

**IRB Submission Guidelines
INITIAL REVIEW**

Required submission documents:

1. IRB Application
2. Protocol (see below)

Required if applicable to your research:

3. Supporting Documents (see below)
4. Consent Form
5. Assent Form (if recruiting minors under age 18)
6. Parental Permission Form (if recruiting minors under age 18)
7. Scripts (phone, screening, etc.)
8. Recruitment/Advertisements (see below)
9. Study Tools (see below)

IDENTIFY THE PRINCIPAL INVESTIGATOR

Every research study requires a single individual identified as the Principal Investigator (PI). This person takes full responsibility for the conduct of the study and research personnel. Below is a list of who is eligible to serve as PI at Baylor University.

Externally Funded*	Internally Funded	Unfunded
Full time faculty member with one of the following appointments: <ul style="list-style-type: none"> • Assistant Professor • Associate Professor • Professor • University Professor • Distinguished Professor • Assistant Research Professor • Associate Research Professor • Research Professor • Academic Professional • Senior Lecturer 	Same as Externally Funded with the following funding program exceptions: <ul style="list-style-type: none"> • URSA • CFRIP 	Any Baylor Faculty, lecturers, professionals, and students

*Visiting Professors, Lecturers or other part time faculty must receive prior approval from the Office of the Vice Provost for Research before applying for external funding. Postdoctoral Fellows may apply for fellowships and/or transition grants when a faculty member sponsors the fellow's proposal. Others will be considered on a case-by-case basis.

IDENTIFY KEY RESEARCH PERSONNEL

Key research personnel are defined as individuals who will have a significant role in the design or conduct of the research. This includes:

- Co-Investigators or Sub-Investigators
- Persons who are named on a grant or contract application
- Persons who are listed on an FDA Form 1572
- Individuals who:
 - Are listed as a contact person in a consent form or in recruitment material for the research
 - Obtain informed consent from subjects to participate in the research
 - Obtain or have contact with a subject's individually identifiable information or biological specimens

Due to the variability in research situations, PIs are expected to interpret the above guidance and make a good faith effort to identify key personnel.

All key research personnel must be listed in the IRB application.

COMPLETE HUMAN SUBJECTS TRAINING

All research personnel on active IRB projects must have completed CITI training prior to receiving IRB approval. CITI training must be renewed every 4 years. See the BU IRB website for instructions for completing CITI training and training requirements for non-Baylor collaborators.

REGISTER IN IRBNET

All research studies must be submitted to the IRB through IRBNet. In order to add Baylor research personnel to a study in IRBNet, each individual must create an account. Individuals can also link their CITI training record to their account. Note that the chairperson of the principal investigator's academic or administrative department (or his/her designee) must "sign-off" on the initial submission in IRBNet. See the BU IRB website for instructions.

DEVELOP YOUR PROTOCOL or RESEARCH PLAN

The IRB requires the submission of a research plan or protocol. A research plan or protocol describes planned research activities. It should include a clear description of the research design or methodology, the research objectives, how research subjects will be chosen, a description of what will happen during the research (the "procedures"), and what data analysis will be used on the collected data.

Researchers should minimize risks to study participants by using procedures that are consistent with sound study design. For investigators who are writing their own protocols, a "Key Elements of a Protocol" guidance document (G-02) and a protocol template are available on the IRB's website and in the IRBNet Library.

SUPPORTING DOCUMENTS

The following are types of supporting documents that may be applicable to your research:

- Investigator Brochure (for unapproved drugs)
- Package Inserts (for approved drugs)
- Device Brochures
- Grant Application (if research is federally-funded)
- Support Letters from sites where research may be conducted
- IRB approval letters from U.S. sites or the equivalent from International sites

RECRUITMENT/ADVERTISEMENTS

Recruitment activities are the beginning of the informed consent process. Therefore, in accordance with the IRB's authority to approve or disapprove all research activities, prospective review and approval of all recruitment materials is required. This includes any retention programs intended to encourage participants to continue participation and any enrollment/recruitment bonus programs that incentivize research staff or third parties to recruit participants.

Common recruitment activities that may require IRB approval:

Print ads	Websites	Radio scripts & recordings
Flyers / Posters	Facebook posts	TV scripts & recordings
E-mails	Twitter posts (Tweets)	Telephone Screening Scripts
Press Releases	Text messages	Internet screening questionnaires
"Dear Patient" Letters	Banner Ads	Retention programs
Brochures	Blog posts	YouTube videos

STUDY TOOLS

Study Tools are materials that are used during the course of the research with participants. Review and approval of study tools is required to ensure that the materials are not unduly influencing, coercive, or misleading, and do not promise a certainty of cure beyond what is outlined in the consent and protocol.

Common types of study tools:

Questionnaires	Diaries	Information letters
Surveys	Instructions	Appointment reminder cards
Scripts	Medication logs	Videos
Pictures	Symptom logs	Software programs