

Starting a Research Project

BSWH Procedures

1. Complete the Collaborative Institutional Training Initiative (CITI) for Biomedical Researchers (see attachment for instructions).
 - a. Per federal regulations, this human subject research training must be completed before research can be performed. Go to <https://www.citiprogram.org/> and register as a new user using Baylor Scott & White Research Institute (CTX or NTX) as your facility.
 - b. Please note, additional modules may be required if conducting animal or biohazard research or research that is federally funded.

For questions regarding CITI training, please contact:

CTX: Tracy Troxell at 254-771-4869 or Tracy.Troxell@BSWHealth.org

NTX: Heather Whitacre at 214-820-9692 or Heather.Whitacre@BSWHealth.org

2. If the research is federally funded, you will also need to complete the CITI Conflict of Interest module and the CITI Good Clinical Practice Course in addition to the module listed in step #1 above. Certain cases may also require the Responsible Conduct of Research (RCR) course. Instructions are embedded in the CITI registration instructions on page 3.
3. Open and activate an iRIS (integrated Research Information System) account.
 - a. This is the system used by BSWRI to track and house all research documentation and submit research to the appropriate regulatory body(ies) (i.e. IRB, IACUC, or IBC) for approval(s).
 - b. To request an account, send a requisition form to BRI_IRB@baylorhealth.edu.
 - c. After the account has been created, go to <https://briops.baylorhealth.edu> to access your account.
4. Complete a Conflict of Interest Disclosure via COI-Smart. Once your iRIS account is created, you will receive an automated notification from the COI-Smart system to complete this disclosure. Once you receive this email, you will have 5 business days to complete the disclosure.

For questions regarding iRIS account activation, contact BRI_IRB@BSWHealth.org

For questions regarding COI-Smart, please contact Tracy Troxell at 254-771-4869

Tracy.Troxell@BSWHealth.org or Lauren Ellis at 254-771-4813 Lauren.Ellis@BSWHealth.org

**Your CITI certification for human subject research is valid for 3 years and COI is valid for 4 years; this will be communicated to the iRIS system upon completion.*

**If you have completed CITI training at another institution, you will need to affiliate with Baylor Scott & White Health in your CITI account for previously completed activities to be accessed in the Baylor Scott & White Health system.*

**BSWH IRB has specific guidelines in place regarding case reports. For one or two cases, submission to the IRB is not required. For three or more cases, IRB submission is required as it is considered human subject research per the federal guidelines. Of note, if an investigator plans to publish a single or double case report, the journal may require documentation indicating that IRB oversight is not required by BSWH. If the journal requires such verification, IRB submission will need to be completed to document their decision. Investigators are encouraged to submit all case reports to the IRB, regardless of number, to prevent limitations in journal selection when submitting manuscripts.*

New User Account Request

iRIS™ IRB/Study Assistant™

Please Provide the Following Information:

1.	First Name:	Click here to enter text.
2.	Last Name:	Click here to enter text.
3	Degree/Certification:	Click here to enter text.
4.	If you are a Baylor Employee, please provide the following:	
	• 9 digit employee number	Click here to enter text.
	• Baylor System Log-in ID	Click here to enter text.
	• Baylor email address	Click here to enter text.
	• 9 digit department number	Click here to enter text.
	• Manager Name	Click here to enter text.
	• Principal Investigator Name	Click here to enter text.
5.	If you are a member of the Medical or Allied Health Staff for any Baylor facility, please provide the following:	
	• Baylor System Log-in ID	Click here to enter text.
	• Baylor email address	Click here to enter text.
	• Preferred email address (if different from Baylor email)	Click here to enter text.
	• Principal Investigator Name	Click here to enter text.
	• Date of Birth	Click here to enter text.
	• Last Four of Social Security Number	Click here to enter text.
6.	If you do not fit into any of these categories, please provide the following:	
	• Baylor System Log-in ID	Click here to enter text.
	• Preferred email address	Click here to enter text.
	• Date of Birth	Click here to enter text.
	• Last Four of Social Security Number	Click here to enter text.
	• Principal Investigator	Click here to enter text.
	• Location of Research Activities	Click here to enter text.
7.	If this person is a PHS(Public Health Service) funded researcher or grant for which PHS regulations for COI apply, indicate with an X.	PHS Click here to enter text.

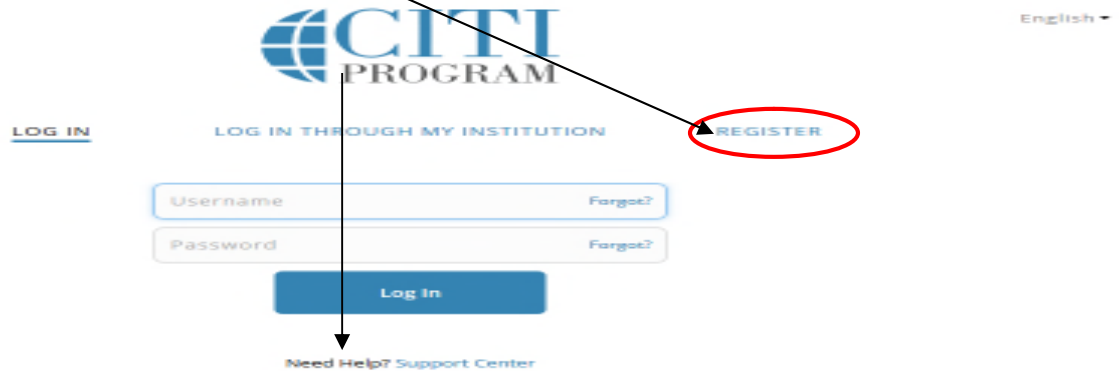
All submissions must include completion of 1 - 3 plus either 4 or 5 or 6 or 7, depending on your status. All questions for the applicable sections must be answered. If you do not have a Baylor System Log-in ID, you must also sign the BIS Confidentiality agreement and one will be requested for you to use as long as you are on an active research project with BRI. Please forward all information to BRI_IRB@baylorhealth.edu
Upon receipt of the information, an account will be established in 3-5 working days.

CITI Registration Instructions

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Log onto <https://www.citiprogram.org/>

To register, click on the "**Register**" button (circled below). If you are re-entering the site after already registering, enter your username and password and click Log In. And if you have forgotten your username and/or password, please click below to have the system send you your information.



CITI - Learner Registration

Steps: **1** 2 3 4 5 6 7

You must make a selection below.

Select Your Organization Affiliation

Search for organization: Enter full or partial name

Baylor Scott & White Research Institute - CTX

Can't find your institution? It may use Single Sign On. Check here.

To find your organization, enter its name in the box above, then pick from the list of choices provided. If the selection is correct, click the "Continue to Step 2" button immediately below. To clear your selection and try again, click the "Search Again" button.

I AGREE to the [Terms of Service](#) for accessing CITI Program materials.

Continue To Step 2

Independent Learner Registration

Use this option if you are paying for your courses. Click the button "Continue as Independent Learner" to affiliate as an Independent Learner. This option is for persons not affiliated with a CITI Program subscriber organization, or who require content that their organization does not provide. Fees apply. Credit card payment with American Express, Discover, MasterCard or Visa is required. Checks are not accepted.

I AGREE to the [Terms of Service](#) for accessing CITI Program materials.

I have confirmed that the course(s) that I will purchase as an Independent Learner are not available from an organizational subscriber to CITI Program with which I am affiliated. Note: CITI Program does not issue refunds for courses if you later determine that your organization provides access.

Continue As Independent Learner (Fees Apply)

Please **select:**
Baylor Scott & White Research Institute - CTX as your institution if you will be conducting the research at BSWRI and/or using protected health information of BS&W patients. **Please do not select Texas A&M** (except under certain circumstances – please contact **Evelyn Kile** at **254-771-4836** to determine if you should select Texas A&M as your institution; you will be required to re-enter your CITI account and affiliate with BS&W and take any additional modules required if you select Texas A&M). You will have the option later on the affiliate yourself with other institutions.

Question 1 - Select the 1st option below (note Conflict of interest and Good Clinical Practice are required when using federal funding):

Select Curriculum - Baylor Scott & White Research Institute - CTX (381)

* Indicates a required field.

* To enable the software to present the appropriate course work for your needs, you will be asked a series of questions. Please read the questions carefully and provide the most appropriate answer.

Do you conduct research in any of the following settings?
Choose all that apply

- Yes, I conduct research with live human beings, human samples or with data derived from human beings.
- Yes, I conduct research or teaching activities that utilizes live, animal subjects or tissues derived from live animal subjects.
- Would you like to take the Conflict of Interest Course (required prior to conducting research and must be renewed every 3 years)?
- Would you like to take a Good Clinical Practice Course (optional but recommended for clinical researchers and coordinators)?
- Would you like to take the Responsible Conduct of Research (RCR) Course?
- Would you like to take the Information Privacy and Security (IPS) Course?

Next Start Over

Optional

Question 2 - Select the 1st option below.

* Which type of human subjects training do you need?
Choose one answer

- Biomedical Researchers
- IRB Administrator: Do NOT select this Learner Group. For IRB Administrator Use Only. All CITI modules are available for ongoing use and reference when you join this Learner Group. However, if you are required to complete the CITI modules as a prerequisite for conducting human subjects research, you must enroll in the appropriate Group in accordance with Scott and Whites's requirements.

Next »

Question 3 – Select additional modules if applicable.

CITI PROGRAM Collaborative Institutional Training Initiative Search Support Center

Main Menu My Profiles My CEUs My Reports Support Admin

Main Menu » Add a Course

Select Curriculum - Baylor Scott & White Research Institute - CTX (381)

* Indicates a required field.

* Please choose one learner group below based on your role and the type of activities you will conduct.
Choose one answer

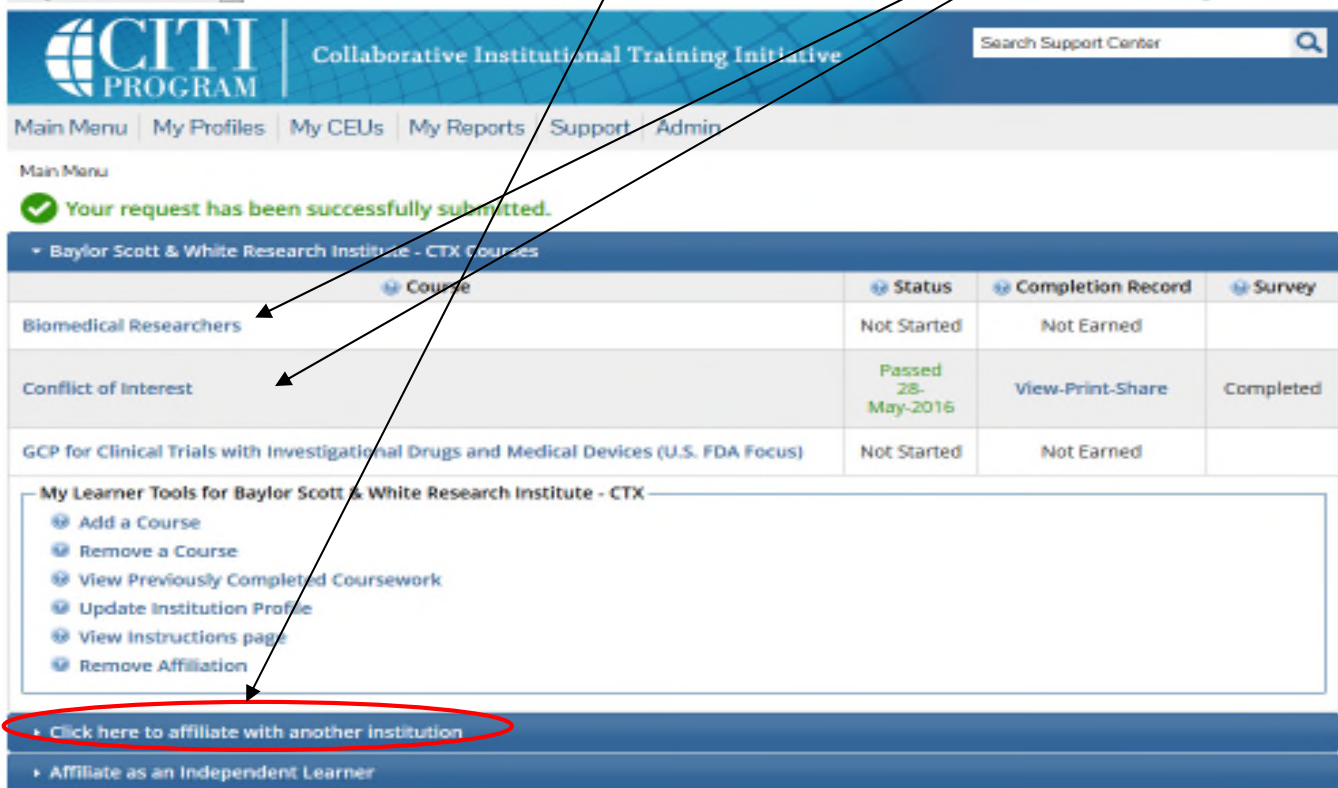
- GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)
- GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus)

CITI Registration Instructions

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If you have reached the below screen, you are successfully registered. Click on the [course title](#) link to begin each course.

If you wish to affiliate with more than one institution (such as BS&W and Texas A&M or the Temple VA), click where it reads "[Click here to affiliate with another institution](#)" on your Main Menu page:



The screenshot displays the CITI PROGRAM interface. At the top, there is a navigation bar with the CITI PROGRAM logo and the text "Collaborative Institutional Training Initiative". Below this is a search bar for the Support Center. The main menu includes links for "Main Menu", "My Profiles", "My CEUs", "My Reports", "Support", and "Admin". A green checkmark icon indicates a successful registration: "Your request has been successfully submitted." Below this, a table lists courses for "Baylor Scott & White Research Institute - CTX Courses". The table has columns for "Course", "Status", "Completion Record", and "Survey". The courses listed are "Biomedical Researchers", "Conflict of Interest", and "GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)". Below the table, there is a section for "My Learner Tools for Baylor Scott & White Research Institute - CTX" with options like "Add a Course", "Remove a Course", "View Previously Completed Coursework", "Update Institution Profile", "View Instructions page", and "Remove Affiliation". At the bottom, there are two links: "Click here to affiliate with another institution" (circled in red) and "Affiliate as an Independent Learner".

Course	Status	Completion Record	Survey
Biomedical Researchers	Not Started	Not Earned	
Conflict of Interest	Passed 28- May-2016	View-Print-Share	Completed
GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)	Not Started	Not Earned	

Once you have successfully completed the courses, CITI will automatically e-mail your completion report to the IRB Office.

Please contact **Evelyn Kile** at **254-771-4836** or Evelyn.Kile@BSWHealth.org if you have any questions.