1. Application

You will need to download and fill out the New IRB Application Form and include a copy in your IRBNet package.

2. Financial Conflicts of Interest in Research Reporting

All employees must complete their certification online on UT System’s portal (http://outsideactivity.utsystem.edu). Students (not employed by UTRGV) must complete the Outside Affiliations Disclosure Certification Form. All members of the research team must complete this requirement. This certification is made on a yearly basis.

3. CITI Training: Human Subjects Protection Courses and Responsible Conduct of Research Courses

Note: Effective 6 / 29 / 2017 all persons conducting research are required to complete the Responsible Conduct of Research (RCR) training on the CITI Program Website, in addition to any other training required by the committee in which approval is being sought. When your project comes due for renewal or upon submission of an amendment, this will be required.

An active CITI Human Subjects Protection Training and Responsible Conduct of Research Training is required for all members of the research team. The Human Subjects Protection Courses are good for 2 years, while the Responsible Conduct of Research Courses are good for 4 years.

Human Subjects Protection Courses

- Group 1: Social Behavioral Research Course
- Group 2: Biomedical Research Course

Responsible Conduct of Research Courses

- Biomedical Responsible Conduct of Research Course
- Social Behavioral Responsible Conduct of Research Course

Note: If you completed your CITI training in the past under UTPA or UTB, we will only accept the training if it was completed prior to September 30th 2015. Any trainings completed after September 30th 2015 under those two institutions will not be accepted. Once the course expires, you will be required to affiliate with the UTRGV on the CITI Program website and complete a new Basic Course.
Please note, there are also CITI Optional/Supplemental Modules that may be required as part of your research. For instance, if your study involves an online survey you will need to complete the CITI Optional/Supplemental Module for Internet Based Research. Or, if your study involves data collection from children at a school you will need to complete the CITI Optional/Supplemental Modules for Research with Children and Research in Public Elementary and Secondary Schools. If your study only involves children and not data collection at a school, then you only need to complete the CITI Optional/Supplemental Module for Research with Children. These modules must be completed with a 100% score, any score below that will not be accepted.

**Depending on the type of study, some of the following items may or may not apply to you:**

**4. Recruitment Materials**

Whenever a research study involves interaction with human subjects some type of recruitment material is required. This should be used in first-contact with participants. We have templates available for you to use with your application. Here is a brief breakdown of each form.

The **Professor Permission Script** is used whenever researchers will be entering classrooms to collect data. You must obtain permission from each professor in order to enter their classrooms.

The **In-Person Recruitment Script** is used whenever you will be contacting potential participants in person.

The **Telephone Recruitment Script** is used whenever you will be contacting potential participants over the phone. Please note, for studies that will be conducted entirely over the phone you can combine this script with consent form language to use as a **Telephone Recruitment/Consent Script**.

The **Email Recruitment Script** is used for studies involving an online survey, where all contact and data collection is done online. However, some studies involve a combination of both email recruitment and in-person data collection.

*Other recruitment materials that may be required is a copy of flyers or advertisements, or a copy of a post to social media or other websites.*

**5. Consent / Assent / Parental Consent**

Whenever a research study involves interaction with human subjects a consent form of some sort is required. We have templates available for you to use with your application. Here is a brief breakdown of each of our templates:
The **Simplified Consent Form** is only used for Exempt studies, that is non-sensitive anonymous studies with adults. If you will notice this form does not have a signature line, this is because Exempt studies do not require documentation of consent. Therefore, a request for waiver of documentation of consent is not required.

The **Anonymous Self-Report Survey Consent Script and Handout** is only used for Exempt studies that include an anonymous non-sensitive self-report survey for data collection with adults. If you will notice this form does not have a signature line, this is because Exempt studies do not require documentation of consent. Therefore, a request for waiver of documentation of consent is not required.

The **Confidential Self-Report Survey Consent Script and Handout** is used for Expedited studies that include a confidential non-sensitive self-report survey for data collection with adults. If you will notice this form does not have a signature line, therefore a request for waiver a documentation of consent is required in your IRB application.

The **Informed Consent Form** is used for Expedited and Full Review studies, usually confidential studies involving adults and/or children. This is a full consent form which includes a signature line. We also have a version of this informed consent form that is intended to be used for studies involving compensation to human subjects. There is a Payment for Participation section that includes required language regarding the type of compensation, eligibility and tax implication. Depending on your study, some language may be deleted or may be required to be added to this section.

The **Child Assent Form** is used for Expedited and Full Review studies that involve data collection from children ages 7 to 17.

The **Child Assent Script** is used for Expedited and Full Review studies that involve data collection from children ages younger than 7.

The **Parental Informed Consent Form** is used for Expedited and Full Review studies that involve data collection from children. It is required in addition to the Child Assent Form and/or Child Assent Script.

The **Online Consent Page** is used for studies that will involve administration of an online survey. The consent page must be the first page of any online survey, and must stand alone. The survey questions should follow on the second page of the survey, and on.

The **Audio Release Form** is used for Expedited and Full Review studies that will involve the use of audio recorded data collection. This form must be signed along with the full informed consent form.
The Photo-Visual Recording Release Form is used for Expedited and Full Review studies that will involve photographs or visual recorded data collection. This form must be signed along with the full informed consent form.

6. On-Site Research – Permission Letter

The Permission Letter Template is required for any studies involving on-site research. Please note, this is not required if you are doing on-site research at UTRGV, unless you will be collecting data from a center, department and/or program at UTRGV where authorization is required.

7. Facilitation of Research – Support Letter

The Support Letter Template is required when someone will be facilitating your research. For instance, help with identification of subjects, help with recruitment, providing access to records or help with obtaining consent or data collection.

8. Data Collection Materials

These are required to be submitted with your application whether you are conducting a survey, interview, intervention, etc. If you do not plan on conducting a structured interview, you must submit an interview protocol which outlines your procedures and the direction you want to go with the interview. For intervention studies, we require a detailed protocol. For studies involved chart reviews, we require a list of information of which you are obtaining from these records.

An Online Survey Link is required to be submitted in your application (Section J1) and pasted into the comments section for the submission of your protocol to the board through IRBNet.

Other Documents

The Compensation Agreement for Use of Personal Funds is used for research projects that involve offering some form of compensation using out-of-pocket (or Personal) funds. This does not mean funds that have been awarded to you, those are not personal funds that is university funds. The purpose of this form is confirm that the researcher is taking full responsibility to comply with IRS guidelines and to provide disclaimers to participants regarding origin of compensation and tax reporting.

The Debriefing Document is required for any studies where deception or incomplete disclosure is used.

The Research Study Information Sheet is used when either a waiver of consent is granted or when a consent script is being used. The purpose of this form is to provide the subject with contact information for the researcher(s) conducting the study.
The Confidentiality Agreement for Professional Transcriber is required when a research team is going to hire someone to transcribe research material.

Translated Materials (includes recruitment materials, consent forms and data collection materials) are required for any studies where English is not required for participation.

Other Application Requirements

Signatures - The package must be electronically signed by the PI, any Co-PI’s and the Faculty Advisor (if PI is a student) before submission of the package to the IRB. Research Assistants do not need to sign the package.

Faculty Advisor – All students must identify a faculty advisor to serve as their mentor on the research project. If you are conducting this research for your thesis or dissertation, this can be someone from your committee (your committee members should not be listed on your IRB application as part of the research team unless they are going to conduct the research with you or if one of them is serving as your faculty advisor). If not, it should be someone from your department (area of discipline). It is recommended to choose someone who has been through the IRB process before, because your faculty advisor will not only guide you on your research but they should also provide feedback when you are drafting your application and during the IRB review process.

Sharing Access - Students should always share full access with their faculty advisor.

For studies that involve Co-PI’s, level of access is up to the PI. It is recommended to grant at least one Co-PI full access. Full access will allow this person to edit, share the project with others, delete document packages, and submit subsequent packages for the study on your behalf.