UNIVERSITY OF SOUTH ALABAMA

# 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 study visit by any subject, as required by the protocol." For a multi-site study, only a single consent form from the entire study is required to satisfy the posting requirement – not a consent form from each participating site.

The purpose is to be more transparent about the consent forms being used, and, over time, improve the quality of consent forms. Only one IRB-approved version of a consent form that has been used in the course of the study to enroll participants needs to be posted.

## Procedures

The Department of Health and Human Services, Office of Human Research Protections, has identified two publicly federal websites that will satisfy the consent form posting requirement. These include ClinicalTrials.gov and a docket folder (HHS-OPHS-2018-0021) on http://Regulations.gov

The DHHS Office of Human Research Protections has posted guidance to satisfy this requirement via uploading to Regulations.gov or ClinicalTrials.gov. See Related Guidance section below for detailed steps regarding posting of clinical trial informed consent.

## Regulated Documentation

DHHS 45 CFR 46.116(h)

## Related Guidance

Uploading a Clinical Trial Informed Consent to Regulations.gov or ClinicalTrials.gov

## HISTORY

Effective Date: January 21, 2019
Revisions:

## Responsible Party:

Office of Research Compliance and Assurance