

UC SAN DIEGO CLINICALTRIALS.GOV POSTING INFORMED CONSENT INSTRUCTIONS

The Department of Health and Human Services (HHS) Regulation (“Revised Common Rule”) requires a clinical trial conducted or supported by a Common Rule department or agency to post a copy of the approved consent form to a publicly available federal website within a specific timeframe. The following is an overview of the regulations requiring posting an informed consent form.

What is the regulation?

45 CFR §46.116(h) *Posting of clinical trial consent form*

1. For each clinical trial conducted or supported by a Federal department or agency, one Institutional Review Board (IRB)-approved informed consent form used to enroll subjects must be posted by the awardee or the Federal department or agency component conducting the trial on a publicly available Federal website that will be established as a repository for such informed consent forms.
2. If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal website (*e.g.* confidential commercial information), such Federal department or agency may permit or require redactions to the information posted.
3. The informed consent form must be posted on the Federal website after the clinical trial is closed to recruitment and no later than 60 days after the last study visit by any subject, as required by the protocol.

What is the definition of a clinical trial?

The Revised Common Rule, Section 45 CFR 46.102(b): Clinical trial means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcome

What is the start date for this new regulation?

This new regulation applies to all clinical trials initiated on or after January 21, 2019. Clinical trials initiated before January 21, 2019 are not required to post a copy of a consent form.

What version of the informed consent form must be posted?

The regulation requires that one unsigned IRB-approved informed consent form that was used to enroll subjects must be posted. Only one consent form is required to be posted even if there are multiple consent forms for different populations (*i.e.* assent forms) or phases in the research. If your study has assent and/or parental permission forms, you are required to post only one form. If your study has a consent form, assent form, and parental permission form, you can choose which one to post.

All consent forms that are posted must protect participant privacy in accordance with applicable federal, state, and local laws and regulations (e.g., the HIPAA Privacy Rule, Certificates of Confidentiality) and any applicable terms of their NIH award, meaning the copy posted should be unsigned.

If your study has a separate HIPAA authorization form do not post HIPAA authorization forms.

Who is responsible to post the informed consent form?

The awardee or the Federal department or agency component conducting the trial is responsible for posting a consent form, i.e., the Principal Investigator is responsible to ensure that the consent form is posted in a timely manner. For multi-institution studies, only one posting is required. The Principal Investigators for such studies must agree and designate a single entity to post the consent form ahead of time to avoid duplicate posting.

Where does the informed consent form need to be posted?

The informed consent form must be made publicly available on a Federal website that will be established as a repository for such informed consent forms. Currently there are two options:

1. ClinicalTrials.gov
This may be the easiest choice if you have already registered your clinical trial at ClinicalTrials.gov. Specific instructions on how to upload your informed consent form on ClinicalTrials.gov are available at the end of this factsheet.
2. Regulations.gov
Specific instructions on how to upload your informed consent form on Regulations.gov are available at the end of this factsheet.

NOTE: ClinicalTrials.gov only allows English informed consent forms to be uploaded, therefore if you have a non-English consent form you must use Regulations.gov.

What regulatory agencies require the posting of the informed consent form (ICF)?

Any clinical trials conducted or supported by a Common Rule department or agency as listed below:

1. Department of Homeland Security
2. Department of Agriculture
3. Department of Energy
4. National Aeronautics and Space Administration
5. Department of Commerce
6. Social Security Administration
7. Agency for International Development
8. Department of Housing and Urban Development
9. Department of Justice
10. Department of Labor
11. Department of Defense
12. Department of Education
13. Department of Veterans Affairs

14. Environmental Protection Agency
15. Department of Health and Human Services
16. National Science Foundation
17. Department of Transportation
18. Office of the Director of National Intelligence
19. Central Intelligence Agency
20. Consumer Product Safety Commission

Do I have to post the informed consent form at a certain time?

You must post the informed consent form on the Federal website after the clinical trial is closed to recruitment and no later than 60 days after the last study visit.

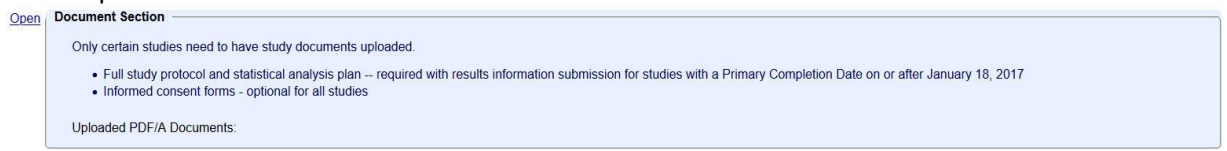
What if the consent form contains information that should not be made publicly available?

If the federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a federal website (e.g. confidential commercial information). If the Principal Investigator believes redactions should be made, contact the agency Program Official for guidance.

Uploading a Clinical Trial Informed Consent form to ClinicalTrials.gov:

To use ClinicalTrials.gov to satisfy the 45 CFR 46.116(h) requirement, you must submit the informed consent form under the “Documents Section” of your ClinicalTrials.gov study record. Each document uploaded to the ClinicalTrials.gov website must include a cover page that has the NCT number, the title and the document date.

1. Click “Open” next to the “document Section:




2. A notice page will populate that provides important information about the study documents section:

- All documents must be written in English.
- Each document must include a cover page with the Official Title of the study, NCT number (if available), and date of the document.
- Uploaded study documents should be the most recent version reviewed by IRB (if applicable).
- Documents must be uploaded in Portable Document Format Archival (PDF/A) format. The PDF/A format ensures a document can be reproduced exactly the same way, regardless of what software is used.

3. Click the “+ New Document” button.

Important information about study documents:

- **Uploaded documents will be posted publicly** on the ClinicalTrials.gov web site after PRS Review.
- **Documents must be in English and** in PDF Archive (PDF/A) format. 
- **A cover page with official title, NCT number and document date** must be included in each document.
- **Ensure the names of research participants are not included** in an uploaded document.
- Documents that may be uploaded include:
 - **Study Protocol and Statistical Analysis Plan - only required with results** information for studies with a Primary Completion Date on or after January 18, 2017
 - Informed Consent Form - optional for all studies

Documents:

4. Select the Document Type “Informed Consent Form (only)” if you are only submitting the consent form. Select “Study Protocol, including Informed Consent Form” if you are submitting the consent form with your other required ClinicalTrials.gov documents.
5. Under the “Document Date”, enter the date the consent form was approved by the IRB. This should match the document date on the cover sheet that is required with each document submission.
6. Under “Select File”, you can browse your computer to upload the consent form. Only PDF/A files can be uploaded.
7. Click “Upload.”

Document Type:

Study Protocol (only)
Do NOT use this option if Study Protocol document contains statistical analysis details.

Study Protocol, including:
Check one or both.

Statistical Analysis Plan (SAP)

Informed Consent Form (ICF)

Statistical Analysis Plan (only)

Informed Consent Form (only)

Document Date:

Month: Day: Year:

Last update/approval date from document cover page.

Select File:

No file selected.

Only PDF/A files can be uploaded.

Uploading a Clinical Trial Informed Consent form to Regulations.gov:

To use Regulations.gov to satisfy the 45 CFR 46.116(h) requirement, you must submit the informed consent form as a comment to the appropriate docket folder ([Docket ID: HHS-OPHS-2018-0021](#)).

1. Navigate to the designated docket folder using this link: [Docket ID: HHS-OPHS-2018-0021](#).
2. Scroll to the "Primary Documents" section. The first item is titled "Announcement" and has a blue "Comment Now!" button next to it. Click the blue "Comment Now!" button.

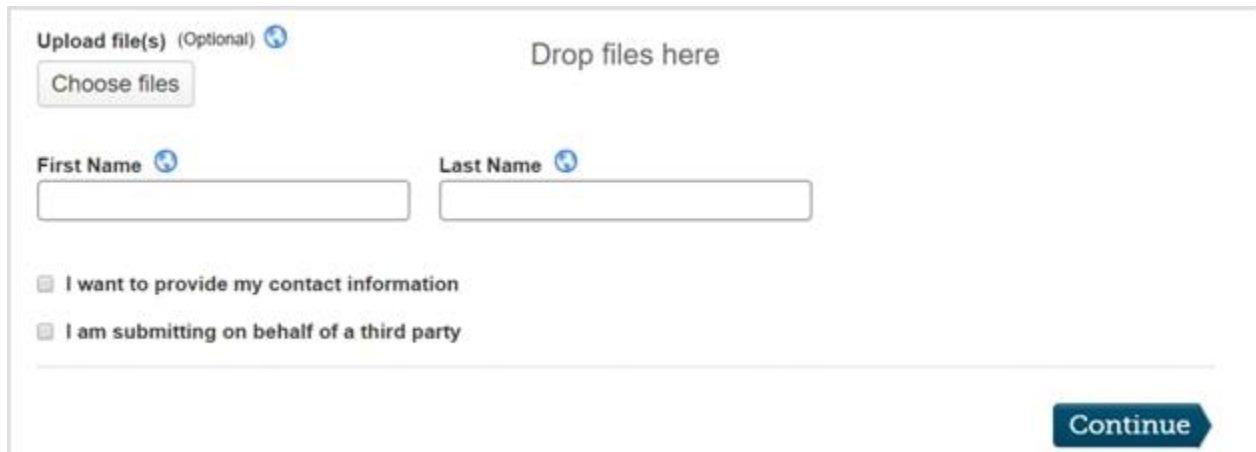


3. After you click on the blue "Comment Now!" button, you will be taken to a page that says "You are commenting on: The Department of Health and Human Services (HHS) other: Announcement."



Scroll past the large "Comment" box. You do not have to add anything in the "Comment" box as long as you include an attachment with your submission.

Scroll down until you see the grey "Choose files" button under the "Upload file(s)" heading.

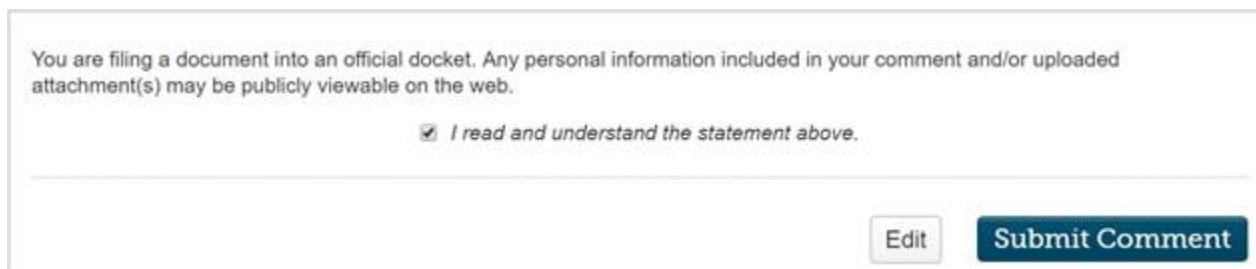


After uploading your file, the site will ask you to fill out the "First Name" and "Last Name" boxes. This is built into Regulations.gov, but is not needed to post consent forms on this docket. You should leave both boxes blank and Regulations.gov will input "Anonymous" in both fields.

When you have finished inputting all required information, select the blue "Continue" button.

4. You will be taken to a preview page. Review the information you provided. You will then need to review a disclaimer statement and select the checkbox saying that you have read and understood the disclaimer.

If you would like to change anything in your submission, select the grey "Edit" button at the bottom of the page. If you are satisfied with your submission, select the blue "Submit Comment" button.



5. After you have submitted the informed consent form (in the form of a comment), you will be taken to a page titled "Your Receipt." Keep your receipt. You will be given a comment tracking number and the opportunity to have the receipt emailed to you.

Your comment (with the informed consent form attached) will be viewable on Regulations.gov once an Office of Human Research Protections (OHRP) staff person posts it. If you have a question about the status of your submission, contact ohrp@hhs.gov with your comment tracking number provided by Regulations.gov. Note that each submission will receive a unique tracking number.

3 Your Receipt

Your Comment Tracking Number: [REDACTED]

Your comment may be viewable on Regulations.gov once the agency has reviewed it. This process is dependent on agency public submission policies/procedures and processing times. Use your tracking number to find out the status of your comment.

Email Address [] Email Receipt ⓘ

Resources:

1. [45 CFR §46.116\(h\) Posting of clinical trial consent form regulation](#)
2. [Guidance on Posting Informed Consent Forms for NIH-Funded Clinical Trials](#)
3. [NIH Implementation of the Final Rule on the Federal Policy for the Protection of Human Subjects \(Common Rule\)](#)
4. [Clinical Trial Informed Consent Form Posting \(sec. 116\(h\) of the revised Common Rule\)](#)
5. [Guidance on Posting Informed Consent Forms for AHRQ-Funded Clinical Trials](#)