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
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

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XVII. Approval Signature

[Signature]

Kathleen Brady

Date: 8/13/18

Vice President of Research