THE OHIO STATE UNIVERSITY
COLLEGE OF MEDICINE

Standard Operating Procedure 100-001
ClinicalTrials.gov Compliance

BACKGROUND

The College of Medicine Office of Research (COMOR) is committed to maintaining an effective, and robust research compliance program. An important component is monitoring compliance of College of Medicine (COM) research studies registered on ClinicalTrials.gov in order to detect and prevent potential compliance risks that could impact the College and The Ohio State University (Ohio State).

ClinicalTrials.gov is a National Institutes of Health (NIH) nationwide registry of applicable clinical trials (ACT), consisting of an online database for clinicians, researchers, and patients of publicly and privately-funded human subjects research (HSR) studies on a variety of diseases and conditions. Sponsors or investigators are required to provide information and updates about ACTs on ClinicalTrials.gov in accordance with (IAW) Section 801 of the Food and Drug Administration Amendments Act of 2007 (FDAAA 801) and Title 42 Code of Federal Regulations (CFR) Part 11, Clinical Trials Registration and Results Information Submission.

PURPOSE

To maintain transparency with university partners and the COM research community by systematizing a process for ensuring that COM Principal Investigators (PI) are aware of their responsibilities and understand COMOR requirements regarding ClinicalTrials.gov record compliance.

APPLICABILITY

This SOP applies to any research performed by a COM PI that is considered an ACT IAW 42 CFR § 11.22 and should be registered in ClinicalTrials.gov.

DEFINITONS

Applicable Clinical Trial (ACT):

- Controlled clinical investigations (other than phase 1 investigations) of any FDA-regulated drug or biological product for any disease or condition

- Certain studies of FDA-regulated medical devices, excluding small clinical trials to determine feasibility and certain clinical trials to test prototype devices, but including FDA-required pediatric post-market surveillances of a device product

Principal Investigator (PI): An individual with the appropriate scientific and/or scholarly training and expertise to assume direct responsibility for the ethical conduct of a study involving human subjects, providing technical and administrative oversight of the research and making important study-related decisions

Problem Record: A study flagged for errors related to data entry, FDAAA 801 or the PRS Administrator

Record Owner: Primary contact for study record such as Admin, User, or PI

Responsible Party: The entity or individual (Sponsor, Sponsor-Investigator or PI) responsible for registering an ACT and submitting ACT information to the Clinical Trial Registry Data Bank.

PROCEDURE

1. Compliance Monitoring and Enforcement

1.1 PIs are responsible for registering any ACT on ClinicalTrials.gov, for which the trial sponsor is not assuming responsibility for ClinicalTrials.gov record maintenance.

1.2 The COMOR Compliance Team (COMOR-CT) will monitor ClinicalTrials.gov compliance and problem records at least twice per fiscal year and at the time of an audit. Monitoring will include review and analysis of Ohio State ACTs listed on the public-facing website, FDAAA TrialsTracker.

1.3 For departments and divisions whose research is not administratively managed by The Ohio State University Comprehensive Cancer Center (OSUCCC) Clinical Trials Office (CTO):

1.3.1 On a quarterly basis, COMOR-CT will prepare and distribute a ClinicalTrials.gov compliance dashboard to COM leadership, with information about compliant and noncompliant records within COM departments and divisions.

1.3.2 COMOR-CT will send notifications of noncompliance via email to Record Owners and Responsible Parties (excluding

those from departments and divisions under the OSUCCC CTO) during compliance evaluation periods.

1.3.3 Record Owners and Responsible Parties will receive a 30-day deadline for addressing required updates and/or queries on problem records. Reminder emails will be sent 14 days, seven (7) days and one (1) day prior to deadline. COMOR-CT will adjust this deadline if needed, to account for any delays emanating from the ClinicalTrials.gov Protocol Registration and Results System (PRS) that are beyond the control of Ohio State.

1.3.4 Responsible Parties whose problem records remain unresolved by the 30-day deadline will be subject to Ohio State network account deactivation in collaboration with COM Research Technology Services (COMRTS) until problem records are brought into compliance.

1.3.5 Record Owners and Responsible Parties will contact COMOR-CT at COMResearchCompliance@osumc.edu once problem records have been resolved and COMOR-CT will initiate Ohio State user account reactivation once record compliance is confirmed.

1.4 For departments and divisions whose research is administratively managed by the OSUCCC CTO, the OSUCCC CTO will collaborate with COMOR-CT by providing information as needed with regard to ClinicalTrials.gov records.

2. Additional Reporting Requirements, Potential Penalties, and Other Consequences of Noncompliance

2.1 The FDA makes determinations about whether Responsible Parties are complying with legal requirements for submitting information to ClinicalTrials.gov for ACTs.

2.1.1 When these requirements have not been met, FDA has the authority to take enforcement action. Responsible Parties receiving a *Pre-Notice of Noncompliance*, have not complied with their legal reporting obligations.

2.1.2 Failure to act following receipt of a *Pre-Notice of Noncompliance*, will result in FDA issuing a *Notice of*

Noncompliance. The *Notice of Noncompliance* grants the Responsible Party 30 days to submit required information. Otherwise, FDA is authorized to seek civil monetary penalties for violations, including additional civil monetary penalties for failure to submit the required information within the 30-day period.

2.1.2.1 *Notices of Noncompliance* are publicized on the FDA's website and information about the noncompliance is posted within the study record on ClinicalTrials.gov by NIH. NIH regularly updates ClinicalTrials.gov records for ACTs that are subject to a *Notice of Noncompliance* to include whether the noncompliance has been corrected and the amount of civil monetary penalties assessed.

2.1.3 Any Ohio State Responsible Party receiving a *Pre-Notice of Noncompliance, Notice of Noncompliance* or similar warning letter, is required to immediately notify COMOR-CT and provide a copy of the correspondence via email at: COMResearchCompliance@osumc.edu COMOR-CT will internally track these notifications.

2.1.4 In addition to civil monetary penalties, violations of § 301(jj) of the Federal Food, Drug, and Cosmetic Act (21 USC 331 (jj)) could result in other regulatory action, such as injunction and/or criminal prosecution.

2.1.5 IAW § 402(j)(5)(A) of the Public Health Service Act (42 USC 282(j)(5)(A)), grant or progress report forms for ACTs funded in whole or in part by the US Department of Health and Human Services (HHS), must include a certification that the Responsible Party has made all required registration and results submissions. Otherwise, any remaining funding for a grant or funding for a future grant to such grantee will not be released.

2.2 When a PI plans to depart Ohio State, they must update their ClinicalTrials.gov records accordingly as part of their COM offboarding responsibilities. This includes ensuring that the record is in good standing and:

2.2.1 Completing the record; or

2.2.2 Updating the record to reflect transfer to a new PI; or

2.2.3 Transferring the record to the PI's new institution

RESOURCES

1. PIs and study teams should consult the following provided by COMOR-CT with questions about ClinicalTrials.gov:

- Managing ClinicalTrials.gov
- ClinicalTrials.gov FAQs

Should the resources provided not address the PI's or study team's questions, contact ClinicalTrials.gov PRS Administration for further guidance at: register@clinicaltrials.gov

2. College of Medicine Offboarding & Laboratory Closeout Checklist

REFERENCES

Title 42 Code of Federal Regulations Part 11 (42 CFR 11), Clinical Trials Registration and Results Information Submission

Title 21 United States Code Section 331 (jj), (21 USC § 331 (jj)), Prohibited Acts

Title 42 United States Code Section 282 (i), and (j) (42 USC § 282 (i)(j)), Data bank of information on clinical trials for drugs for serious or life-threatening diseases and conditions, Expanded clinical trial registry data bank

CONTACT

For questions about this SOP, please contact COMOR-CT at: COMResearchCompliance@osumc.edu.

APPROVED

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