Clinical Trials Registration

ClinicalTrials.gov is a public registry aimed at increased transparency and improved public awareness of research. Information about individual clinical trials is added to ClinicalTrials.gov through a registration process. Various regulatory bodies and committees have promoted both definitions of those clinical trials required to register and the necessity of results reporting.

Regulatory Requirements

Registration of a clinical trial in ClinicalTrials.gov and maintenance of the clinical trial record is required by several regulatory bodies and committees. Additionally, failure to comply can result in penalties. Food and Drug Administration Amendments Act of 2007 801, International Committee of Medical Journal Editors and Centers for Medicare and Medicaid Services are the most commonly referenced requirements. Please note that the clinical trial may be subject to other policy or sponsor requirements and registration and maintenance is recommended for a clinical trial receiving funding and/or support from the National Institutes of Health.

Regulation/Policy	Timeline for Registration	Results Reporting Required	Penalty for Not Complying
Food and Drug Administration Amendments Act of 2007 801	21 days post first subject enrollment	Yes	Initial $10,000 and $10,000/day for the duration of the violation (uncorrected violations), withholding of funds, sanctions
ICMJE	At or before first subject enrollment	No	Inability to publish in many prominent journals
CMS	Prior to submission of claim	No	Claims will not be paid
NIH	Recommended - 21 days post first subject enrollment	Recommended - Yes	Recommended - not enforced

For more information about ClinicalTrials.gov requirements and registration:

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

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

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

Training Resources

PRS User Guide: https://prsinfo.clinicaltrials.gov/prs-users-guide.html

PRS Guided Tutorial: https://prsinfo.clinicaltrials.gov/tutorial/content4/index.html#/

Training Materials: https://clinicaltrials.gov/ct2/manage-recs/present

Office of Research Integrity and Assurance Responsibilities

The Office of Research Integrity and Assurance performs the following functions:

- Administers ClinicalTrials.gov accounts
- Assists in determining if a clinical trial is an Applicable Clinical Trial and requires compliance with Food and Drug Administration Amendments Act of 2007 801 requirements.
- Monitors research community activity and responsibilities within ClinicalTrials.gov
- Handles inquiries/concerns from the research community

Researcher Responsibilities

Principal Investigators determined to be the Responsible Parties of Applicable Clinical Trials (ACT) that meet the requirements for registration on ClinicalTrials.gov perform the following functions:

- Request an account to register the ACT
    - Please contact Katie Brooks at kbrook14@gmu.edu to set up an account
- Correctly identify the Responsible Party for a clinical trial requiring action on ClinicalTrials.gov
- Create records on ClinicalTrials.gov
- Approve and release actions associated with ClinicalTrials.gov records
    - Confirm accuracy of content in record
- Resolve problems on ClinicalTrials.gov
- Maintain records on ClinicalTrials.gov including content updates (at least once every 12 months), modification of the verification date, and results reporting if required
    - **Note: Notifications of necessary updates will be sent via email to the PI on the project. The administrator will also receive email notices about problem records and may send reminders to the PI to follow up on progress updating the ClinicalTrial.gov record, but it is the responsibility of the PI to maintain an accurate and updated record on the site.**
    - **Sections 46.102(b) and 46.116(h) of the revised Common Rule require that clinical trials post one IRB-approved version of a consent form that has been used to enroll participants on a public federal website designated for posting such consent forms. The form must be posted after recruitment closes, and no later than 60 days after the last study visit. You can upload an IRB-approved version of the form to the ClinicalTrials.gov study record.**
- **Note that ClinicalTrials.gov does not accept non-English documents. Be sure to follow the Protocol Registration and Results System (PRS) instructions for document uploads.**Attend or utilize training (online training can be found at: https://clinicaltrials.gov/ct2/manage-recs/present#OnlinePresentations)
- Notify Office of Research Integrity and Assurance of receipt of any correspondence from an external agency regarding Food and Drug Administration Amendments Act of 2007 801 requirements, a ClinicalTrials.gov record, registration requirements or maintenance requirements within seven days of receipt

- Notify Office of Research Integrity and Assurance 30 days prior to an expected and 14 days following an unexpected Principal Investigator/Responsible Party personnel change. If required, complete the modification to the Principal Investigator/Responsible Party in the impacted ClinicalTrials.gov record 30 days prior to an expected and 14 days following an unexpected personnel change or work with Office of Research Integrity and Assurance in completing a record transfer

  References: Based on guidance from Indiana University's Quality Improvement Office "ClinicalTrials.gov Compliance Program" at: http://researchcompliance.iu.edu/qio/qio_ctgov.html.