UNC School of Medicine Clinical Research Support Office

CRSO: IN THE KNOW

Clinical Trials Requirement to Post Informed Consent Form

July 2022

Most research teams are aware of the requirements to list clinical trials and upload results to clinicaltrials.gov, but did you know you are also required to post the consent form? The 2018 Requirements state that a consent form must be posted to a designated federal website after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject.

Contributing Authors: UNC OCT, SOM CRSO

The revised Common Rule requires that for each clinical trial conducted or supported by a federal department or agency, one IRB-approved consent form used to enroll subjects must be posted on a publicly available federal website by the awardee or the federal department or agency component conducting the trial. This requirement is most often satisfied by uploading the consent form to clinicaltrials.gov, though another option is to utilize a designated docket folder on Regulations.gov.

Posting earlier or at the beginning of the study does not satisfy the legal requirement. If a consent form is posted before a clinical trial closes recruitment, it would have to be re-posted after the clinical trial closes recruitment to satisfy this requirement.

Please note:

- This requirement applies to clinical trials initiated on/after 01/21/2019.
- The consent form that is uploaded is required to have a coversheet that indicates the official study title, NCT number, and document version date.
- Do not post any documents that have been signed by research subjects or that contain names of individual research subjects.

More Information Available

UNC OCT Notice of Requirement

HHS Informed Consent Posting Instructions

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