Uploaded Document Guidance for UPittsburgh ClinicalTrials.gov PRS

Please note that uploaded documents will be posted for public access on ClinicalTrials.gov.

**Protocol & Statistical Analysis Plan**
Results submissions for studies that have a Primary Completion Date on or after January 18, 2017 must include a copy of the protocol and the statistical analysis plan (if not included in the protocol), including all amendments that have been approved by a human subjects protection review board (if applicable) and that apply to all clinical trial Facility Locations. These documents may be uploaded voluntarily at any time.

The responsible party must include the Official Title, NCT number, and date of the protocol and the statistical analysis plan on the cover page of each document.

The responsible party may redact names, addresses, and other personally identifiable information, as well as any trade secret and/or confidential commercial information (as those terms are defined in the Freedom of Information Act (5 U.S.C. 552) and the Trade Secrets Act (18 U.S.C. 1905)) contained in the protocol or statistical analysis plan prior to submission, unless such information is otherwise required to be submitted as part of clinical trial registration or results information.

Documents must be submitted in Portable Document Format Archive (PDF/A) format.

**Definitions from ClinicalTrials.gov:**
Study Protocol: The written description of the clinical study, including objective(s), design, and methods. It may also include relevant scientific background and statistical considerations.

Statistical Analysis Plan (SAP): The written description of the statistical considerations for analyzing the data collected in the study. Includes how data are analyzed, what specific statistical methods are used for each analysis, and how adjustments are made for testing multiple variables. If some analysis methods require critical assumptions, the written description should allow data users to understand how those assumptions were verified.

**Guideline:**
1. If a protocol document has been approved as part of your IRB application, use that document.

2. If the first option does not apply, you may utilize your approved IRB application to create a document based on a template (see below).
Protocol Template Guidance:
The protocol template can be retrieved from our website under the Results Submission tab. The following elements are required under 42 CFR 11.48(a)(5):

Official Title: The Official Title entered in your ClinicalTrials.gov study record.

ClinicalTrials.gov ID (NCT number): The NCT number identifying your study record.

Protocol Date: Most recent IRB approval date.

The following are suggested section headings. You may choose to modify these, so long as you address all of the elements included in the definitions provided above. Relevant OSIRIS sections are listed for each suggested section heading below. Please note that this will likely require more effort than just copying and pasting text. You may also pull from applicable sections of your grant.

Scientific Background: 1.3-1.4

Study Objectives: 1.1-1.2

Study Design & Methods: 2.3, 2.5-2.9, 5.7, 5.13

Eligibility Criteria: 3.1-3.2, 3.13-3.14

Statistical Considerations: 2.17-2.18, 3.12

Informed Consent Form (ICF)
The ICF is not required by ClinicalTrials.gov, but may be uploaded voluntarily at any time. If uploaded, it must include a cover page with the Official Title of the study, NCT number, and date of the document.

Definition from ClinicalTrials.gov: The final version of the legal document approved by a human subjects protection review board. It is written in lay language and describes, among other things, the study’s purpose, procedures, risks and potential benefits.