HRPP Document: POL041 [II.4.A.] [II.4.B.] [II.3.F.] [II.3.F.] [III.1.F.]

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Revision Date:

Subject: Policy for Posting of Consent Forms for Clinical Trials to Public Federal Website

POLICY

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

There are several revisions to 45 CFR 46.116, which focus on the process of obtaining subject informed consent. These changes include revisions and additions to the general requirements and basic elements, as well additional elements. Additionally, researchers conducting clinical trials will now be 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.

This provision only applies to consent forms from clinical trials conducted or supported by a Common Rule department or agency. See [POL001](http://www.uab.edu/policies/content/Pages/UAB-RA-POL-0000637.aspx) for the DHHS definition of clinical trial.

The Office for Human Research Protections (OHRP) has just identified “two publicly available federal websites that will satisfy the consent form posting requirement” in the revised Common Rule: [http://ClinicalTrials.gov](https://clinicaltrials.gov/) and a docket folder (HHS-OPHS-2018-0021) on [http://Regulations.gov.](https://regulations.gov/) More may be identified in the future.