

<b>Policy Identification Number</b>	(leave blank)
<b>Policy Title</b>	MUSC Policy on ClinicalTrials.gov Registration and Results Reporting
<b>Classification</b>	Research
<b>Approval Authority</b>	Office of the Vice President of Research
<b>Responsible Entity</b>	Office of Clinical Research
<b>Policy Owner</b>	Royce Sampson

### **I. Policy Statement**

This policy outlines MUSC’s commitment to clinical trial transparency through disclosure of registration and results reporting on ClinicalTrials.gov.

### **II. Scope**

This policy applies to anyone within the Medical University of South Carolina organization that participates in human subjects research, including any third party consultants, contractors or other individuals that support research at MUSC.

### **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 clinical trial disclosure on ClinicalTrials.gov. It outlines how MUSC will address each aspect of the federal requirements for registering and reporting results on clinical studies involving human subjects.

### **V. Who Should Be Knowledgeable about This Policy**

All MUSC enterprise employees engaged in human subjects research

### **VI. The Policy**

This policy is established in response to the requirements of the Health and Human Services Department (HHS) regulation ([52 CFR 11](#)) and applies to all MUSC investigators conducting clinical trials/studies as defined by the Food and Drug Administration (FDA), International Committee of Medical Journal Editors, National Institutes of Health (NIH) or submitting qualified research billing claims to the Centers for Medicare and Medicaid Services (CMS). It requires registration and results reporting for qualifying clinical trials and promotes the responsible dissemination of information about clinical trials to the public in alignment with Federal requirements.

The HHS regulations mandate registration and results reporting for applicable clinical trials ([ACTs](#)) regardless of funding type.

[NIH policy](#) mandates registration and results reporting for clinical trials that are funded in whole or in part by NIH, even if they are not ACTs. NIH defines a [clinical trial](#) as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which include placebo or

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other control) to evaluate the effects of those interventions on health related biomedical or behavioral outcomes. This MUSC policy also recognizes the NIH policy regarding [dissemination](#) of clinical trial results for NIH funded studies.

In addition, this policy recognizes [ICMJE recommendations](#) to register clinical trials prior to enrollment and [CMS policy](#) to require a ClinicalTrials.gov NCT number when billing for routine care associated with ACT.

Given the differences in registration and results reporting requirements across all policies and in order to comply with new laws, maintain positive NIH standing and preserve the ability to publish in ICMJE journals, MUSC’s policy dictates that **all** sets of requirements must be met.

Any MUSC researcher, in the role of Principal Investigator (PI), who initiates or conducts an investigator-initiated clinical trial not already registered, shall be designated as the [Responsible Party](#) (RP) and is ultimately responsible for the study registration, timely record updates and results reporting.

The Office of Clinical Research will require an NCT number for all ACTs and for all NIH-funded studies prior to approval.

In Medicare Bulletin #2955 regarding Medicare Policy Transmittal and dated January 1, 2014, the ClinicalTrials.gov National Clinical Trials Identifier Number (NCT#) is to be provided on Medicare claims for services provided in clinical trials. Trials that have budgeted patient care charges to be billed to Medicare or other third-party payers must provide an NCT number to the Office of Clinical Research to avoid payer denials.

**VII. Special situations**

N/A

**VIII. Sanctions for Non-compliance**

Noncompliance with the HHS regulations or NIH policy to submit results for an ACT or NIH-CT within their time requirements relative to the [Primary Completion Date](#), or repeated violations of the HHS regulations, NIH policy, or this policy can result in administrative action by MUSC and/or the NIH.

**IX. Related Information**

NIH and HHS policy are effective as of Jan 18, 2017.

[Clinicaltrials.gov/FDAAA](#)

[MUSC Office of Clinical Research](#)

**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

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through the OCR and Office of the Vice President for Research email listserves. 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**

ClinicalTrials.gov provides a [glossary of common site terms](#) accessible to both the general public and researchers.

**XVI. Review Cycle**

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

**XVI. Approval History**

<i>Approval Authority</i>	<i>Date Approved</i>

**XVII. Approval Signature**



Kathleen Brady

8/13/18  
Date

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Vice President of Research