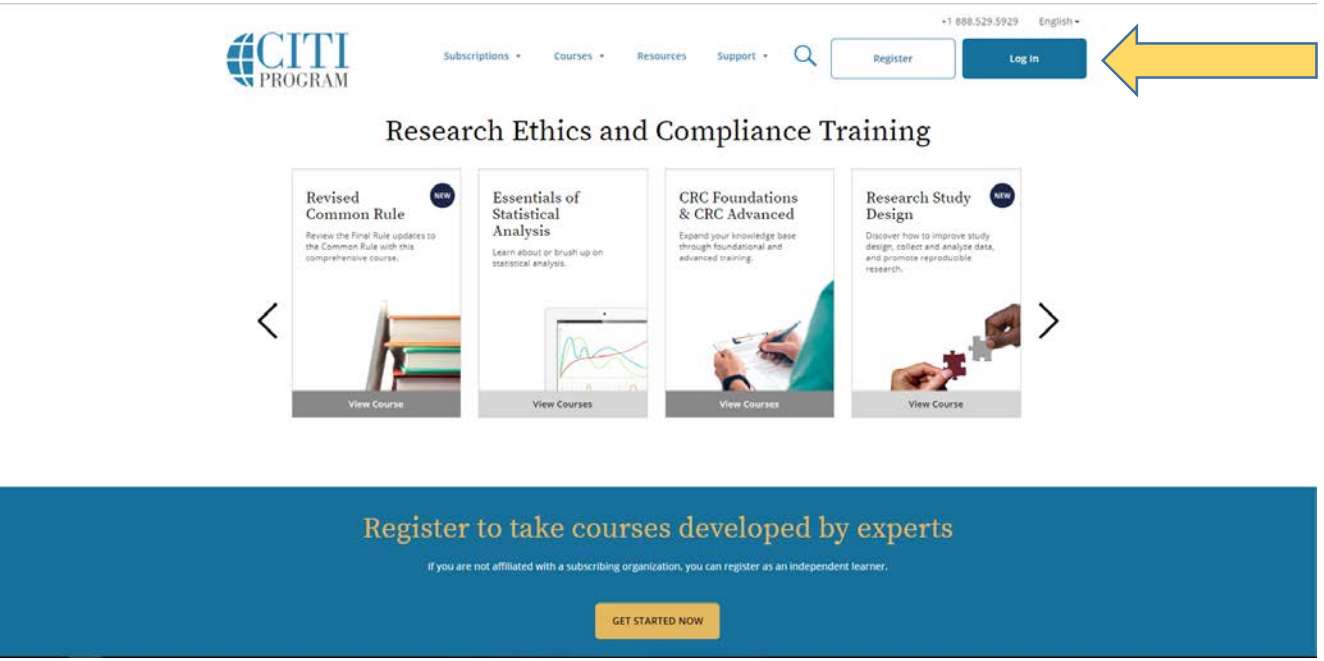
Setting up a Collaborative Institutional Training Initiative (CITI) account for Georgia Tech users

Georgia Institute of Technology

March 2020



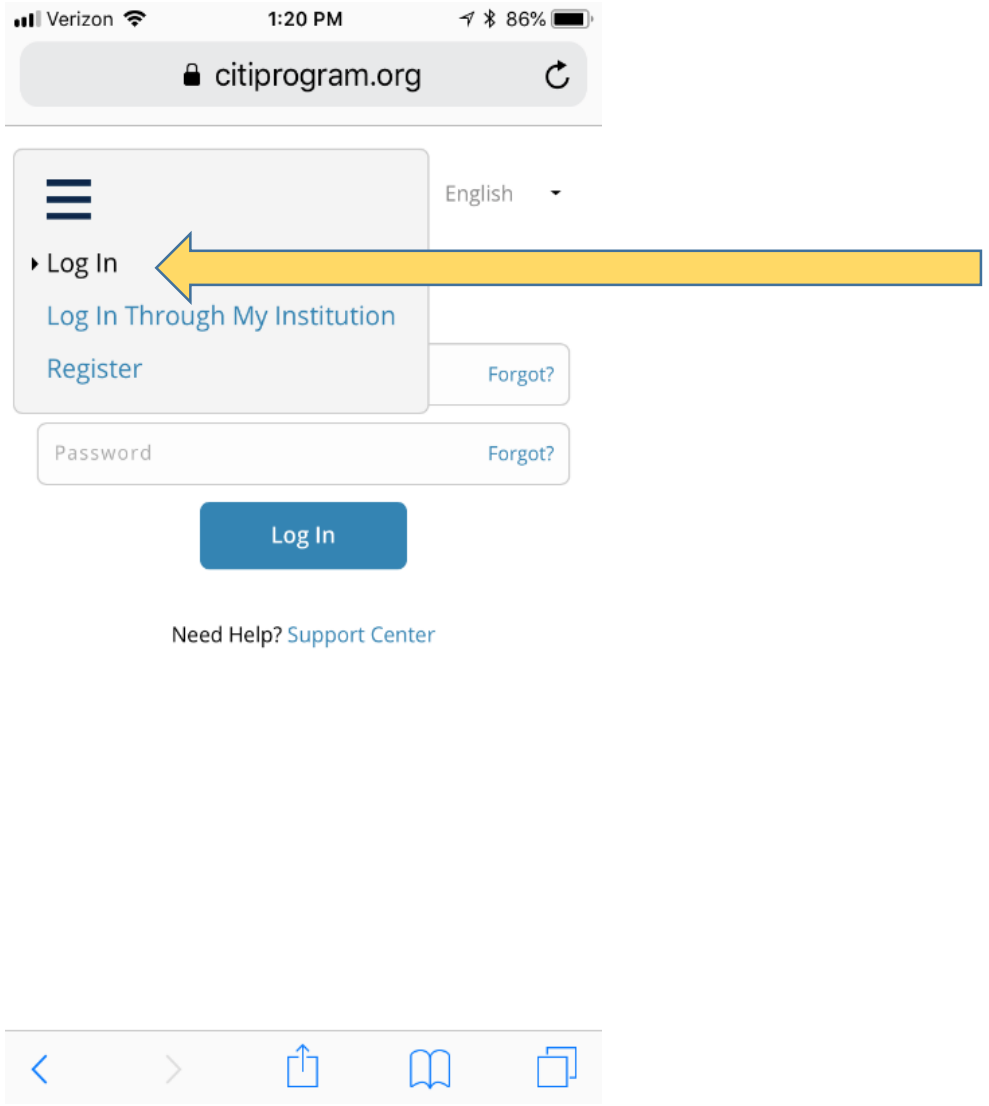
1. All Georgia Tech users (new and returning) should click "Log In."

Non-GT users (community members of the board, collaborators): See separate instructions on the Research Integrity Assurance webpage at https://oria.gatech.edu/irb-required-training

1a. If you are using a mobile device, you will need to select the three menu bars on the left side of the screen.

If not using a mobile device, then please skip to step 2.

Non-GT users (community members of the board, collaborators): See separate instructions on the Research Integrity Assurance webpage at https://oria.gatech.edu/irb-required-training



1b. All GT users using a mobile device then need to select "Log In."

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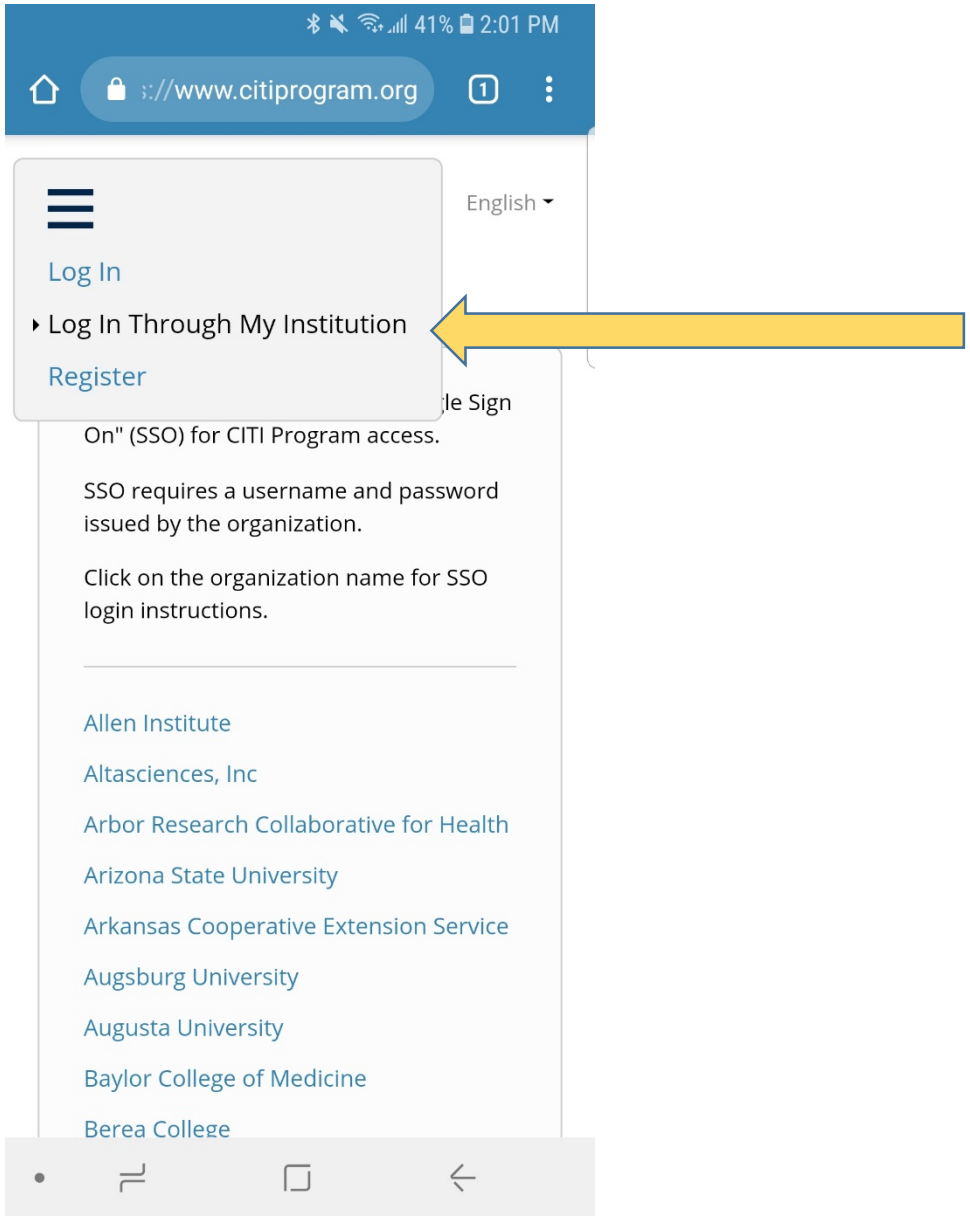

1c. Next, all GT users using a mobile device will need to select click the three menu bars again and then select "Log In Through My Institution."

All returning GT Please skip to step 3 if using a mobile device.

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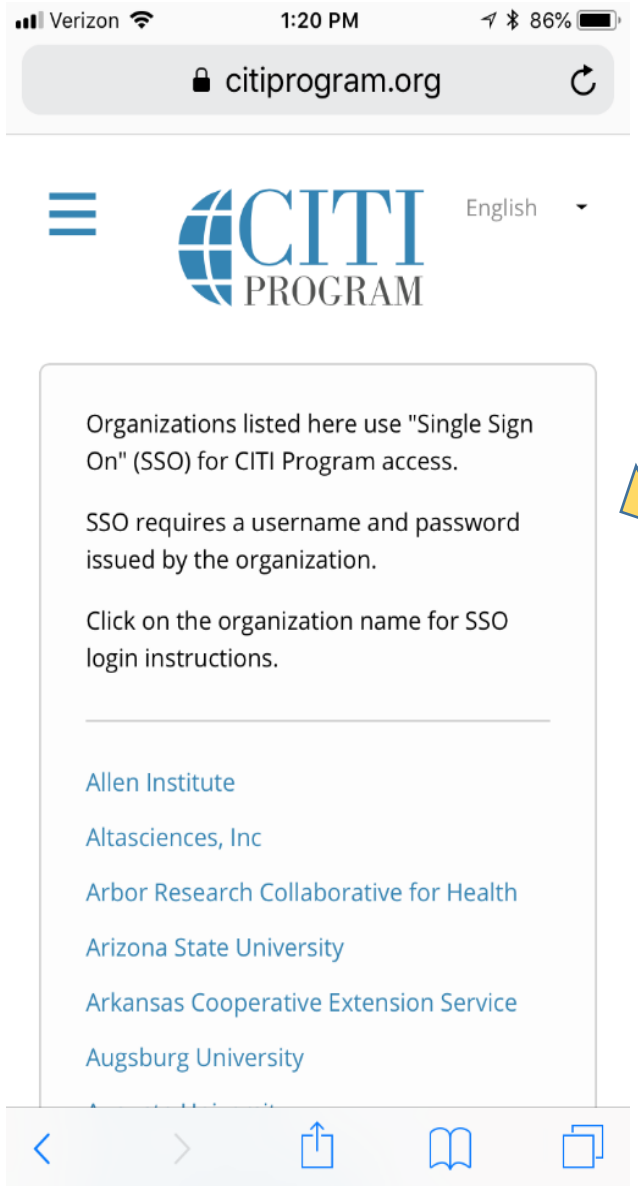

1d. Lastly, all new GT users using a mobile device will need to select Georgia Institute of Technology in the institution list. Please skip step 2 if using a mobile device.

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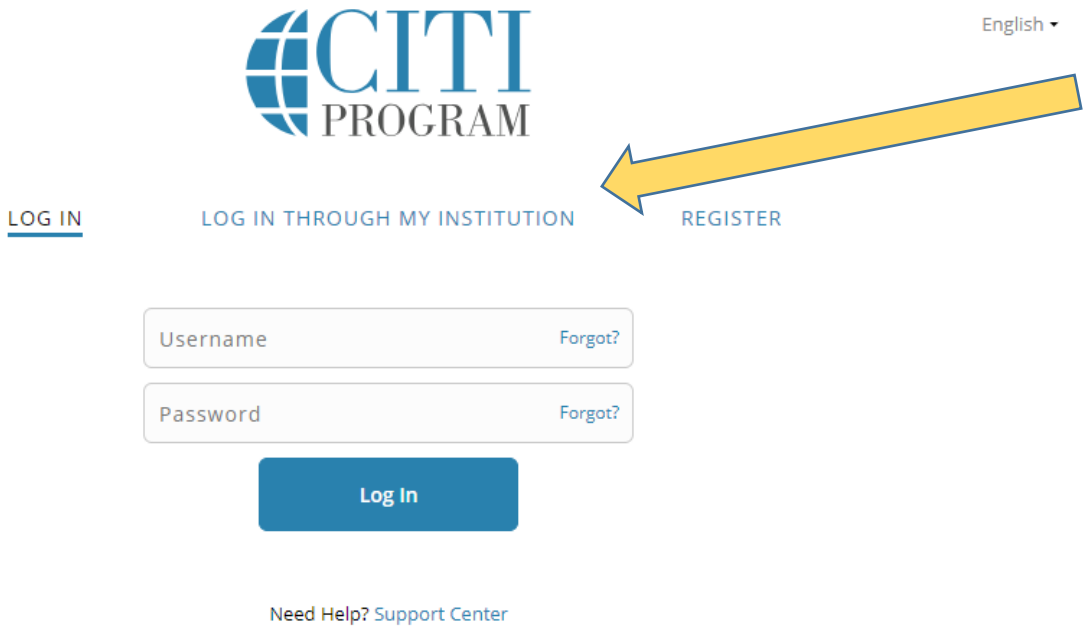
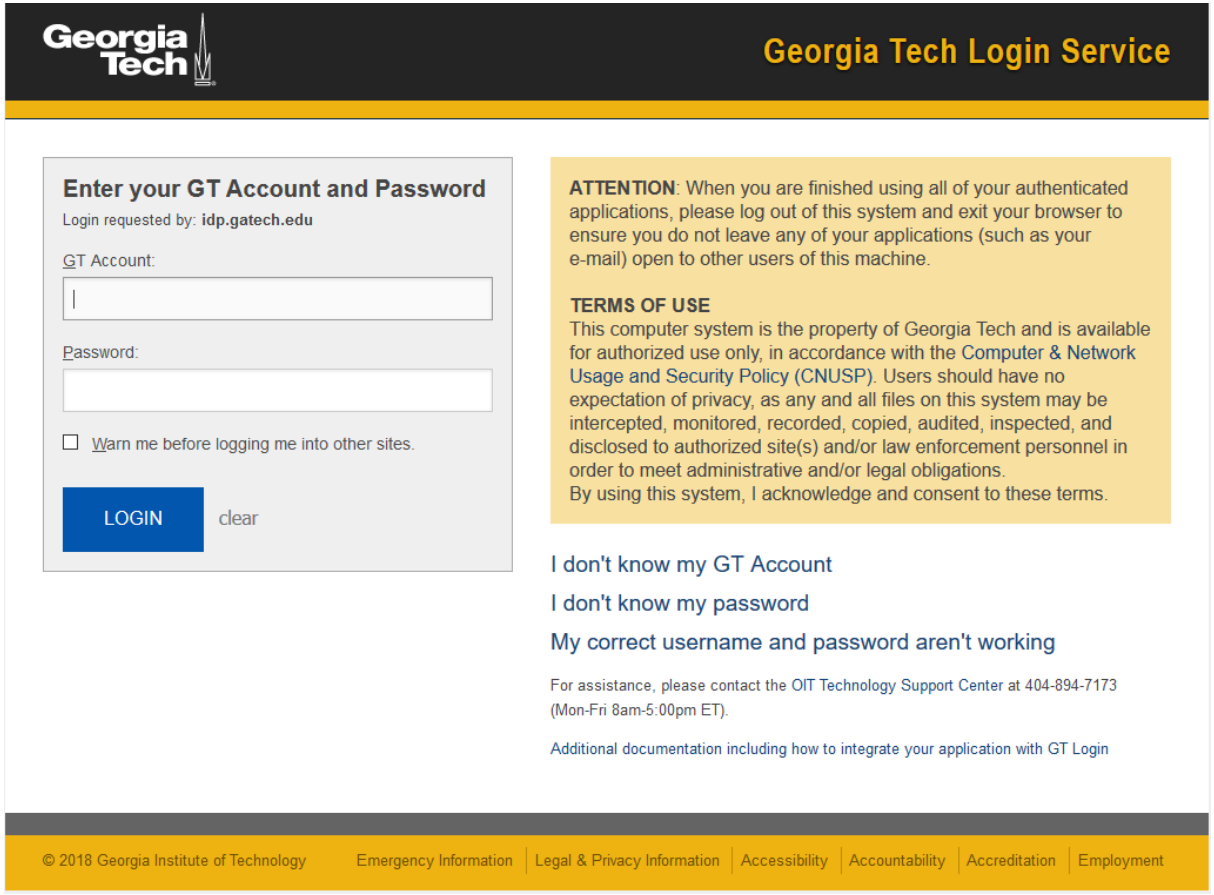


2. You will be brought to this page after clicking "Log In" on the first page from a computer. All GT users, both new and returning, click "Log In Through My Institution."

After clicking this, a list will display. Please select "Georgia Institute of Technology" from this list.



3. After clicking on Georgia Tech, you will be re-directed to the GT Single Sign-On page. Please enter in your GT username and password when on this site.

Please note that if you are already logged into Single Sign-On, you will be automatically redirected to the CITI webpage.

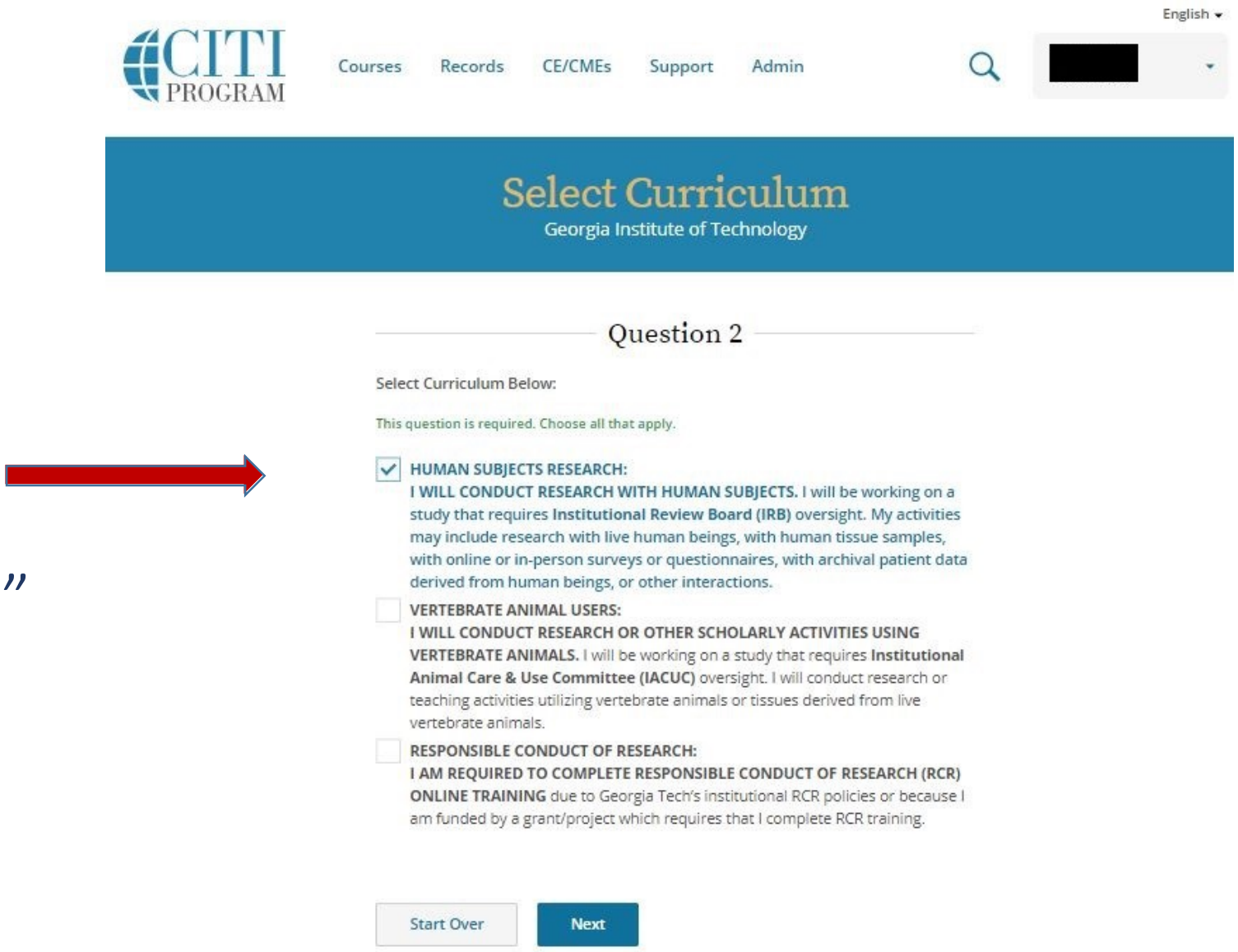
All returning GT users, please skip to step 8.

3a. All new users and users going through Single Sign-On for the first time will be asked to associate your account with a CITI Program account.

If you already have an existing CITI account, select the first option (you will be asked to enter your existing CITI username and password so that CITI can match your accounts).

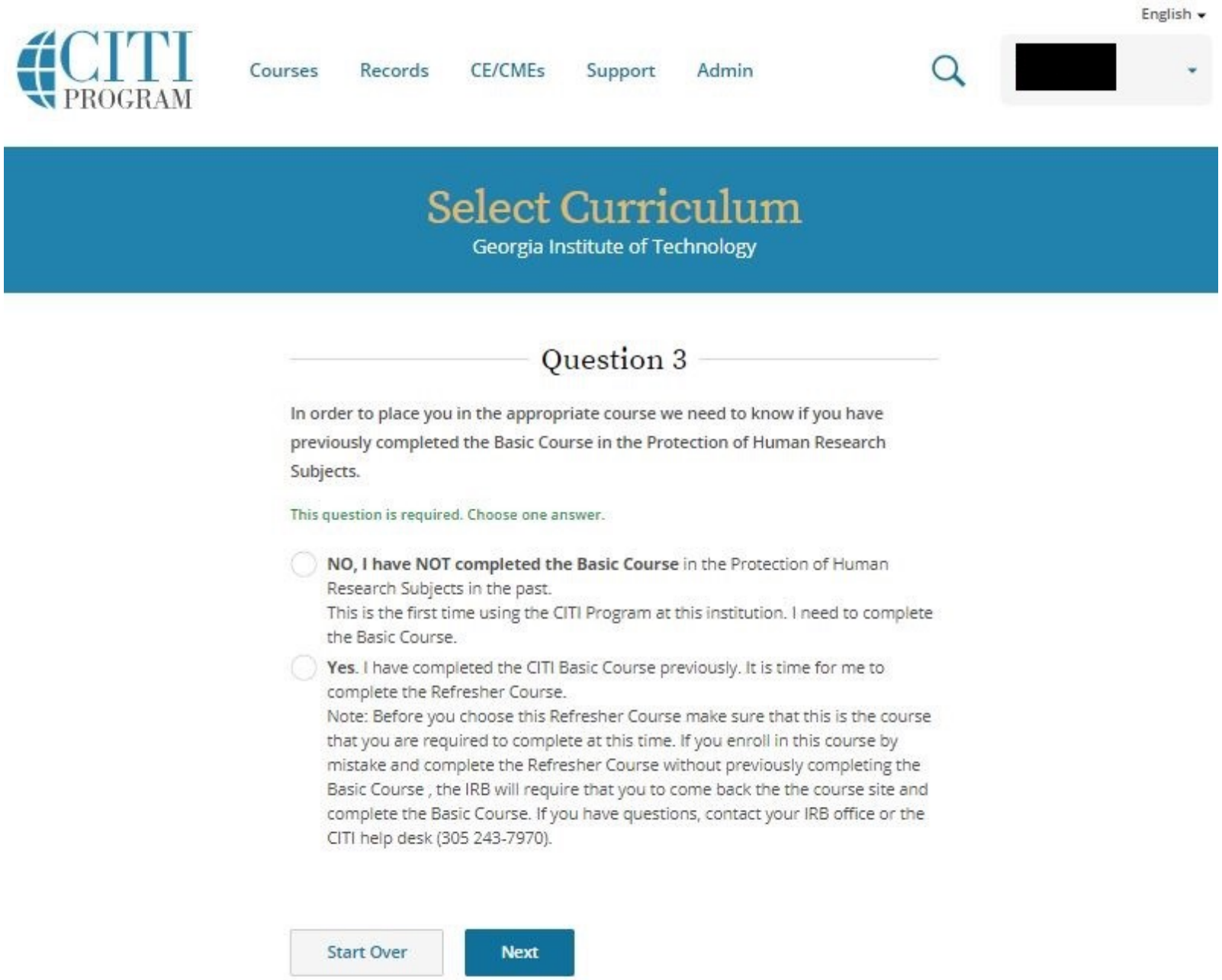
If you don't have an existing CITI account, then please select the second option.

4. Select Curriculum: “Human Subjects Research”



5. If you have not previously completed the basic modules, select “NO, I have NOT completed the Basic Course…”

If you just need the refresher course, required every 3 years, select “YES, I have completed the CITI Basic Course…”

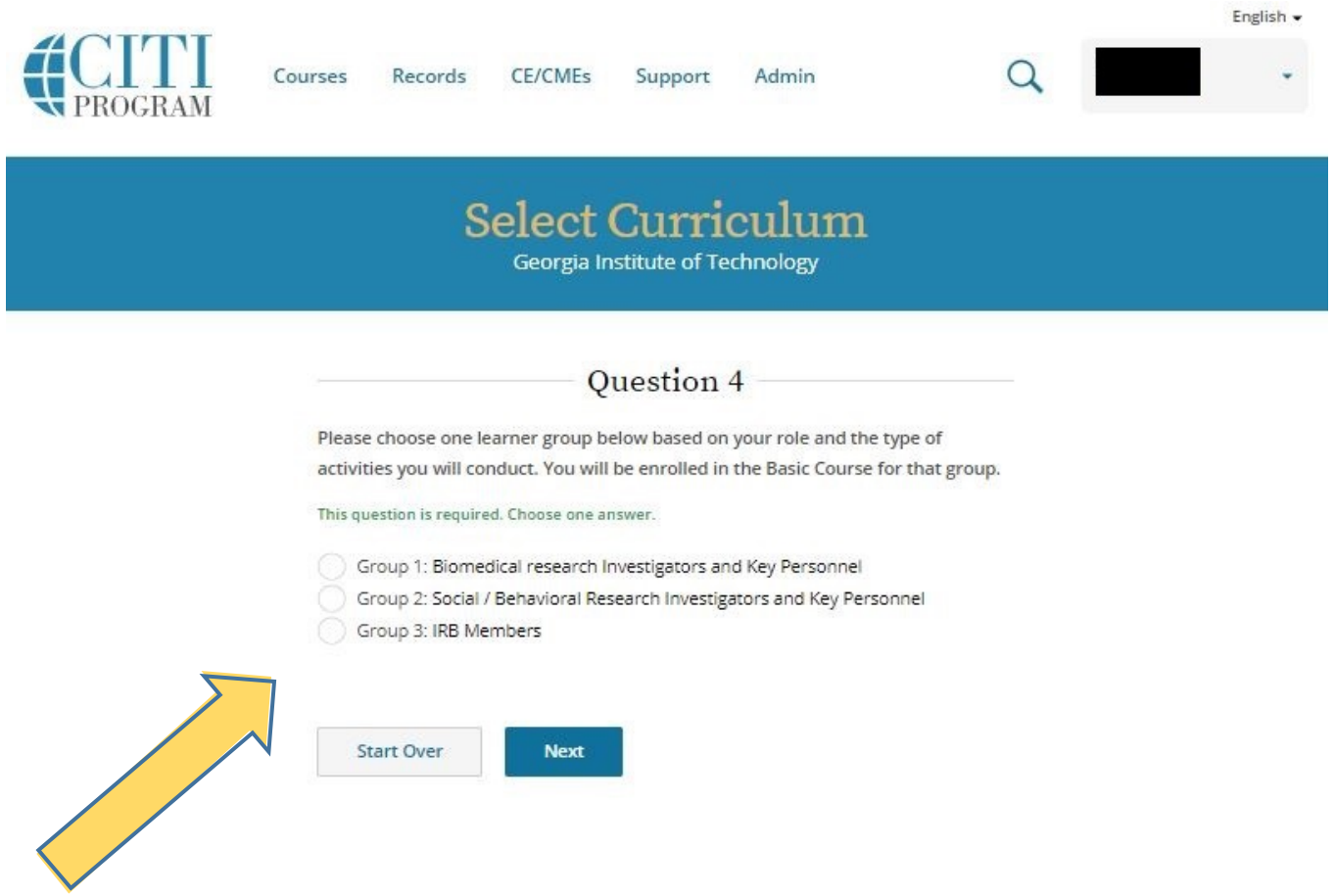


6. Depending on your proposed research study, select either "Group 1: Biomedical Research Investigators and Key Personnel"

or

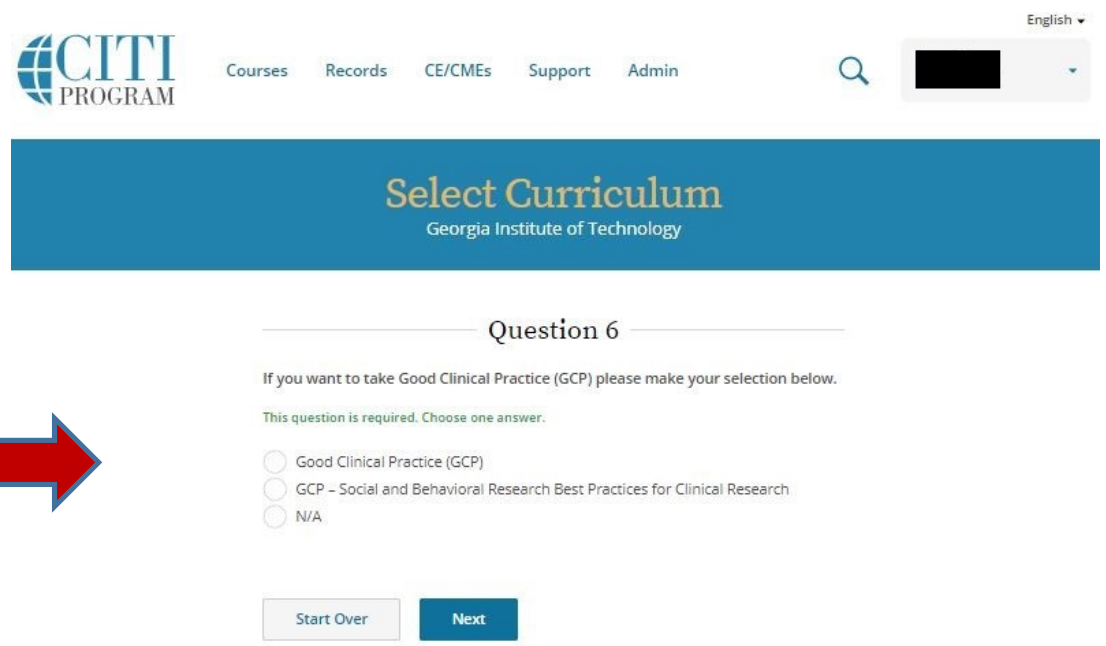
"Group 2: Social/Behavioral Research Investigators and Key Personnel"

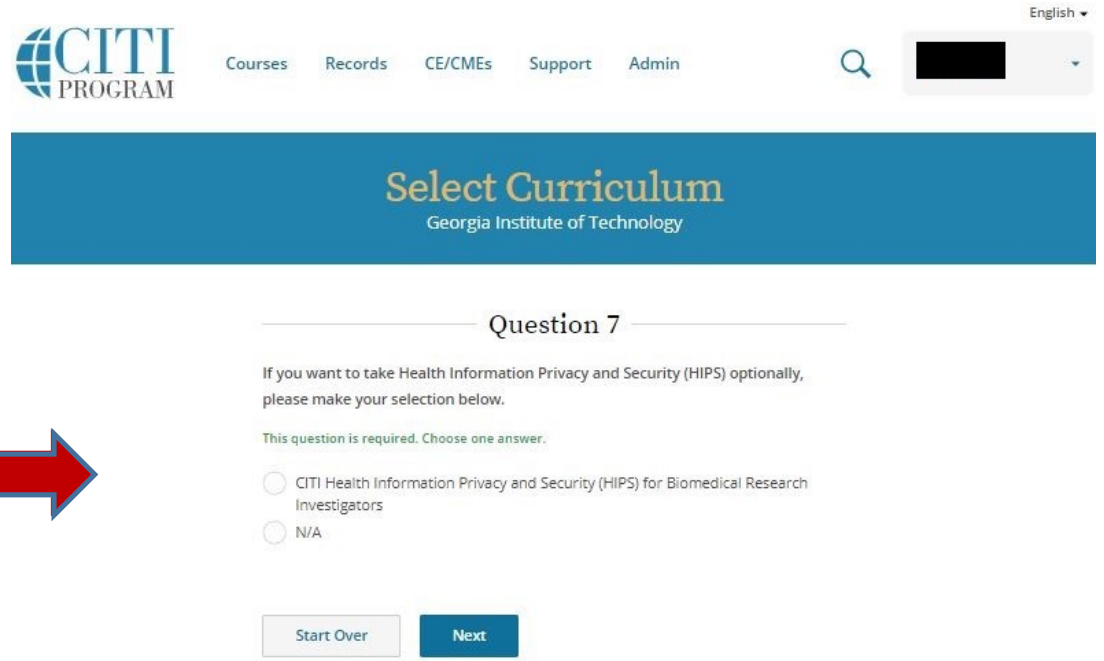
ONLY IRB Members (members of the reviewing committees) should select Group 3.



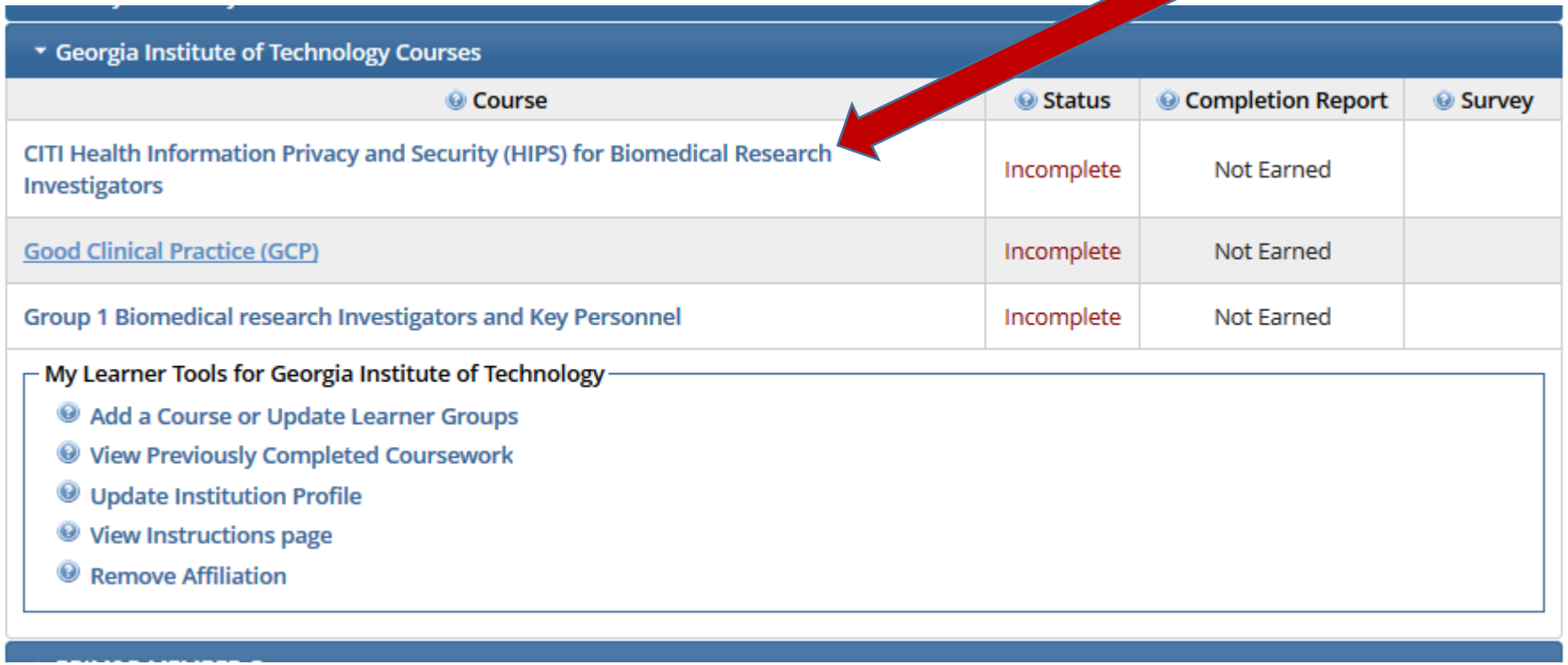
7. If you are conducting a clinical trial as defined by the FDA, OHRP, or NIH, and/or conducting research on a medical device, drug, biologic, or an in vitro diagnostic involving human subjects or human subjects specimen(s), you will also need to complete the CITI course for "Good Clinical Practice (GCP)." If your study is an NIH funded socio-behavioral clinical trial, then you will need to complete the CITI course for “GCP – Social and Behavioral Resaerch Best Practices for Clinical Research."

If you will access Protected Health Information (PHI), which includes medical records, also select “CITI Health Information Privacy & Security (HIPS).”





8. After selecting courses, CITI will return you to the main page. Click on any course title to begin completing modules.
You may stop at any time and return to the curriculum later.



Social/Behavioral Research Investigators and Key Personnel Modules

- ✓ **Belmont Report & CITI Course Introduction**
- ✓ **Students in Research**
- ✓ **History & Ethical Principles**
- ✓ **Defining Research with Human Subjects**
- ✓ **The Federal Regulations**
- ✓ **Assessing Risk**
- ✓ **Informed Consent**
- ✓ **Privacy & Confidentiality**
- ✓ **Research with Children**
- ✓ **Research in Public Elementary & Secondary Schools**
- ✓ **International Research**
- ✓ **International Studies**
- ✓ **Internet-Based Research**
- ✓ **Research & HIPAA Privacy Protections**
- ✓ **Vulnerable Subjects – Research Involving Workers/Employees**
- ✓ **Conflicts of Interest in Research Involving Human Subjects**

CITI Health Information Privacy & Security (HIPS) Modules

- ✓Basics of Health Privacy
- ✓Health Privacy Issues for Researchers
- ✓Basics of Information Security, Part 1
- ✓Basics of Information Security, Part 2
- ✓Protecting Your Computer

Biomedical research Investigators and Key Personnel - Basic Course Modules

- ✓ Belmont Report & CITI Course Introduction
- ✓ History & Ethics of Human Subjects Research
- ✓ Basic Institutional Review Board Regulations & Review Process
- ✓ Informed Consent
- ✓ Social & Behavioral Research for Biomedical Researchers
- ✓ Records-Based Research
- ✓ Genetic Research in Human Populations
- ✓ Populations in Research Requiring Additional Considerations and/or Protections
- ✓ Vulnerable Subjects – Research Involving Children
- ✓ Vulnerable Subjects – Research Involving Pregnant Women, Human Fetuses, and Neonates
- ✓ International Studies
- ✓ FDA- Regulated Research
- ✓ Research and HIPAA Privacy Protections
- ✓ Vulnerable Subjects – Research Involving Workers/Employees
- ✓ Conflicts of Interest in Research Involving Human Subjects
- ✓ Avoiding Group Harms – U.S. Research Perspectives
- ✓ Stem Cell Research Oversight (Part 1)

Good Clinical Practice Modules

- ✓ The CITI Good Clinical Practice Course for Clinical Trials Involving Drugs & Devices
- ✓ Overview of New Drug Development
- ✓ Overview of ICH GCP
- ✓ ICH – Comparison between ICH GCP E6 and U.S. FDA Regulations
- ✓ Conducting Investigator-Initiated Studies According to FDA Regulations & GCP
- ✓ Investigator Obligations in FDA-Regulated Research
- ✓ Managing Investigational Agents According to GCP Requirements
- ✓ Overview of U.S. FDA Regulations for Medical Devices
- ✓ Informed Consent in Clinical Trials of Drugs, Biologics, Devices
- ✓ Detecting and Evaluating Adverse Events
- ✓ Reporting Serious Adverse Events
- ✓ Audits and Inspections of Clinical Trials
- ✓ Monitoring of Clinical Trials by Industry Sponsors
- ✓ Completing the CITI GCP Course

Finished!

- ✓Print your certificate of completion for your records.
- ✓No need to provide a copy to Research Integrity Assurance.
- ✓The Office of Research Integrity Assurance will receive notification from CITI.