

CHECKLIST for Submission of Human Subjects Research Protocols (HSRP)

Protocols must be submitted to the IRB mailbox (IRB@tamucc.edu).

SUBMIT the Protocol Form along with these Items: (Please send all documents in one email.)

- Recruitment Script
- Informed Consent Form (or “Information Sheet”)
- Biosketch/CV – abbreviated short version (max. 2-3 pp)
- CITI Training Certification record – for PI, and co-PIs.

Other Documents frequently needed:

- Assent Form (for children, or other vulnerable populations)
- Permission to use Facilities: (Outside organizations; Internal offices)
- Translated documents (Translator certification)

The Protocol Form should list all those “engaged” in the research project. (+ Definition below)

- Page 1: Researchers: The PI is the lead person conducting the research project. The term “Co-PI” is interchangeable with “study personnel” or other similar terms (for faculty or staff).
- Level of Review (Category): initially set by the PI. The Compliance office will accept or change.
- If “Taping” is involved, the Category is classified as Expedited 6 or for Full Board review.

+ Per HHS guidance, an institution/person becomes “engaged” in research when they obtain:

- Data about the subjects of the research through intervention or interaction; OR,
- Identifiable private information about the subjects of the research; OR,
- Informed Consent of human subjects for the research.

In general, simply informing potential subjects about a research study is not considered engagement in research. Also, providing written information about a research study, including how to contact the investigators for information and enrollment, and seeking and obtaining prospective subjects' permission for investigators to contact them are not considered engagement in research. However, obtaining informed consent from a research participant is considered engagement in research.