Policy Identification Number	(leave blank)
Policy Title	MUSC Policy on Informed Consent Posting Requirement (45 CFR 46.116(h))
Classification	Research
Approval Authority	Office of the Vice President of Research
Responsible Entity	Office of Clinical Research (OCR)
Policy Owner	Royce Sampson

I. Policy Statement

The revised Common Rule requires that for any clinical trial conducted or supported by a Common Rule department or agency, one consent form be posted on a publicly available federal website within a specific time frame. The consent form must have been used in enrolling participants. MUSC will use clinicaltrials.gov as the appropriate federal website in which documents will be posted.

II. Scope

The revised Common Rule applies to the research community operating studies that are federally funded.

III. Approval Authority

Office of the Vice President of Research

IV. Purpose of This Policy

The purpose of this policy is to address the federal requirements regarding the Revised Common Rule Informed Consent Posting requirement. ((45 CFR 46.116(h))

V. Who Should Be Knowledgeable about This Policy

All MUSC enterprise employees engaged in human subjects research federally funded and approved after January 21, 2019.

VI. The Policy

To maintain compliance with this requirement, researchers will be required to post a blank copy of their study's informed consent used to consent patients on a federally operated website, (clinicaltrials.gov) within the timeframe outlined in 45 CFR 46.116(h).

VII. Special situations

N/A

VIII. Sanctions for Non-compliance

Noncompliance with the HHS regulations can result in the withholding of federal funds, or "for cause compliance evaluations" conducted by the Office of Health and Research Protections.

IX. Related Information

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Date Approved	

https://www.hhs.gov/ohrp/regulations-and-policy/informed-consent-posting/index.html

X. Communication Plan

Information related to publicizing new or revised policy information as well as any educational resources, workflows, or training materials will be posted on the OCR website and communicated through the OCR and Office of the Vice President for Research email list serves. In addition, the South Carolina Clinical and Translational Research Institute (SCTR) will support dissemination of information through their communication channels including use of a weekly newsletter or other channels as appropriate.

XI. Definitions

XVI. Review Cycle

Policy review will take place a minimum of every 3 years or as federal requirements or policy changes.

XVI. Approval History

Approvol Authority	*Date Approved*

XVII. Approval Signature

Kathleen Brady

6/26/19

Date

Vice President of Research