

How to Post a Consent Form to a Federal Website

Requirement

Federally-supported clinical trials that receive initial IRB approval on or after January 21, 2019 must post an unsigned copy of the study consent form to a publicly available federal website. The posted form must be a version that was used in enrolling participants. This is a requirement of the revised federal Common Rule regulations about human subjects research.

Additional Details

- *If your study has more than one consent form.* For example, you may have a different consent form for each study group. You are required to post only one form. You can choose which one to post.
- *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.
- *If your consent form is revised during the study.* Only one version of the consent form should be posted. You do not need to replace an already-posted consent form with the revised version, though you can voluntarily choose to do so.
- *If your study has a separate HIPAA authorization form.* Do not post HIPAA authorization forms.
- See this federal [website](#) at the Office of Human Research Protections for additional information and any updates.

When to Post

After the study is closed to recruitment and no later than 60 days after the required study visit by any subject.

Which Website to Use

There are two options for where to post the consent form. The researcher chooses which one to use.

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 register with ClinicalTrials.gov and upload documents (including consent forms) are at this [ClinicalTrials.gov website](#). If you have already registered your trial: see [Appendix A.1](#) of the ClinicalTrials.gov Results Data Elements Definitions document for information on posting consent forms.
2. *Regulations.gov*
Upload the consent form to docket folder [HHS-OPHS-2018-0021](#) by following the instructions located on the [Clinical Trial Informed Consent Form Posting webpage](#) of the federal Office of Human Research Protections.