EFFECTIVE DATE: June 2023

The University and federal regulations require registration and results reporting of certain clinical trials (as defined below) at ClinicalTrials.gov, a publicly-accessible registry, to promote responsible dissemination of information about clinical trials to the public, ensure compliance with pertinent Federal and State law and funding agency requirements, and to meet professional publication standards.

This policy and procedure applies to all University of South Alabama faculty and staff who are considered sponsors on clinical trials requiring registration and results reporting on ClinicalTrials.gov, as defined herein. This policy also applies to anyone designated by the sponsor as the responsible party for inputting study results and data into ClinicalTrials.gov.

As defined by Title VIII of the Food and Drug Administration Amendment Act of 2007 (FDAAA): is the person who can control, manage, or direct the entity and the disposition of the entity's funds and assets.

When a clinical trial is conducted under an investigational new drug application (IND) or investigational device exemption (IDE), the IND or IDE holder will be considered the sponsor. When a clinical trial is not conducted under an IND or IDE, the single person or entity who initiates the trial, by preparing and/or planning the trial, and who has authority over the trial, will be considered the sponsor.

c) Qualifying clinical trials which will render claims for items and services to the Center for Medicare and Medicaid Services (CMS)
d) Clinical trials that meet the clinical trial definition of the International Committee of Medical Journal Editors (ICMJE) and, the results of which, the investigator plans to publish in a member journal.

The sponsor is the responsible party for registering applicable clinical trials, submitting updates, and submitting results on clinicaltrials.gov within timelines as defined in procedures below. Alternatively, the sponsor may designate the study's Principal Investigator to register and maintain the study in clinicaltrials.gov, so long as the PI is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements for the submission of clinical trial information.

It is the responsibility of the sponsor to ensure registration and results reporting are completed and

https://clinicaltrials.gov/ct2/manage-recs

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1. The study sponsor is responsible for updating clinical trial records registered at a publicly-accessible registry, reviewing the record for accuracy, and verifying that data-entry occurs within the required time frames. All timeframes apply for and qualified studies.

    1.1. Registration information must be updated ;

    1.2. Recruitment/enrollment status changes (such as suspending recruitment or enrollment closed) must be input ;

    1.3. Trial closure (regardless of the reason for closure—completion, low enrollment, etc.) must be input .

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All applicable clinical trials, or NIH funded interventional trials, must have results reported in ClinicalTrials.gov. The primary completion date (PCD) determines the time frame for results reporting. The sponsor has one year from this date to enter trial results on the primary outcome. Secondary outcomes must be reported within one year, unless investigators apply for and qualify for a Certification of Initial or New use of Uncleared Products. With this certification, the deadline for reporting secondary results can be extended up to three years.

Patient status dates and primary outcome time frame determine the primary completion date. Once a study is closed to accrual, the PI or designee will then monitor the patient status (on treatment, off treatment, off study), to determine the PCD. This date can be entered in ClinicalTrials.gov as "anticipated" and updated as the study moves forward. Once the date is set as "actual" then the sponsor has one year from that date to enter results.

1. Study sponsors are responsible for reporting results of clinical trials registered at a publicly-accessible registry, review the record for accuracy and ensure data-entry occurs within required time frames, as follows:

    1.1. Aggregate results and adverse event reporting on ClinicalTrials.gov must occur

    1.2. : Aggregate results and adverse event reporting on ClinicalTrials.gov must occur ;

    1.3. If the study qualifies as a clinical trial under FDAAA or NIH, results and event reporting must occur If

the study does not qualify as a clinical trial under FDAAA or NIH, results reporting is voluntary.

1.4. If the study qualifies as a clinical trial under FDAAA or NIH, results and event reporting must occur If the study does not qualify as a clinical trial under FDAAA or NIH, results reporting is voluntary.

2. Detailed instructions for submission of study results are found on the ClinicalTrials.gov https://clinicaltrials.gov/ct2/manage-recs/how-report.

3. The study sponsor is responsible to respond to registry reviewer requests for information or changes, as applicable, in a timely fashion.

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The University requires compliance with clinical trials registration and results reporting. If a study sponsor fails to comply with this policy, the Clinical Trial Office will notify the applicable department chair(s) and research dean(s). Failure to comply will result in notification to the Office of Research Compliance and Assurance noting regulatory noncompliance in research registration and/or results reporting.

Additionally, the FDA has the authority to issue a Notice of Noncompliance to a responsible party for failure to comply with certain requirements, including:

Failing to submit required clinical trial information
Submitting false or misleading clinical trial information

FDA also has the authority to issue a Notice of Noncompliance to a submitter who has failed to submit or knowingly submitted a false certification to FDA.

FDA has authority to assess civil money penalties for these violations. If a responsible party does not take adequate corrective action within 30 days after receiving a Notice of Noncompliance

May 2026

Director, Clinical Trials Office