Informed Consent Form (ICF) Upload per the Revised Common Rule

Overview

For clinical trials that are subject to the Revised Common Rule and that are supported by a Federal department or agency, one IRB-approved informed consent form (ICF) that was used to enroll subjects must be posted by the awardee on a publicly available 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 (45 CFR 46.116(h)). (NOTE: ICF upload is separate from and does not fulfill ClinicalTrials.gov registration and results entry requirements.)

Requirements

Which studies?	Subject to the Revised Common Rule - Approved by an IRB on or after January 21, 2019 - Approved by an IRB before January 21, 2019 but transitioned to the Revised Common Rule - OHRP guidance here and here AND Clinical Trial - See 45 CFR 46.102(b) for definition of "clinical trial" AND Supported by a Federal Department or Agency - NIH (see NOT-OD-19-050 and NOT-OD-19-110) - See 82 FR 7149 for list of all Common Rule Agencies
Who?	The awardee - In cases where a UTHealth PI is the federal awardee, the UTHealth PI will be responsible for posting the ICF according to the requirements
What?	One blank IRB-approved informed consent form used to enroll subjects - Only one ICF version is required, and there is no restriction as to which version, even for multi-site trials or trials with different ICFs for different groups (45 CFR 46, Preamble pages 7227-7229)
When?	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 - Aim to upload the ICF as soon as the last participant is enrolled and the study is closed to recruitment - The ICF cannot be posted before the study is closed to recruitment
Where?	ClinicalTrials.gov OR Regulations.gov are currently the two choices - UTHealth will use ClinicalTrials.gov - In rare cases where ClinicalTrials.gov cannot be used, use Regulations.gov (for instance, when a ClinicalTrials.gov record will not be created for the study; or when there is only a non-English ICF, which ClinicalTrials.gov does not currently support)
How?	ClinicalTrials.gov - Investigate whether redactions are necessary and/or allowed - Convert ICF file to PDFA - Upload ICF in the Document Section o Click Help in the Document Section for instructions Regulations.gov - Investigate whether redactions are necessary and/or allowed - Submit ICF to Docket ID: HHS-OPHS-2018-0021 o See Clinical Trial ICF Posting for instructions *Contact UTHealth's CTRC for assistance (clinicaltrials@uth.tmc.edu)*

Adapted from Stanford Medicine's document "ICF Disclosure Under the Common Rule"