

# BURRELL COLLEGE OF OSTEOPATHIC MEDICINE

## STANDARD OPERATING PROCEDURES

<b>Title: ClinicalTrials.gov Registration and Reporting</b>		<b>SOP #: RSP.031.00</b>
Effective Date	08/17/2023	
Last Revision/Review		

### 1. Purpose

To provide a general understanding of the requirements for maintaining compliance with federal regulations under the Department of Health and Human Services (DHHS), NIH regulations, and policies concerning ClinicalTrials.gov.

### 2. Related Policy/Authority

[NIH Definition of a Clinical Trial](#) (NIH, Grants & Funding)

[NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information](#) (Federal Register)

[Guidance \[from NIH Office of Extramural Research\] on New Law \(Public Law 110-85\) Enacted to Expand the Scope of ClinicalTrials.gov Registration.](#)

[Code of Federal Regulations \(CFR\): ClinicalTrials.gov Registration and Results](#)

[Information Submission](#) (42 CFR Part 11)

[ClinicalTrials.gov FDAAA 801 and the Final Rule](#)

### 3. Faculty/Staff Responsibilities

Principal Investigator (PI) of a clinical trial or designee that assumes the responsibility of conducting the trial, controls and holds access to the trial data, holds the right to publish the results, and can meet all requirements for submitting clinical trial information.

### 4. Definitions/Abbreviations

[ClinicalTrials.gov](#): A public registry aimed at increasing transparency and enhancing public awareness of research. It contains information on publicly and privately funded clinical studies across a broad spectrum of diseases and conditions. The registry's goals include improving public access to clinical trial information, aiding clinicians in finding suitable trials for their patients, and providing researchers with insights into specific fields of study and changes in research design.

Maintained by the National Library of Medicine at the National Institutes of Health (NIH), ClinicalTrials.gov is overseen by several agencies, including the Food and Drug Administration (FDA), National Institutes of Health (NIH), the Centers for Medicare & Medicaid Services (CMS), and the International Committee of Medical Journal Editors (ICMJE).

Protocol Registration and Results System (PRS): is the ClinicalTrials.Gov registry.

Sponsor Organization: A company, university, medical center, or other research organization that conducts clinical trials. Each study record has a Sponsor Organization, and all PRS accounts associated with that record should be under the Sponsor Organization. Investigators apply to be users of the Sponsor Organization's PRS account. If an investigator is conducting trials for more than one Sponsor Organization, they will need an account from each of those organizations to register the studies properly.

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**Administrator:** Individual designated by the organization to manage the organization's PRS account, create accounts for users, and serve as the point of contact for PRS Staff. At Burrell these responsibilities are assigned to the Assistant Dean for Research and the Human Research Protection, Compliance, and Integrity Specialist. The Administrator creates user accounts and oversees the maintenance of the organization's records. When the Sponsor is the Responsible Party. Administrators are responsible for releasing records for PRS Review and posting to ClinicalTrials.gov.

**User:** Any PRS account holder who is authorized to enter information into the PRS, including investigators or research assistants. Users create and modify their own records, but cannot access other users' records unless authorized by the Record Owner or by an Administrator.

**Record Owner:** Record Owners can maintain the record themselves or give one or more users access to a record to make changes. An Administrator can change the Record Owner after the record has been created.

**Responsible Party:** Entity or individual responsible for verifying the accuracy of a study record and releasing it to ClinicalTrials.gov. The Responsible Party for a particular study may be the Sponsor, Sponsor-Investigator, or Principal Investigator. When the Responsible Party is the Sponsor, an Administrator performs these record functions. The person identified as the Responsible Party for the Sponsor Organization account acts as the official contact person for that account and full contact information for that person must be listed in the PRS account.

## **5. Procedural Steps**

### **5.1 Responsible Party**

1. Principal Investigators (PIs) must determine their obligation to register and subsequently provide updates, including results reports, in accordance with [NIH 42 CFR part 11](#).
2. Registration information must be submitted within 21 days after the first enrollment. ICMJE requires trial registration before the first enrollment date. Generally, updates to clinical trial registration on ClinicalTrials.gov should occur at least once every 12 months, with certain data elements possibly requiring more frequent updates within 15-30 days.
3. The Responsible Party shall submit study results in accordance with ClinicalTrials.Gov guidelines.
  - a. ClinicalTrials.Gov mandates data submission in tabular format, summarizing participant flow, demographic and baseline characteristics, primary and secondary outcomes, scientifically appropriate statistical tests, and adverse event details. Additionally, the full protocol and statistical analysis plan (if separate) must be submitted.
  - b. ClinicalTrials.Gov results information must be submitted no later than 1 year after the "primary completion date," which is the date of final data collection for the primary outcome measure. In some cases, results submission may be delayed by up to 2 additional years for trials involving products still under development or seeking approval.

### **5.2 Record Owner**

The Record Owner shall be responsible for study records maintenance, designating records responsibilities to another user, and notifying the Office of Research if they wish to add or remove users from the study. Each user must have their own individual ClinicalTrials.Gov login and be listed in the study protocols. Record owners shall request login from the Office of Research.

### **5.3 ClinicalTrials.gov Information**

- Basic Information on ClinicalTrials.gov is available on the [About ClinicalTrials.gov](#) link.
- Research studies that involve people, have health-related research questions, and are reviewed and approved by an Institutional Review Board are registered in the ClinicalTrials.gov database. The Research studies fall into two types of studies: 1) *Clinical Trials* in which researchers assign participants into groups to get one or more interventions to test what happens in people and 2) *Observational studies* in which researchers simply collect data from participants or look at data that was already collected. For observational studies, researchers do not assign participants to get an intervention. Researchers should contact the Office of Research for questions and further guidance.
- Study sponsors and investigators submit the information to ClinicalTrials.gov. Sponsors and investigators are responsible for ensuring that their studies follow all relevant laws, regulations, and policies.
- The Principal Investigator must obtain IRB approval for the study and is responsible for registering the study on ClinicalTrials.gov.
- For Burrell College sponsored projects, principal investigators must contact the Office of Research for guidance and access to the Burrell institution linked ClinicalTrials.gov study site.
- Noncompliance repercussions include public notices, withholding of grant funds, grant termination, monetary penalties, and rejection of manuscripts for journal publication.
- The responsible party is accountable for compliance, and their department chair(s) shall be informed of non-compliant studies within their department(s).

### **5.4 Study Transfer, Completion, or Closure**

The Responsible Party must inform the Office of Research if their status with Burrell College changes or if they wish to transfer a study record to another organization's ClinicalTrials.gov account.

### **5.5 Federally Sponsored Research**

- **FDA Research:**  
Principal Investigators engaging in research involving FDA-regulated agents, drugs, or devices falling under the FDA's Code of Federal Regulations, Title 21 (21 CFR), will need to conduct their research under an external Institutional Review Board (IRB) possessing the expertise and experience in reviewing studies under 21 CFR. Alternatively, they can consider seeking assistance from regulatory experts and consultants who specialize in 21 CFR studies. This collaboration aims to provide the Burrell College IBR with valuable insights and guidance, ensuring proper oversight and adherence to regulations.  
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>
- **NIH Research:**  
The Responsible Party must make the determination as to whether a trial is subject to the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information.  
<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-149.html>

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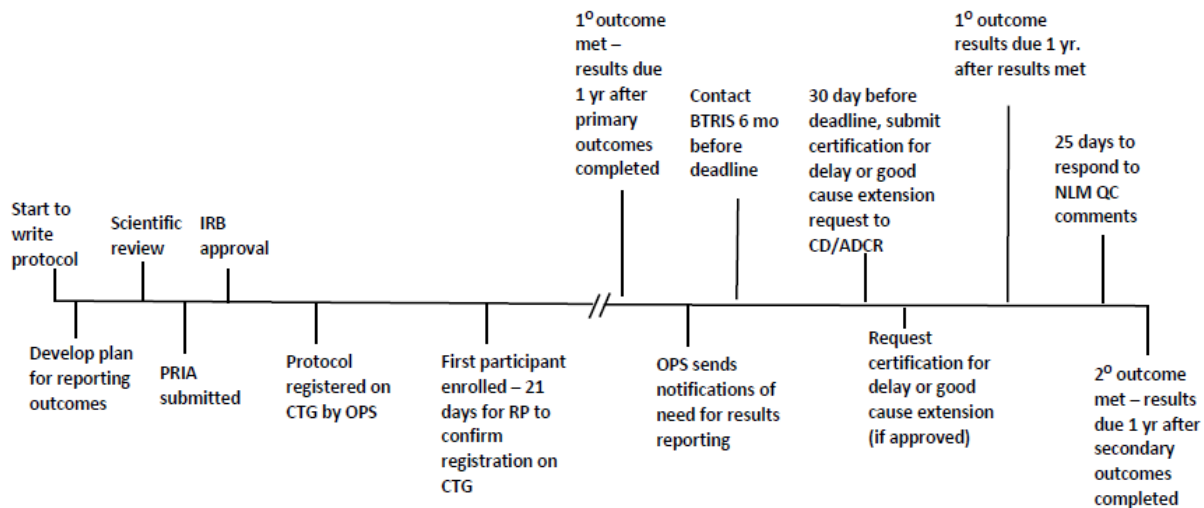
### 6. Reports/Charts/Forms/Attachments/Cross References

#### APPLICABILITY OF REQUIREMENTS IN 42 CFR PART 11

Initiation date	Primary completion date	Registration information submission required?		Results information submission required?	
		Approved, licensed, or cleared products	Unapproved, unlicensed, or uncleared products	Approved, licensed, or cleared products	Unapproved, unlicensed, or uncleared products
On or before September 27, 2007 .....	After December 26, 2007 and before Effective Date of Final Rule.	Yes, as specified in section 402(j)(2)(A)(ii) of the PHS Act.	Yes, as specified in section 402(j)(2)(A)(ii) of the PHS Act.	Yes, as specified in section 402(j)(3)(C) and section 402(j)(3)(I) of the PHS Act.	No.
After September 27, 2007 and before the Effective Date of the Final Rule.	Before Effective Date of Final Rule.	Yes, as specified in section 402(j)(2)(A)(ii) of the PHS Act.	Yes, as specified in section 402(j)(2)(A)(ii) of the PHS Act.	Yes, as specified in section 402(j)(3)(C) and section 402(j)(3)(I) of the PHS Act.	No.
After September 27, 2007 and before Effective Date of Final Rule.	On or after Effective Date of Final Rule.	Yes, as specified in section 402(j)(2)(A)(ii) of the PHS Act.	Yes, as specified in section 402(j)(2)(A)(ii) of the PHS Act.	Yes, as specified in 42 CFR part 11.	Yes, as specified in 42 CFR part 11.
On or after Effective Date of Final Rule	On or after Effective Date of Final Rule.	Yes, as specified in 42 CFR part 11.	Yes, as specified in 42 CFR part 11.	Yes, as specified in 42 CFR part 11.	Yes, as specified in 42 CFR part 11.

<https://classic.clinicaltrials.gov/ct2/manage-recs/fdaaa#WhichTrialsMustBeRegistered>

### Timeline for ClinicalTrials.gov Compliance



<https://policymanual.nih.gov/3007>

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*ClinicalTrials.gov*

*ClinicalTrials.gov is a service of the  
National Institutes of Health.*

### Checklist for Evaluating Whether a Clinical Trial or Study is an Applicable Clinical Trial (ACT) Under 42 CFR 11.22(b) for Clinical Trials Initiated on or After January 18, 2017<sup>1</sup> (NOT FOR SUBMISSION<sup>2</sup>)

**Instructions:** Answer the following questions to evaluate whether the study is an applicable clinical trial (ACT). Use the accompanying "Elaboration" for additional information to help answer the questions.

Question	Yes	No
1. Is the study interventional (a clinical trial)? <i>Study Type</i> data element is "Interventional"	<input type="checkbox"/>	<input type="checkbox"/>
2. Do ANY of the following apply (is the answer "Yes" to <u>at least one</u> of the following sub-questions: 2a, 2b, OR 2c)?  a. Is at least one study facility located in the United States or a U.S. territory? <i>Facility Location – Country</i> data element is "United States," "American Samoa," "Guam," "Northern Mariana Islands," "Puerto Rico," "U.S. Virgin Islands," or other U.S. territory.  b. Is the study conducted under a U.S. FDA Investigational New Drug application (IND) or Investigational Device Exemption (IDE)? <i>U.S. Food and Drug Administration IND or IDE Number</i> data element is "Yes."  c. Does the study involve a drug, biological, or device product that is manufactured in and exported from the U.S. (or a U.S. territory) for study in another country? <i>Product Manufactured in and Exported from the U.S.</i> data element is "Yes."	<input type="checkbox"/>	<input type="checkbox"/>
3. Does the study evaluate at least one drug, biological, or device product regulated by the United States Food and Drug Administration (U.S. FDA)? <i>Studies a U.S. FDA-regulated Device Product</i> data element is "Yes" and/or <i>Studies a U.S. FDA-regulated Drug Product</i> data element is "Yes."	<input type="checkbox"/>	<input type="checkbox"/>
4. Is the study <u>other than</u> a Phase 1 trial of a drug and/or biological product or is the study <u>other than</u> a device feasibility study? For drug product trials, <i>Study Phase</i> data element is NOT "Phase 1" and for device product trials, <i>Primary Purpose</i> is NOT "Device Feasibility."	<input type="checkbox"/>	<input type="checkbox"/>

If "Yes" is answered to all 4 questions, and the study was initiated on or after January 18, 2017, the trial would meet the definition of an ACT that is required to be registered under 42 CFR 11.22.

<sup>1</sup> All pediatric postmarket surveillance studies of a device product as required by U.S. FDA under section 522 of the FD&C Act and for which FDA approved the plan on or after January 18, 2017 meet the definition of an ACT in 42 CFR Part 11.22(b) and are subject to the final rule requirements.

<sup>2</sup> The outcome generated by the checklist tool will not be retained by the Agency and will not be binding on either the user or any Government agency in any future actions.

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### **7. Maintenance**

Reviewed on an annual basis by the Office of Research.

### **8. Signature**

Approved by

Assistant Dean for Research

8/18/2023

Date

### **9. Distribution List**

Internal/External

### **10. Revision History**

Revision Date	Subsection #	Summary of Changes	New/Cancellation/Replacement Procedure? (if applicable)	Approval Date