ClinicalTrials.gov Requirements for Informed Consent Form

1. Requirement For Public Posting (Revised Common Rule)

Clinical trials that receive IRB approval after January 21, 2019 and have federal funding must upload an unsigned copy of the Informed Consent Forms (ICF) used to enroll participants in the study. The ICF must be uploaded 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.

You can read more information about the revised Common Rule on the OHRP website (https://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/index.html).

2. Clinicaltrials.Gov Disclosure Statement

Per FDA regulation, the following statement is required on Informed Consent Forms used in Applicable Clinical Trials:

_A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time._

**NIH-funded** trials also require the disclosure statement on informed consent forms. While additional explanation can be provided, the disclosure statement may not be modified.

Find more information about requirements for informed consent forms at: https://www.fda.gov/RegulatoryInformation/Guidances/ucm404975.htm