IRB SOP 706
Posting of Consent Forms for Clinical Trials to Public Federal Website

Purpose

The purpose of this document is to describe the applicable clinical trials and requirements for posting clinical trial consent forms on a publicly available federal website.

Definitions

Clinical Trials: 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. (45 CFR 46.102)

Scope

This policy applies to investigators conducting clinical trials and the USA IRB.

Applicability

This provision of the Final Common Rule **only** applies to consent forms from clinical trials conducted or supported by a Common Rule department or agency

Policy

The Final Common Rule to update the current regulations at 45 CFR 46, Subpart A – "Federal Policy for the Protection of Human Subjects" (the Common Rule) published by the Department of Health and Human Services (DHHS) on 19 January 2017 in the Federal Register.

Researchers conducting clinical trials are now required to post trial consent forms on a federal website, “after the clinical trial is closed to recruitment, and no later than 60 days after the last