UTRGV IRB TRAINING REQUIREMENTS:

CITI training is not required for exempt review studies.

For Expedited and Full Review studies, all research team members must complete or have a current training course for **Human Subjects Protection** and **Responsible Conduct of Research**. Both of these courses are good for 4 years.

If you will be conducting clinical research or a clinical trial, you must complete a **Good Clinical Practice** training course in addition to the above-mentioned courses.

Human Subjects Protection, Basic Course

- Social Behavioral Research Investigators and Key Personnel
 - Biomedical Research Investigators and Key Personnel

Responsible Conduct of Research Course

- Social and Behavioral Responsible Conduct of Research
 Biomedical Responsible Conduct of Research
 - Physical Science Responsible Conduct of Research
 - Humanities Responsible Conduct of Research

Good Clinical Practice Training

- Social and Behavioral Research Best Practices for Clinical Research
 Clinical Investigations of Devices
 - Clinical Trials with Investigational Drugs and Biologics
- Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)

Detailed instructions (with screenshots) are located on the following pages

- Section 1: How to register and access the basic course
- Section 2: How to add an additional course
- Section 3: How to access completed course certificates and/or reports
- Section 4: How to affiliate with a new institution (UTRGV)

Section 1:

How to Register and Access the CITI 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

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 <u>not</u> required to register/pay for CME/CEU credits for UTRGV IRB approval. This is optional.

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4) Follow steps 2-6 by entering the required information (marked with an asterisk).After the fields have been completed, click "Continue"

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	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.			
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5) To complete step 7, indicate the course that you wish to take.

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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 biomedical 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 665-2093 before selecting your learner group.
- Click "Next"



7) Indicate whether you want to affiliate with another institution

• Click "Finalize Registration"



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"

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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"

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	History and Et	hical Principle	s - SBE (ID: 490)	Incomplete	0/0 (0%)			
	Defining Rese	arch with Hum	ian Subjects - SBE (ID: 491)	Incomplete	0/0 (0%)			
	The Regulation	se - SPE /ID- S/	121	Incomplete	0/0 (0%)			

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 (m*ost* 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.

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Assessing Risk - SBE (ID: 503)	Incomplete 0/	'0 (0%)
Informed Consent - SBE (ID: 504)	Incomplete 0/	'0 (0%)
Privacy and Confidentiality - SBE (ID: 505)	Incomplete 0/	0 (0%)
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Optional Modules		(Carabana A

• 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".

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Section 2:

How to Add an Additional Course

1) Click on **Add a Course** at the bottom of the menu, under My Learner tools for UTRGV

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- 2) Indicate the course that you wish to take.
- Select Responsible Conduct of Research.
- After you have made your selection, click "Next"

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- 3) Indicate the group4) Then, click "Next" at the bottom to finish.

Note: this screenshot shows Social and Behavioral selected, but you may choose whichever group best fits your research.

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5) Your course will be added to your main menu, as show below.

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Section 3:

How to Access CITI Certification and/or Reports for Previously Completed Courses

1) 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 Records" at the top of the Main Menu.

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2) Select View-Print-Share, under Completion Record.

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3) You may use the first link to obtain a completion with scores and dates listed, this is a full report.

4) You may use the second link to obtain a certification which is a summarized proof of completion.

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Course.	Social behavioral Research investigators and key Personnel
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Section 4:

How to Affiliate with a New Institution (UTRGV)

You may have a CITI account already. If you are registered under another institution and are now with UTRGV, you may change your account by affiliating with another institution.

Please do not create a new account.

To set up your affiliation with The University of Texas Rio Grande Valley, please follow these steps:

- 1. Log In
- 2. Select blue tab below your Course that reads "Click here to affiliate with another institution"
- 3. Type in "Rio Grande Valley" in the search box, our institution should pop up directly below the search box
- 4. Select "University of Texas Rio Grande Valley"
- 5. Enter the required information for your profile

To Add the Human Subjects Protection, Basic Course

- 6. Select "Basic Course, Human Subjects Protection"
- 7. Select "Group 1: Social Behavioral Research Course" or "Group 2: Biomedical Research Course"

To Add the Responsible Conduct of Research Course

- 6. Select "Responsible Conduct of Research"
- 7. Select "Biomedical Responsible Conduct of Research Course" or "Social and Behavioral Responsible Conduct of Research Course"

The CITI course will be added to your main menu.