

UC SAN DIEGO CLINICALTRIALS.GOV INSTRUCTIONS FOR UPLOADING STUDY DOCUMENTS AND REDACTION GUIDE

For clinical trials with primary completion dates on or after January 18, 2017, the protocol and statistical analysis plan (SAP) must be uploaded to [ClinicalTrials.gov](https://clinicaltrials.gov) under the “Documents Section.” All documents uploaded to ClinicalTrials.gov will be posted publically after it undergoes Protocol Registration and Results System (PRS) review.

General Tips to Upload Study Documents:

1. All documents uploaded must be in English.
2. All documents uploaded must be in a PDF Archive (PDF/A) format.
3. All documents uploaded must contain no research participant’s names or other personal identifiable information.
4. All documents uploaded must have a cover page with the official title, the NCT number and the protocol version date.

Documents to Upload to ClinicalTrials.gov:

1. Protocol:

ClinicalTrials.gov regulations define a protocol as “the written description of the clinical trial, including objective(s), design, and methods. It may also include relevant scientific background and statistical considerations.” The protocol must clearly delineate the primary and secondary outcome measures.

Suggested best practice: load all documents within 30 days after the last day of data collection (i.e. within 30 days after the study completion date).

2. Statistical Analysis Plan:

The ClinicalTrials.gov regulations do not define Statistical Analysis Plan (SAP), however the United States Food and Drug Administration defines SAP as “a document that contains a more technical and detailed elaboration of the principal features of the analysis described in the protocol, and includes detailed procedures for executing the statistical analysis of the primary and secondary variables and other data.” The SAP either may be a standalone document or can be a section of the protocol.

Suggested best practice: load all documents within 30 days after the last day of data collection (i.e. within 30 days after the study completion date).

3. Informed Consent Documents:

The New Common Rule requires that clinical trials, which receive IRB approval after January 21, 2019, and are supported by federal funding, must publish, “The informed consent form on the federal website after the trial is closed to recruitment and no later than 60 days after the last study visit by any subject, as required by the protocol.” ClinicalTrials.gov is one of the federal websites approved to upload the Consent Form. An unsigned copy must be uploaded.

Research Compliance and Integrity

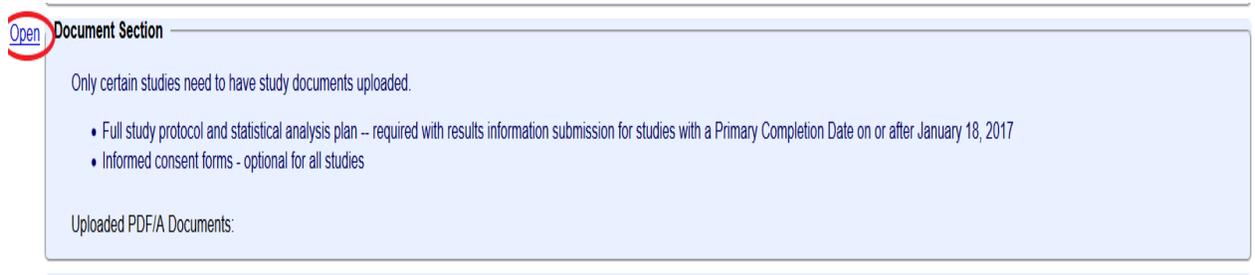
Tel: 619 543-7321 / Email: rci@ucsd.edu

<https://blink.ucsd.edu/sponsor/ora/index.html>

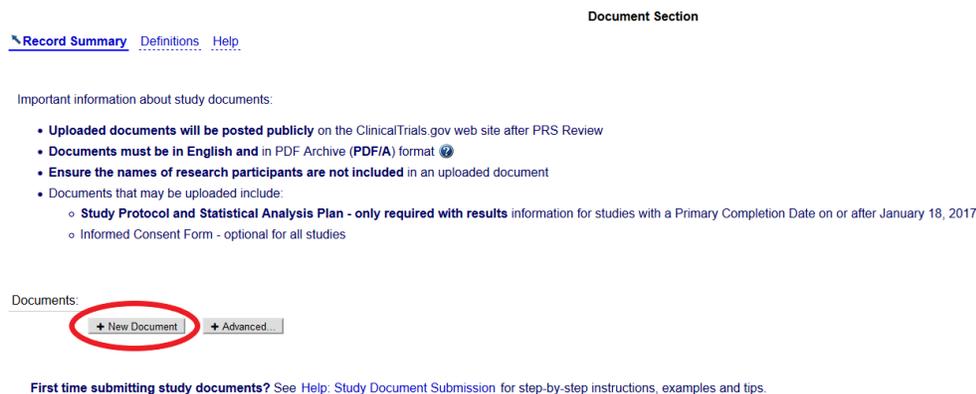
Suggested best practice: Since study teams have to update their ClinicalTrials.gov records to change study completion date from anticipated to actual within 30 days of last study visit, this would be an efficient time to upload the informed consent form.

How to Upload Documents on ClinicalTrials.gov:

1. Click "Open" next to the "Documents Section."



2. Click "New Document."



3. Select the “Document Type” that will be uploaded. For “Document Date” put the date the document was last updated or approved by the IRB (if applicable).

The screenshot shows a web form for uploading study documents. It includes the following elements:

- Document Type:** A section with radio buttons for:
 - Study Protocol (only) (with a note: "Do NOT use this option if Study Protocol document contains statistical analysis details.")
 - Study Protocol, including:
 - Check one or both.
 - Statistical Analysis Plan (SAP) (checkbox)
 - Informed Consent Form (ICF) (checkbox)
 - Statistical Analysis Plan (only)
 - Informed Consent Form (only)
- Document Date:** A section with a dropdown for Month, and input fields for Day and Year. A note below says "Last update/approval date from document cover page".
- Select File:** A section with a "Browse..." button and the text "No file selected." and "Only PDF/A files can be uploaded."
- Buttons:** "Upload" and "Cancel" buttons at the bottom. The "Upload" button is circled in red.

4. Click Upload.

Redacting Documents Uploaded to ClinicalTrials.gov:

Some Protocols may include information that is necessary to be redacted before making public. Such information may include personal identifiable information, trade secrets, and confidential information (e.g., exploratory endpoints).

1. Personal Identifiable Information (PII): Information that can be used to distinguish or trace an individual’s identity, either alone or when combined with other personal or identifying information that is linked or linkable to a specific individual. The following identifiers of the individual or of relatives, employers, or household members of the individual must be removed:
 1. Names
 2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent geocodes
 3. All elements of dates (except year) for dates that are directly related to an individual, including birth date, admission date, discharge date, death date, and all ages over 89
 4. Telephone numbers
 5. Fax numbers

6. Email addresses
 7. Social security numbers
 8. Medical record numbers
 9. Health plan beneficiary numbers
 10. Account numbers
 11. Certificate/license numbers
 12. Vehicle identifiers and serial numbers, including license plate numbers
 13. Device identifiers and serial numbers
 14. Web Universal Resource Locators (URLs)
 15. Internet Protocol (IP) addresses
 16. Biometric identifiers, including finger and voice prints
 17. Full-face photographs and any comparable images
 18. Any other unique identifying number, characteristic, or cod
2. Trade Secrets and/or confidential commercial information: Certain items like, exploratory endpoints may be redacted since they are not required on ClinicalTrials.gov and may contain confidential commercial information. The following information was taken from the FDA's 2008 "[Guidance for Industry Advisory Committee Meetings — Preparation and Public Availability of Information Given to Advisory Committee Members](#)" as general guidance on what is generally considered to be disclosable under Freedom of Information Act (FOIA) and what maybe be exempt.

Information in Briefing Materials that Typically will Be Disclosable under FOIA: We generally will consider the following information in advisory committee briefing materials to be disclosable without redaction, unless the sponsor demonstrates that disclosure of the information is likely to cause substantial competitive harm (the list is not exhaustive nor absolute):

1. Summaries of clinical safety and effectiveness data;
2. Summaries of non-clinical safety and effectiveness data;
3. Summaries of adverse drug reaction data;
4. Written discussion or analysis of safety or effectiveness data relevant to the topic of the meeting;
5. A general description (such as that which would typically be included in product labeling) of product functions, mechanics, and/or engineering;
6. A general description of physical characteristics and performance parameters;
7. Clinical or preclinical protocols or summaries of protocols;
8. Statistical protocols and analyses;
9. Information that is proposed to be included in product labeling, such as indications and usage, dosage and administration, and safety information such as warnings and precautions;
10. Literature references;
11. Any other information that has been previously publicly disclosed by the sponsor;
12. Copies of the sponsor's slides to be presented at the advisory committee meeting, if

- included in the briefing materials; and
13. Guidance documents.

Information in Briefing Materials That Will Typically Be Exempt from Disclosure: We generally will consider the following types of information to be exempt from disclosure under FOIA (the list is not exhaustive nor absolute):

1. Information about product functions, mechanics, engineering, and schematic drawings not in the proposed labeling and not within the scope of the agenda for the meeting;
2. Proprietary physical characteristics and performance parameters not in the proposed labeling and not within the scope of the agenda for the meeting;
3. Manufacturing process information;
4. Manufacturing quality control information;
5. Clinical raw data; (For the purposes of this guidance, FDA considers "raw data" to be a complete data set of case report forms, case report tabulations, or line listings. Data that summarize individual or multiple subject outcomes or results are considered summaries. Summaries may include examples of specific findings.
6. Non-clinical raw data;
7. Supplier names, customer lists, production costs, inventory information, failure rates of products, production quality control information;
8. Information for which the release would constitute an unwarranted invasion of personal privacy; and
9. Product formulation information not in the labeling.

Redaction tools

Generally, protocol files will be either MS Word files or PDF files; both file types [can be redacted](#) and saved as a PDF/A.

General Tips to Redact Study Documents:

1. Keep copies of the redacted and non-redacted versions.
2. Do not redact by printing a document, and blacking out the information with a marker, then scanning the document (this may not fully conceal the text underneath).
3. Do not electronically place a filled in shape, or using black highlight over text to be redacted (this may leave the text underneath intact and text can still be recovered even if the document is converted to a PDF).
4. Do not change the color of the text to a different color (like white), since white text can be read by highlighting the text or copying and pasting it.
5. [Remove any metadata](#) prior to saving study documents as a PDF/A.