[SITE NAME]

STANDARD OPERATING PROCEDURE

Title:		No.: ISCORE-RC-108.00	
ClinicalTrails.gov Disclosure		Page 1 of 3	
		Date of Issuance: dd, month, yyyy	Date Effective: dd, month, yyyy
		Supersedes:	
Prepared by:	Reviewed by:	Approved by:	

Purpose:

This standard operating procedure (SOP) describes the policies and procedures followed at this investigative site [SITE Location] for the disclosure of clinical trials in Clinicaltrials.gov for Applicable Clinical Trials (ACT) according to the requirements of the Food and Drug Administration (FDA), Health and Human Services (HSS) regulations and the NIH policy on the Dissemination of NIH-Funded Clinical Trial Information.

Scope:

This SOP applies to all Applicable Clinical Trials according to the following specifications:

- Food and Drug Administration Amendments Act (FDAAA) of 2007 as implemented by the HHS Final Rule
- NIH Policy (2017) for Clinical Trials Registration Requirement
- Qualifying trial which will render claims for items and services from the Centers for Medicare and Medicaid Services (CMS)

Clinical trials that are not applicable to the above policies should be considered for registration on Clinicaltrials.gov to comply with the International Committee of Medical Journal Editors (ICMJE) requirements for publication.

Materials:

Attachment 1- Guide for Timeline Requirements on ClinicalTrials.gov

Responsibility:
This SOP applies to all personnel involved in the conduct or supervision of clinical trials at the [SITE] and for which the responsibility for ClinicalTrials.gov disclosure is with the Principal Investigator/[SITE] (eg. Investigator-initiated clinical trials).

For clinical trials associated with an externally-held IND/IDE (eg. Industry study), the Sponsor is responsible for clinicaltrials.gov registration. For trials sponsored or funded, even in part, by a federal agency the overall Principal Investigator (PI) should contact the Sponsor or agency to determine responsibilities.

Procedure:

A. Any [SITE] Researcher, in the role of PI, who initiates or conducts an applicable investigator-initiated clinical trial, shall be designated as the Responsible Party (RP). The RP must ensure that registration, required record updates, and results reporting are completed and released in a timely manner.

B. The [SITE] IRB number will be used as the Protocol ID in the system. Applicable Clinical Trials must be registered in Clinicaltrials.gov prior to first participant enrollment.

C. Each [SITE] institution or department conducting Clinical Trials should appoint a ClinicalTrials.gov administrator to assist Investigators in establishing Protocol Registration and Results System (PRS) accounts for registration and management of protocols for which they are the designated RP.
D. Registration must be done via the "[SITE]" ClinicalTrials.gov PRS, unless the project receives external funding that is administered by another institution. The National Clinical Trial Identifier Number (NCT#) will be generated by the system once registration comple

E. Repeated noncompliance with this policy to register or submit results for applicable clinical trials can result in withdrawal of further research privileges by [SITE] Executive Leadership.

References:
1- FDAAA 801: Section 801 of the Food and Drug Administration Amendments Act of 2007 as implemented by 42 CFR Part 11: Final Rule
2- NIH Policy on Dissemination of NIH-Funded Clinical Trial Information
3- Centers for Medicare & Medicaid Services (CMS): CR 5790, Requirements for Including an 8-Digit Clinical Trial Number on Claims

History of Revisions to SOP

Effective Date	Nature of Revision