Western Michigan University
Kalamazoo, MI 49008

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REGISTERING WITH CLINICALTRIALS.GOV PROCEDURE

1. Procedure

The Office for Research and Innovation (ORI) provides administration, monitoring, auditing, training and oversight to foster compliance with the Food and Drug Administration Amendments Act (FDAAA) and the National Institutes of Health (NIH).

The research community has the responsibility to create and maintain records in ClinicalTrials.gov while making determinations about registrations required to comply with International Committee of Medical Journal Editors (ICMJE) and the Center for Medicare and Medicaid Services (CMS). Additionally, the research community must notify ORI when there is an external agency notification and when a Principal Investigator/Responsible Party personnel change on a ClinicalTrials.gov record has occurred.

2. Registration

Principal Investigators are responsible to register clinical trials at a publicly-accessible registry, review the content of the information uploaded to the registry to verify completeness and accuracy, and ensure all data-entry activities occur within required time frames, as follows

2.1. FDAAA: The Principal Investigator must register and input required clinical trial information through the Protocol Registration System (PRS) at the ClinicalTrials.gov website no later than 21 days after enrollment of the first participant (https://www.clinicaltrials.gov/ct2/manage-recs/fdaaa).

2.2. NIH: The Principal Investigator must register and input required clinical trial information at the ClinicalTrials.gov website no later than 21 days after enrollment of the first participant (https://www.nih.gov/news-events/summary-hhs-nih-initiatives-enhance-availability-clinical-trial-information).

2.3. CMS: The Principal Investigator must register and input required clinical trial information and obtain an NCT# at the ClinicalTrials.gov website before submitting claims for such services to CMS.

2.4. ICMJE: The Principal Investigator must register with an ICMJE qualified publicly-accessible registry at or before the first patient is enrolled in the study as a condition for publication in a participating journal (http://www.icmje.org/about-icmje/faqs/clinical-trials-registration).

3. How to Register

An account must be created before you can log in to create your record within the PRS system. To create an account, email the Research Compliance Office at research-compliance@wmich.edu

The email must contain:

- Full name
- WMU email address
- Phone number

The Research Compliance Office will typically create your account within 3 business days. If there are others who will need to access the record, please provide their full name, WMU email and phone number so an account can be created for them, as well.

- Your account information and temporary password will be sent to the email address you provided.
- When you have received your account information and temporary password, navigate to http://register.clinicaltrials.gov and input your username and password. For "Organization," indicate WMU. Next, click "New Record" in the top left of the Home page in the Quick Link section. Then follow the prompts to enter your protocol information. You will automatically become the Record Owner for this protocol if you are the initial person to register the study.
- Please be aware that, when prompted to provide a "Unique Protocol ID" by the PRS system, the **IRB protocol number must be used.**

4. Updating Records

Principal Investigators are responsible to update clinical trial records registered at a publicly-accessible registry, review the record for accuracy and verify that data-entry occurs within the required time frames. FDAAA, NIH, CMS and ICMJE require the following:

4.1. Registration information must be updated no less than once every six months;

4.2. Recruitment/enrollment status changes (such as suspending recruitment or enrollment closed) must be input within 30 days of any change;

4.3. Trial closure (regardless of the reason for closure—completion, low enrollment, etc.) must be input within 30 days of trial closure.

4.4. For studies registered in ClinicalTrials.gov, the National Clinical Trial Number (NCT#) assigned by ClinicalTrials.gov must appear on all Continuing Reviews and Study Closure Reports submitted to the University's IRB. For studies registered elsewhere, the registration number assigned by that registry must appear. Failure to provide the applicable registration number will cause delays in the IRB review and approval process.

5. **Results Reporting**
   Principal investigators are responsible to report results of clinical trials registered at a publicly-accessible registry, review the record for accuracy and ensure data-entry occurs within required timeframes, as follows:
   - **5.1.** FDAAA: Aggregate results and adverse event reporting on ClinicalTrials.gov must occur within 12 months of the Primary (endpoint) Completion Date;
   - **5.2.** NIH: Aggregate results and adverse event reporting on ClinicalTrials.gov must occur within 12 months of the Primary (endpoint) Completion Date;
   - **5.3.** CMS: If the study qualifies as a clinical trial under FDAAA or NIH, results and event reporting must occur within 12 months of the Primary (endpoint) Completion Date. If the study does not qualify as a clinical trial under FDAAA or NIH, results reporting is voluntary.
   - **5.4.** ICMJE: If the study qualifies as a clinical trial under FDAAA or NIH, results and event reporting must occur within 12 months of the Primary (endpoint) Completion Date. If the study does not qualify as a clinical trial under FDAAA or NIH, results reporting is voluntary.
   - **5.5.** If a clinical trial is subject to registration requirements by more than one entity—FDAAA, NIH, CMS or ICMJE--it need only be registered once at ClinicalTrials.gov. Registration and results reporting must occur within the timeframe set by the applicable entities, whichever is sooner.

6. **Transfer of PI Responsibilities**
   - **6.1.** During the course of a clinical trial, the PI may relocate to another institution or otherwise be unavailable to fulfill his/her role responsibilities as PI. Before leaving the University, the PI must work with the Department Chair or other appropriate supervisor to ensure an orderly transition of his/her responsibilities to the new PI at the University or to initiate transfer of the registry account/record(s) and PI responsibilities to the new institution.
   - **6.2.** If a clinical trial remains at the University and there are continuing registry reporting obligations without a named PI, then the Department Chair or other appropriate supervisor must personally assume or appoint a PI to serve and assume any remaining reporting obligations.

Related Policies:
Policy No: 17-5.9 Registering with Clinicaltrials.Gov Policy
ClinicalTrials.gov Registration Policy
https://www.clinicaltrials.gov/

References:

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