The Main Reasons Why a Research Submission is Held Up By the SMU IRB

A submission to the SMU IRB requires only four main documents and a small number of supporting documents. The four main documents are:

(1) Protocol Submission Checklist
(2) Protocol Approval Form
(3) Protocol Format (Research Proposal)
(4) Consent Form.
(5) Revision Submission (if required)

Below are the main reasons that may delay IRB review:

(1) **Protocol Submission Checklist:**

The Protocol Submission Checklist contains 19 specific items that must be completed and/or submitted with the SMU IRB application. The following items are often missing or incomplete.

(a) Letters of support from all institutions involved in the research or department chair are often missing and/or not submitted on institutional letterhead.
Letters of support must contain:
(1) Name of the study
(2) Name of the PIs
(3) Statement that the institution cannot collect fees for the research component of the study
(4) Statement that the institution is liable for subject injury

(b) Instrument(s) used in the research must include manufacturer name, address and model number. The IRB must know exactly what instrument(s) will be used with subjects.

(c) NIH or CITI certificates of training are not included for ALL members of the research team, including student researchers.

(d) Data collection forms, subject questionnaires and/or recruitment materials are not submitted in their final form.

(2) Protocol Approval Form

(a) The roles of all the members of the research team are not identified and defined in the **Protocol Approval Form**. For example, after the PI's names, 1 to 5 student names are often listed without explanation as to their roles.

(b) All co-investigators (co-PIs) fail to sign the **Protocol Approval Form**.

(3**) Protocol Format (Research Proposal):**

The function of the IRB is to ensure the rights and safety of each subject in the research study. The IRB will address issues with regard to the **Protocol Format** submission only when the research design is so problematic that the research project cannot ensure patient safety or the

risk benefit/ratio of the protocol does not justify the project. These issues with regard to the protocol are very rare occurrences.

(4) **Consent Form:**

The vast majority of problems with a submission are with the Consent Form. Among the most common problems are the following:

(a) The number of subjects, number and/or frequency of examinations, etc. are not identical in the **Protocol Approval Form, the Protocol Format,** and the **Consent Form**.

(b) Not written at a level consistent with the reading level of the age of the subjects (in other words, what children would be able to understand).

(c) Interventions (examinations) of the subjects not clearly explained. The distinction between standard of care and what is part of the research study is not clearly differentiated.

(d) Total time commitment for each participant is not clearly stated.

(e) Assent form for subjects under 18 years old is not included.

(f) Confidentiality and anonymity distinctions are not clearly stated and/or provided for.

One additional reason an IRB submission is held up is the revision process.

(5) **Revision Submission (if required):**

Requested revisions are not returned in a timely manner.

Each item that the IRB requests is not present in the revision. Always include a return letter to the IRB that documents each request and specifically states the exact changes to the **Proposal**, **Protocol Approval Form** and/or **Consent Form.** Requested changes should be highlighted in the corresponding documents.