UK Office of Research Integrity (ORI) Posting Federally Funded Clinical Trial Consent Forms

Provision of the Revised Federal Policy for the Protection of Human Subjects Common Rule [45 CFR 56]

Purpose as described in the Common Rule Preamble:

Contrary to current practices, under which consent documents are not freely accessible, the posting requirement subjects the documents to public scrutiny and provides a means for accessing useful consent models. The impetus for the requirement, is to:

- increase transparency;
- facilitate and promote the development of more informative consent forms;
- enhance confidence in research enterprise; and
- increase accountability.

Consent Posting Requirement from Common Rule Regulation 45 CFR 46.116 (h):

SCOPE	ONLY applies to clinical trials conducted or supported by * Federal Common Rule Agency approved by the University of Kentucky (UK) Institutional Review Board (IRB) after January 22, 2019 *(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 outcomes.* *Open Link to see list of Common Rule Agencies
WHO?	The awardee
WHAT?	Posts one IRB-approved, blank informed consent form used to enroll subjects
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.
WHERE?	On a publicly available Federal Web site: 1. ClinicalTrials.gov; or *2.* Folder on Regulations.gov (Docket ID: HHS-OPHS-2018-0021) (*may have size limitations)*
HOW?	See Office for Human Research Protections (OHRP) Guidance On Clinical Trial Informed Consent Form Posting https://www.hhs.gov/ohrp/regulations-and-policy/informed-consent-posting/index.html
REDACTIONS	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 Web site (e.g. confidential commercial information), such Federal department or agency may permit or require redactions to the information posted.

University of Kentucky ClinicalTrials.GOV Assistance
The Office of Sponsored Projects Administration, Protocol Review and Results System (PRS) Administrator provides information and access to ClinicalTrials.GOV. For contact information see the UK Clinicaltrials.gov website.