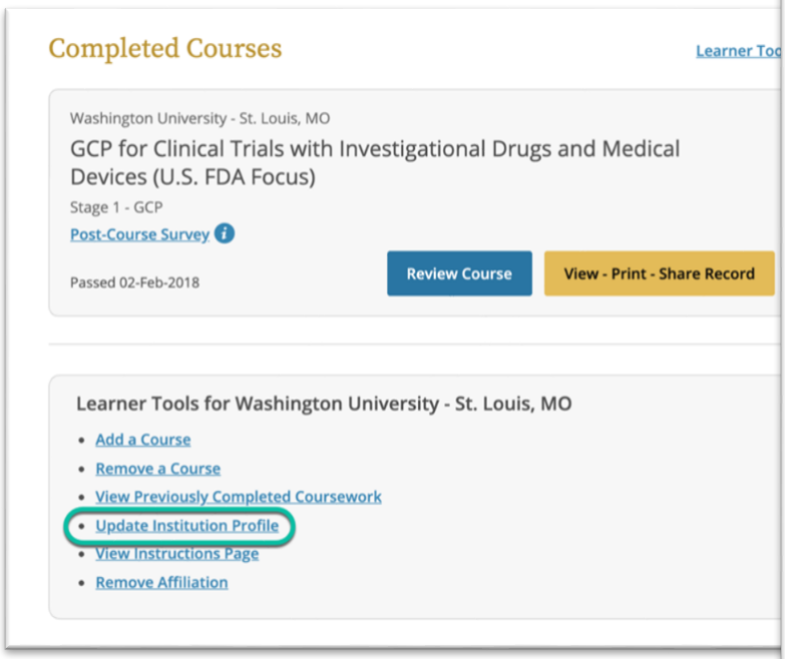
If you would like to take a different GCP course through CITI, re-enroll using the steps in Taking a New Course.

Note: If your GCP course does not appear under Courses Ready to Begin, CITI has not yet flagged it as being due. You will not be able to retake this course. You have two options:

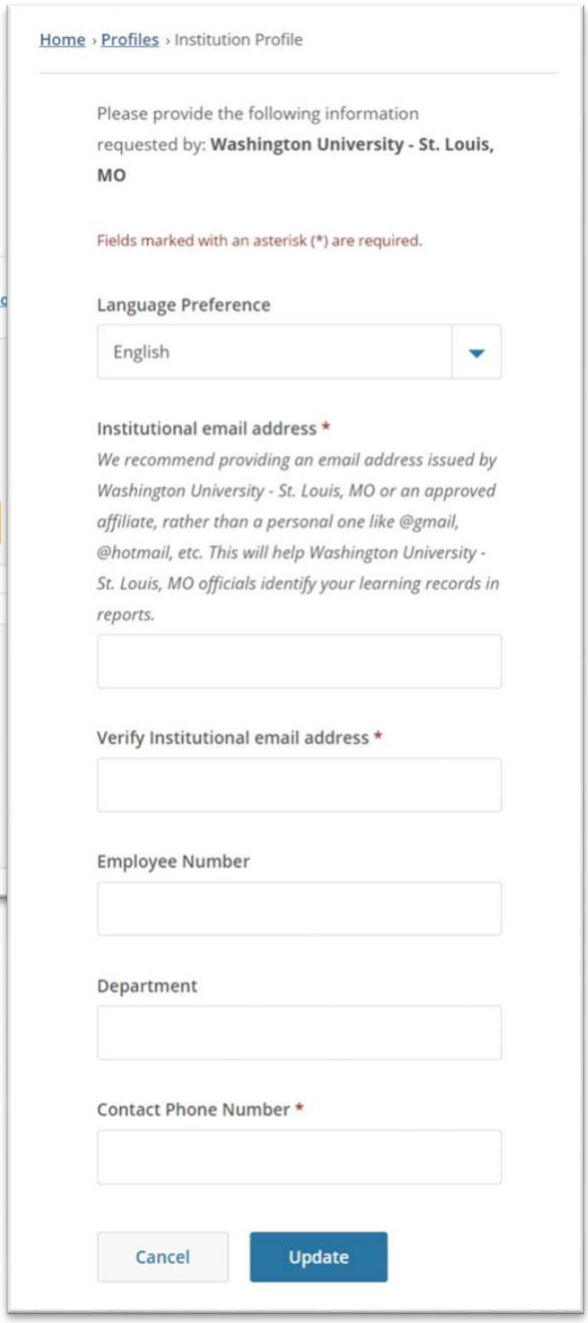
1. Complete a different GCP course using the steps in Taking a New Course.
2. Call the CITI Help Desk at 888.529.5929 and ask to be reset for the course. This will allow you to re-take the same course before the current course is expired.

Editing Your Profile

1. At the time of account creation, CITI may prompt you to complete a set of profile questions. You may also edit your profile at any time by clicking Update Institution Profile at the bottom of the page.



2. Add or update the information as needed. Required fields are marked with an *. **Do not replace the institutional email address with a personal email.**



Support

For help within the CITI program, contact the CITI helpdesk at 888.529.5929.

For Human Subjects Education assistance email hrpo@wustl.edu.

For GCP assistance email ovcrinfo@wustl.edu.

APPENDIX B – CTEP & RCR INSTRUCTIONS

NIH NATIONAL CANCER INSTITUTE

Registration and Credential Repository

NCI Person Registration Quick RCR Reference Guide for Investigator (IVR), Non-Physician Investigator (NPIVR), and Associate Plus (AP) Registration Types

The following provides high-level instructions to obtain a CTEP-IAM account, access the RCR system, and complete your annual NCI Person Registration.

Obtain your CTEP-IAM Account

To submit your registration documents through the RCR system, all persons with a Registration Type of *Investigator* (IVR), *Non-Physician Investigator* (NPIVR), and *Associate Plus* (AP) will require a CTEP Identity and Access Management (CTEP-IAM) account. The CTEP-IAM username and password are used to access RCR and to electronically sign your registration documents prior to submission to CTEP.

For IVRs without a CTEP-IAM account:

- Access CTEP-IAM https://ctepcore.nci.nih.gov/iam/
- Select "Request New Account".
- Answer the "Have you ever registered with CTEP?" question by selecting "Yes" and "Proceed".
- Enter your < CTEP Person ID >, < First Name >, and < Last Name > (check your registration notification email) and select "Continue".
- Answer the "Does the above information identify you?" question by selecting "Yes" and "Proceed".
- Answer the "Would you like to request for an IAM Account?" question by selecting "Yes" and "Continue".
- Complete the new account request and select "Continue".

For IVRs, NPIVRs, and APs with a CTEP-IAM account and uncertain of username and password or needing to update their primary organization, address, and contact information:

- Access CTEP-IAM https://ctepcore.nci.nih.gov/iam/
- Select "Request New Account".
- Answer the "Have you ever registered with CTEP?" question by selecting "Yes" and "Proceed".
- Enter your < CTEP Person ID >, < First Name >, and < Last Name > (check your registration notification email) and select "Continue".
- Answer the "Does the above information identify you?" question by selecting "Yes" and "Proceed".
- Answer the "Would you like to update your CTEP-IAM Account?" question by selecting "Yes" and "Continue".
- Complete the account request and select "Continue".

For questions, please contact the CTEP Registration Help Desk at CTEPRegHelp@nih.gov

Follow the RCR instructions below after receiving or reactivating your CTEP-IAM username and password.

Access the RCR system

This applies for IVR, NPIVR, and AP users.

1. Enter the URL for RCR: https://ctepcore.nci.nih.gov/rcr in your browser.
2. Enter your CTEP-IAM username and password.
3. Click "I Agree and Logon".

Complete Form FDA 1572

This section is mandatory for IVR and NPIVR users only.

1. Select one of the following to access the **Form FDA 1572** workflow:
   a. From the Message Board on the Home page, select "Update Form FDA 1572" from the "Would you like to" drop-down field and click "Go!".
   b. Select "Form FDA 1572" from the left "Jump To" menu from any workflow page.
2. To add Practice Sites to your 1572:
   a. Click "***Populate Sites***" to automatically add sites that you are rostered to and sites at which you are the Site-Protocol PI.
   b. Click "Add New Record" to search for and manually add sites.
3. Click "Save and Continue" to move to the **Labs** page, or select "Labs" from the left menu.
4. To add Labs to your 1572, click "Add New Record" to search for and manually add labs.
5. Click "Save and Continue" to move to the **IRBs** page, or select "IRBs" from the left menu.
6. To add IRBs to your 1572:
   a. Click "***Populate IRBs***" to automatically add the IRBs that are associated to your practice site(s).
   b. Click "Add New Record" to search for and manually add an IRB.
7. Click "Save and Continue" to move to the final **Form FDA 1572 Completed** page.

Complete NCI Biosketch

This section is mandatory for IVR, NPIVR, and AP users.

1. Select one of the following to access the **NCI Biosketch** workflow:

a. From the Message Board on the Home page, select "Update NCI Biosketch" from the "Would you like to" drop-down field and click "Go!".

b. If you have completed the Form FDA 1572 workflow, click "Continue" from the **Form FDA 1572 Completed** page.

c. Select "NCI Biosketch" from the left "Jump To" menu from any workflow page.

2. To complete the **Personal Information** page, ensure that all the information is accurate, and modify the "Signature Display" and/or "Correspondence Display" fields, if necessary.

   Click "Save and Continue" to move to the **Education** page.

3. Complete the following mandatory sections or select the "Not Applicable" checkbox if the section doesn't apply to you:

   a. **Education**
   b. **Professional Training**
   c. **Employment**
   d. **Professional Certification**
   e. **Professional License**
   f. **ABMS Board Certification**

   To complete these sections, click "Add New Record" to add a new record (line item), or click "Edit" to update an existing record.

   To move to the next section, click "Save and Continue" or select the next section from the left menu.

4. To complete the **NCI Required Training** page, click "Edit" to add the required details and upload the Good Clinical Practice (GCP) training certificate. Click "Update" to save. See page 4 for GCP training information.
   To move to the next section, click "Save and Continue" or select the section from the left menu.

5. The following sections are optional for NCI registration:

   a. **CV**
   b. **Personal Statement**
   c. **Professional Memberships**
   d. **Honors**
   e. **Publications**
   f. **Research Support**

6. Click "Save and Continue" to move to the final **NCI Biosketch Completed** page.

Complete Financial Disclosure Form

This section is mandatory for IVR, NPIVR, and AP users.

1. Select one of the following to access the **Financial Disclosure Form (FDF)** workflow:

   a. From the Message Board on the Home page, select "Update FDF" from the "Would you like to" drop-down field and click "Go!".

   b. If you have completed the NCI Biosketch workflow, click "Continue" from the **NCI Biosketch Completed** page.

   c. Select "FDF" from the left "Jump To" menu from any workflow page.

2. Answer all four questions on the page. If "Yes" is selected for any question, add the name of the pharmaceutical company/companies by clicking "Add New Record" from the grid that displays.

3. Click "Save and Continue" to move to the final **Financial Disclosure Form Complete** page.

Complete Agent Shipment Form

This section is mandatory only for IVR users who require NCI-supplied agent shipments.

1. Select one of the following to access the **Agent Shipment Form** workflow:

   a. From the Message Board on the Home page, select "Update Agent Shipment Form" from the "Would you like to" drop-down field and click "Go!".

   b. If you have completed the Financial Disclosure Form workflow, click "Continue" from the **Financial Disclosure Form Complete** page.

   c. Select "Agent Shipment Form" from the left "Jump To" menu from any workflow page.

2. From the **Agent Shipment Form Welcome** page, click 'Yes' to confirm your need to order investigational agents. Note: This page does not display if you have existing shipment information.

3. Complete the summary components by selecting the following information:

   a. **Shipping Site**
   b. **Shipping Address**
   c. **Shipping Designee (SD)**
   d. **Shipping Contact Information**
   e. **Ordering Designee(s) (OD)**

4. Click "Save and Continue" to move to the final **Agent Shipment Summary Completed** page.

NIH NATIONAL CANCER INSTITUTE

Registration and Credential Repository

Complete Practice Preferences

This section is required for IVR, NPIVR, and AP users.

1. Select one of the following to access the **Practice Preferences** page:
   a. From the Message Board on the Home page, select "Update Practice Preferences" from the "Would you like to" drop-down field and click "Go!".
   b. If you are a NPIVR or AP and have completed the Financial Disclosure Form workflow, click "Continue" from the **Financial Disclosure Form Complete** page.
   c. If you are a IVR and have completed the Agent Shipment Summary workflow, click "Continue" from the **Agent Shipment Summary Completed** page.
   d. Select "Practice Preferences" from the left "Jump To" menu from any workflow page.
2. Add your preferences for **Medical / Professional Specialty** and **Areas of Interest**.
3. Click "Save and Continue" to move to the **Sign and Submit Welcome** page.

Validate, Sign and Submit Registration Documents

This section is mandatory for IVR, NPIVR, and AP users.

1. Select one of the following to access the **Sign and Submit** workflow:
   a. From the Message Board on the Home page, select "Update Validate, Sign and Submit" from the "Would you like to" drop-down field and click "Go!".
   b. If you have completed the Practice Preferences workflow, click "Save and Continue".
   c. Select "Validate and View Documents" from the left "Jump To" menu from any workflow page.
2. From the **Validation** page:
   a. Select "Start Complete Registration!".
   b. Click "Go To Page" to make necessary corrections. Use the left "Jump To" menu to return to the **Validation** page. Repeat if needed.
   c. Click "Continue" to move to the **Electronic Signature Acknowledgement** page.
3. From the **Electronic Signature Acknowledgement** page, select the checkbox and click "Save and Continue".
4. To electronically sign each registration document:
   a. Select the Acknowledgment checkbox.
   b. Click "Sign" and enter CTEP-IAM credentials in pop-up eSignature window.
   c. Click "Continue" to move to and sign your next registration document.
5. From the **Review and Submit the Packet** page, click "Submit the Packet" to submit your registration documents after all documents have been signed.

For questions, please contact the CTEP Registration and Credential Repository Help Desk at RCRHelpDesk@nih.gov

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Registration and Credential Repository

Good Clinical Practice (GCP) and Human Subject Protection (HSP) Training Information

The following provides an overview of the GCP and HSP training requirements and provides training resources.

Good Clinical Practice Training

Required at least every three years for all persons assigned to the Investigator, Non-Physician Investigator, and Associate Plus Registration Types.

See the Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials:

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-148.html

The **Training Provider**, **Course Title**, **Completion Date**, and **Expiration Date**, if applicable, and the provider's **training certificate** must be uploaded in the NCI Required Training subsection of the NCI Biosketch.

The GCP Expiration Date can be set to either a) an expiration date set by course provider; or b) three years from course completion date, whichever occurs first.

Current acceptable training options are provided below.

- Collaborative Institutional Training Initiative (CITI) - GCP for Clinical Trials with Investigational Drugs and Medical Devices (US FDA Focus) (charges apply, CITI completion and expiration dates apply):

  https://about.citiprogram.org/en/series/good-clinical-practice-gcp/

  https://about.citiprogram.org/en/course/good-clinical-practice-basic-fda/
- Collaborative Institutional Training Initiative (CITI) GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus) (charges apply, CITI completion and expiration dates apply):

  https://about.citiprogram.org/en/series/good-clinical-practice-gcp/

  https://about.citiprogram.org/en/course/good-clinical-practice-basic-ich/
- National Institute of Allergy and Infectious Diseases (NIAID) Good Clinical Practices course (free of charge, NIAID completion date applies, default three year expiration date applies):

  https://gcplearningcenter.niaid.nih.gov/
- National Institute on Drug Abuse (NIDA) Good Clinical Practice Course (free of charge, NIDA completion and expiration dates apply)

  https://gcp.nidatraining.org/
- TransCelerate GCP Mutual Recognition Program

  http://www.transceleratebiopharmainc.com/gcp-training-attestation/

  http://www.transceleratebiopharmainc.com/wp-content/uploads/2017/03/GCP-MR-Minimum-Criteria-R2_FINAL.pdf

Human Subjects Protection Training

Human Subjects Protection (HSP) training is no longer required for NCI registration. Users with existing HSP information will need to delete this training from their NCI Biosketch. Please refer to the RCR Online Help for additional details.