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Subject: What are the Components of an IRB Submission?
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Dear Research Community,

Per the Human Research Protection Program (HRPP) Manual Policies and Procedures:

2.7.2 Documents:

The following documents, *as applicable* to the study and type of submission, must be submitted through iRIS for IRB review:

- completed electronic IRB study application form;
- completed iRIS submission form relevant to the type of submission (i.e., Initial Review form; Continuing Review form; Amendment form; Unanticipated Event form, etc.);
- full protocol - the full protocol should contain a review of prior work in the area, specific objectives, hypotheses, study design, study procedures, statistical analyses and references;

If a TTUHSC El Paso PI is one of the primary investigators for a multisite study, documentation regarding communication between all site IRBs (for example: unanticipated problems, amendments, etc.)

- Investigational New Drug (IND) or Investigational Device Exemption (IDE) number;
- Investigator's Brochure;
- Data Safety Monitoring Reports;
- proposed informed consent document using TTUHSC El Paso IRB-approved template which may include an Authorization to Use and Disclose PHI for Research (HIPAA authorization form);
- any proposed data collection forms;
- letters of approval or support from non-TTUHSC El Paso research sites;
- recruitment materials;
- surveys, questionnaires, or videotapes;
- non-English versions of any materials to be seen by subjects (as needed and after English versions are approved);
- certificate of confidentiality as needed (<http://grants.nih.gov/grants/policy/coc/>);
- documentation of review/approval by required TTUHSC El Paso compliance committees (example: Institutional Biosafety Committee, Conflict of Interest in Research Committee, etc.);
- CV of Investigators and/or others as requested;
- other materials necessary to allow the IRB to effectively review the proposal.

At the very least, each new IRB application must have the Study Application and Protocol, then depending on the type of submission, it could include surveys, data collection sheets, consent form or information sheet, etc.

For additional information and resources, please review the [IRB Website](#).

Thank you,

TTUHSC El Paso Institutional Review Board