

IRB eSubmission Document Upload Guide

Instructions: Documents may be uploaded at specific questions in the application, or at the menu by selecting Document Upload. The following is the list of valid documents types that may be uploaded into PRAMS: doc, docx, xls, xlsx, ppt, pptx, pub, tif TIF, tiff, txt, pdf, rtf, jpg, gif. Below is a list of examples of the types of documents that belong in each folder.

NOTE: The information in “blue” are examples of certain types of documents.

Approval Letter

- **For IRB use only.** Researchers should not upload documents to this folder. The IRB office will upload approval letters to this file.

Correspondence

- Certificate of Confidentiality
- Certification of Translation
- Correspondence
 - Memos from PI
 - Letters to Granting Agencies from PSU
- FDA
 - Correspondence to and from the FDA
- Individual Investigator Agreement
- Investigator Correspondence
- IRB Authorization Agreement
- Other
- Prescreening
- Sponsor
 - Correspondence to and from study sponsor(s)
- Verification Letter

Unanticipated Problems

- Non-reportable Event
- Other
- Problem Report
- Protocol Deviation
- Tracking Log

HIPAA

- Authorization
- Data Use Agreement
- Decedent Research
- De-identified Data
- Limited Data Set
- Other
- Preparation for Research
- Waiver of Authorization

Consent Forms

- Addendum

- Adult Form
- Assent Form (Child)
- Notice of Participation
- Other
- Parental Permission Form
- Scripts
- Short Form
- Sponsor Model Consent
- Summary Explanation of Research
- Witness Form

Data Collection Instruments

- Any surveys, diaries, questionnaires, interview questions, focus group topics, etc. that will be administered *after the consent form is signed*.
- Agreements to be signed by participants (such as equipment liability forms)

Protocol Documents

- Amendment
- Data Safety Monitoring Plans
- Drug Package Insert
- Investigator Brochure
- Other
- Pharmacy Plan
- Protocol
 - Entire scientific protocol and abstracts

Recruitment

- Recruitment Materials
 - Scripts, letters, flyers, ads, brochures, emails, posters, etc.
- Eligibility Screening
 - Any questions that will be asked *before the consent form is signed* to determine eligibility in a study.
 - Phone Screen Procedure
- Debriefing Statement
 - Statement provided to participants after the involvement in the study is complete. It will provide them with a more detailed explanation of the study.

Review – Request Info

- Other
- PI Response
- Returned for Additional Information

Submission Forms

- Abstract
- Annual/Continuing Review
- Closeout Form
 - 5-Year Closeout Forms
 - CR indicating no requested renewal
 - Project Closeout Form

- Correspondence concerning closeout
- Exception Request
- Grant Proposal
 - Grant Proposal
 - Thesis Proposal
 - Could also be Material/Methodology section from Grant Proposal
- Modification
- New Application
- Other
- Revised Application
- Revised CR/AR
- Revised Grant Proposal
- Revised Modification
- Signature Pages

Supporting Documents

- Animal Biohazard/Safety Form
 - Researchers submitting human participants studies should not use this choice. This selection is used for animal research studies.
- Collaborating Approval Materials
- Course Syllabus
- Education Certifications
- List of Publications
- MSDS
- Multi-Center Trial Reports
- Other
- Other Committee Docs
- Outside Audit Reports
- Permit
- Sponsor Annual Reports
- Supplemental Information
 - Background Articles
 - Drug compounds