UTRGV IRB HUMAN SUBJECTS TRAINING REQUIREMENTS:

Training requirements for UTRGV researchers and members of the research team are outlined below.

1) All investigators involved with human subjects research (including analysis of identifiable private information) must complete human subjects training and provide evidence of that training to the IRB with each new IRB protocol submission.

2) The PI on a study (and the faculty advisor, if the study is conducted by a student) must complete the CITI Basic Course.

3) All co-investigators and research assistants involved in the study must also complete the Basic Course.

4) The Basic Course is valid for 2 years. If the completion certificate is over 2 years old at the time of submission, a CITI refresher course must be completed. Both the original CITI Basic Course certificate and the Refresher Course certificate must be submitted with each IRB protocol.

5) To reduce the training requirements for UTRGV researchers, over half of the modules in the default CITI Basic Course have been designated “optional/elective” modules. The UTRGV Basic CITI course is thus greatly reduced in length from standard CITI requirements. Researchers are only required to take the optional/elective modules if one or more of them apply to the specific research protocol (e.g., the study involves prisoners, is conducted online, is conducted with children, etc.). These optional modules are only available if the researcher has already completed the Basic Course.

6) When the researcher is working with community volunteers who may be directly involved with subjects for the purposes of research (e.g., health workers, teachers), the standard UTRGV IRB training requirements for those individuals apply.

The social behavioral course (“learner group”) contains the following REQUIRED modules:

<table>
<thead>
<tr>
<th>Module</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belmont Report and CITI Course Introduction</td>
</tr>
<tr>
<td>History and Ethical Principles</td>
</tr>
<tr>
<td>Defining Research with Human Subjects</td>
</tr>
<tr>
<td>The Federal Regulations</td>
</tr>
<tr>
<td>Assessing Risk</td>
</tr>
<tr>
<td>Informed Consent</td>
</tr>
<tr>
<td>Privacy and Confidentiality</td>
</tr>
<tr>
<td>Records-Based Research</td>
</tr>
<tr>
<td>Populations in Research Requiring Additional Considerations and/or Protections</td>
</tr>
</tbody>
</table>

As part of the basic course you are also required to complete ONE “ELECTIVE” module. The “ELECTIVE” modules are listed below:

<table>
<thead>
<tr>
<th>Module</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research with Persons who are Socially or Economically Disadvantaged</td>
</tr>
<tr>
<td>Research with Decisionally Impaired Subjects</td>
</tr>
<tr>
<td>Illegal Activities or Undocumented Status in Human Research</td>
</tr>
<tr>
<td>Research with Subjects with Physical Disabilities &amp; Impairments</td>
</tr>
<tr>
<td>Research Involving Subjects at the End of Life</td>
</tr>
<tr>
<td>Research with Older Adults</td>
</tr>
<tr>
<td>Research with Critically Ill Subjects</td>
</tr>
</tbody>
</table>
Researchers will need to obtain at least an 80% average on the entire course in order to obtain the CITI Basic Social-Behavioral Completion Report.

Researchers are also required to complete certain “SUPPLEMENTAL” modules if the modules apply to their research. For example, researchers conducting studies in elementary schools must complete both the “Research in Public Elementary and Secondary Schools – SBE” and the “Research with Children – SBE” modules. Researchers must score 100% on any of these “SUPPLEMENTAL” modules and should submit a printout of their CITI grades along with the CITI completion certificate. IRB protocols will not be reviewed until any necessary applicable “SUPPLEMENTAL” modules have been passed.

The “SUPPLEMENTAL” modules are listed below:

<table>
<thead>
<tr>
<th>Module</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research in Public Elementary and Secondary Schools - SBE</td>
</tr>
<tr>
<td>Avoiding Group Harms – U.S. Research Perspectives</td>
</tr>
<tr>
<td>Research with Children - SBE</td>
</tr>
<tr>
<td>Internet-Based Research - SBE</td>
</tr>
<tr>
<td>International Research - SBE</td>
</tr>
<tr>
<td>Research and HIPAA Privacy Protections</td>
</tr>
<tr>
<td>Research with Prisoners - SBE</td>
</tr>
<tr>
<td>Vulnerable Subjects – Research Involving Workers/Employees</td>
</tr>
<tr>
<td>Conflicts of Interest in Research Involving Human Subjects</td>
</tr>
<tr>
<td>Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates</td>
</tr>
<tr>
<td>Human Use Devices</td>
</tr>
<tr>
<td>FDA-Regulated Research</td>
</tr>
<tr>
<td>Genetic Research in Human Populations</td>
</tr>
</tbody>
</table>

**Instructions for Completing the UTPA IRB Human Subjects Protection Training:**

**Online CITI Course**

Detailed instructions, with screen shots, are provided below. The first section explains how to register and take the basic course. The second section explains how to take the “SUPPLEMENTAL” modules. The third section explains how to take the refresher course. The fourth section explains how to access and print out previously completed course certificates.
Section I
Instructions for CITI registration and completion of Basic Course
Instructions for Completing the UTRGV IRB Human Subjects Protection Training: Online CITI Course

1) Go to the CITI website at [www.citiprogram.org](http://www.citiprogram.org)

2) Click on “Register”
3) Complete the seven registration steps.
   - In the first step, type “Rio Grande Valley” and select University of Texas – Rio Grande Valley from the drop-down box.
   - After all sections have been completed, click “Continue”

**Note:** You are not required to register/pay for CME/CEU credits for UTRGV IRB approval. This is optional.
4) Follow steps 2-6 by entering the required information (marked with an asterisk).
   - After the fields have been completed, click "Continue"
Gender, Ethnicity and Race

Why does CITI Program ask about your gender, race and ethnicity? 
Why does CITI Program use these categories? 
Why does CITI Program ask about your gender? 
* indicates a required field.

* Your Gender Is:
- Male
- Female
- I would rather not disclose

* Your Ethnicity Is: (You may choose only one)
- Hispanic or Latino
- Not Hispanic or Latino
- I would rather not disclose

* Your Race Is: (You may choose more than one)
- American Indian or Alaska Native
- Black or African American
- Asian
- Native Hawaiian or Other Pacific Islander

* Are you interested in the option of receiving Continuing Education Unit (CEU) credit for completed CITI Program courses?

If you answer “yes”, you will be provided with information before you start a CEU-eligible course about the amount of credit available, information about the course authors, and other required CEU disclosures. This information must be viewed before a course is started in order for you to be eligible to purchase CEU credit after course completion. However, answering “yes” does not obligate you to purchase CEU credits for any course.

If you answer “no”, you will not see information about the CEU credits available for courses before you start them or after completing them, and you will be ineligible for CEU credit for these courses. You can change this preference at any time by clicking on a “CEU Information” link or using a “My Profile” link to update your Profile.

If you’re not sure, you can change your answer later.
- Yes
- No
- Not sure. Ask me later

If you answered “yes”, please check all the types of CEU credit that may be of interest. This information allows us to ensure that you receive appropriate Pre- and Post-Course information relevant to the kind(s) of CEU credit that you may request.
- AMA PRA Category 1 Credits
- Nurses (CME Credits)
- Other
- Psychologists (CEP Credits)

* Can CITI Program contact you at a later date regarding participation in research surveys?
- Yes
- No
- Not sure. Ask me later
5) To complete step 7, indicate the course that you wish to take.
   - For IRB purposes, researchers only need to take the **Human Subjects Protection course**.
   - You do **NOT** have to complete the Responsible Conduct of Research course for IRB submissions.
   - After you have made your selection, click “Next”
6) **Indicate which Basic Course you wish to complete**
   - Select “Group 1: Social Behavioral Research Course”
     Note: this learner group option is the most common at UTRGV. If you believe the biomedical course is more appropriate to your area of research, you may elect to complete that course. However, the human subjects training will be more biomedically oriented.
   - DO NOT select the IRB Member Course – this is only for IRB members and staff.
   - If you are in any doubt, please contact the Research Compliance Office at 665-2889 before selecting your learner group.
   - Click “Next”

![Image of CITI registration page with Group 1 selected]

7) **Indicate whether you want to affiliate with another institution**
   - Click “Finalize Registration”
     Note: There are other options here, but they are not covered in this training document!

![Image of CITI registration page with affiliation option selected]
8) The CITI Program will send you an email with a link to confirm your email address, clicking on the link will finalize your CITI Website registration.

9) You are at the "Learner's Menu".

To start the training course, click on “Social Behavioral Research Investigators and Key Personnel”
10) You are now at the listing of required modules for the Social-Behavioral Basic Course.
   - To begin, click on “Complete The Integrity Assurance Statement”
11) Each module will be listed. To start the training course, click on each module.

- The required modules must be completed in the order listed. Each time you complete a module, you may move on to the next module (most modules will have short quizzes at the end).
- You will need at least an 80% average on quizzes to print the Basic Course completion certificate. If you score poorly on any quizzes, you may retake them.
• Your performance is stored in the CITI database, so you do not have to complete all modules in one sitting. You can log off and on again. When you log on, you will be directed to the “Learner’s Menu” simply re-enter the course by clicking on “Social Behavioral Research Investigators and Key Personnel”.
12) When all required modules/quizzes have been completed, you will be able to print out the completion certificate/report from the Main Menu page (see below).

- If your study only requires completion of the Basic CITI course, then training requirements have been satisfied after completing the basic “Required” course.

- If you need to complete additional “SUPPLEMENTAL” modules, read the additional instructions on the following pages.
Section II
Instructions for completing SUPPLEMENTAL/ELECTIVE modules
13) If your research involves procedures, special populations, or other topics covered in the “SUPPLEMENTAL” modules listed at the beginning of this document (and repeated on the following page), you will need to access the list of SUPPLEMENTAL modules then print out a report.

- **UTRGV IRB policy requires that you score 100% on each quiz taken for these supplemental modules.**

- **To access these modules, from the Main (“Learner's”) Menu, select “Social Behavioral Research Investigators and Key Personnel”**
14) Please note that CITI provides an extensive list of SUPPLEMENTAL modules, including “Refresher” modules.

- Do not attempt to complete the refresher course using this menu.
- You should only choose from the following:
  
  - Research in Public Elementary and Secondary Schools - SBE
  - Research with Children - SBE
  - Internet-Based Research - SBE
  - International Research - SBE
  - Research and HIPAA Privacy Protections
  - Research with Prisoners - SBE
  - Vulnerable Subjects – Research Involving Workers/Employees
  - Conflicts of Interest in Research Involving Human Subjects
  - Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates
  - Avoiding Group Harms – U.S. Research Perspectives
  - Humanitarian Use Devices
  - FDA-Regulated Research
  - Genetic Research in Human Populations
15) When you have completed an SUPPLEMENTAL module, you can return to the main menu and select “Social Behavioral Research Investigators and Key Personnel”

- You will now see the additional quiz scores for the SUPPLEMENTAL module(s) that you completed.

- If your research requires completion of one or more of these SUPPLEMENTAL modules, you should complete the required modules and **print out a copy of this page to include in your IRB submission** (i.e. in addition to the Basic Course certificate). This allows IRB staff and reviewers to confirm that you have completed all additionally required modules.

- In the example below, the researcher is conducting online surveys and has therefore completed the "Internet-Based Research - SBE" module and quiz. **Remember, you must score 100% on each of the applicable required modules for them to count.**

![](image)

DON’T FORGET: IF YOU HAVE TAKEN ANY SUPPLEMENTAL MODULES YOU SHOULD PRINT OUT AND SUBMIT A COPY OF THIS PAGE WITH YOUR COMPLETION CERTIFICATE/REPORT!
Section III
Instructions for completing
Refresher course
16) If your Basic Course certification is over 2 years old, you will need to take a refresher course prior to submitting a new IRB protocol.

- If your certification has expired, CITI may send you an email informing you that your current CITI Program training will expire [date]. They will provide you with a link to re-enter the CITI program website, where you will need to complete the CITI Refresher Course.
- Or CITI may automatically show the refresher course on the Main Menu under “Course”. If so, you may simply click on that link to start the course, then print the certificate when complete.

If you do not receive an email, and the refresher course link does not automatically appear on the Main Menu, click on “Add a course or update your learner groups”
17) Indicate the course that you wish to take.
   - Select **Human Subjects Protection course**.
   - After you have made your selection, click “Next”
18) Indicate which Basic Course you wish to complete
- Select “Group 1: Social Behavioral Research Course”
- Click “Next”
19) Indicate whether you want to take the Basic Course or Refresher Course.
   - Select “Refresher Course”
     Note: Your screen and options may look slightly different from the one presented below. The specific information will change depending on how many times you have renewed your training.
   - Click “Submit”
20) You are back at the “Main Menu”.

- To start the refresher training course, click on “Social Behavioral Research Investigators and Key Personnel”
Section IV
Instructions for printing previously completed course certificates or modules
21) From the “Main Menu”:

- If you need to access previous completion reports (e.g. Basic Course completion certificate or Refresher completion certificate), you can click on “View Previous Completed Coursework” or “My Reports” at the top of the Main Menu.