ClinicalTrials.gov 101
https://research.weill.cornell.edu/clinicaltrialsgov

Office of Human Research Protection & Compliance
Melissa Epstein, PhD, MBE, CIP Executive Director

Major Entities Requiring Registration

<table>
<thead>
<tr>
<th>ENTITY</th>
<th>TYPE</th>
<th>Penalties</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA</td>
<td>Law</td>
<td>Civil monetary &amp; criminal</td>
</tr>
<tr>
<td>NIH</td>
<td>Policy</td>
<td>Lose funding</td>
</tr>
<tr>
<td>ICMJE</td>
<td>Policy</td>
<td>Reject publication</td>
</tr>
<tr>
<td>Your grantor?</td>
<td>Policy?</td>
<td>(See award terms)</td>
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**NOTE:** Each entity has its own definition of a clinical trial.
FDA Amendment Act (FDAAA) & Applicable Clinical Trials (ACTs)

1. Study is interventional
2. Intervention is an FDA-regulated product
   • Drug or Biologic
   • Medical Device
3. Study is NOT a phase 0, phase 1, or small device feasibility study
   • Phase 0 = exploratory, not designed to evaluate therapeutic or diagnostic intent
   • Phase 1 = safety/toxicity/max tolerated dose, etc.
   • Feasibility = testing prototype device, not evaluating health outcomes


NIH Policy

NIH-funded clinical trials must be registered
NIH definition is very broad
Results reporting is required
Includes ALL INTERVENTIONS and ALL PHASES
Follows FDAAA’s timelines and required info
Applicable to competing applications and contract proposals submitted on or after 1/18/2017
ICMJE Policy

Registration is required *before* enrollment of the 1st subject in order to publish in ICMJE member journals

https://www.icmje.org/journals-following-the-icmje-recommendations/

ALL interventions and ALL phases (same as NIH)

Require certain data elements:

- Official Title, IPD Data Sharing Statement (starting 1/2019), Study Officials

Results Reporting not required***

*** NOTE: If study is an ACT or is NIH funded, results are required.

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<tr>
<td><strong>Registration Timeline</strong></td>
<td>Prior to 1st subject’s enrollment</td>
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</tr>
<tr>
<td><strong>Type of Intervention</strong></td>
<td>FDA-regulated products</td>
<td>ANY</td>
<td>ANY</td>
</tr>
</tbody>
</table>
| **Study Phase** | Not phase 0
Not phase 1
Not device feasibility | ANY | ANY |
| **Results Reporting Required?** | YES with public upload of protocol and statistical analysis plan | YES with public upload of protocol and statistical analysis plan | NO |
| **Depends on Funding?** | NO | YES | NO |
Not all Studies Have to be Registered!

The following are not required:
• Observational studies
• Patient registries (except PCORI-funded)
• Expanded access (manufacturer’s responsibility)

NOTE: Voluntary registration or results submissions must follow all rules and timelines

Updates are Required!

Registration is NOT a “one-and-done”

Records must be updated periodically:
• At least once per year (Record Verification)
• Within 30 days of Recruitment Status changes
• Within 30 days of Completion Dates**
• Within 30 days of relevant amendment changes
• Results data are due within 12 months of completion date

Click the green "Entry Complete" button to progress the record to internal QC review after each update!

**Must list actual completion dates within 30 days of last day of data collection
Informed Consent Upload

A Revised Common Rule Requirement

Upload to ClinicalTrials.gov one unsigned Informed Consent Form used to enroll subjects if ALL of the following are true:

• Clinical trial supported by a Common Rule agency (e.g., NIH, DOD)
• Initial IRB approval occurred on or after January 21, 2019
• Study is closed to recruitment
• 60 or fewer days have passed since last study visit by ANY subject

HELP!

Tools and Resources

For consultations or training requests:
registerclinicaltrials@med.cornell.edu

• HELP link on every page
• DEFINITIONS link on every page
• SUPPORT MATERIALS
  • On the ClinicalTrials.gov public website:
    https://clinicaltrials.gov/ct2/manage-recs/resources
  • At WCM:
    https://research.weill.cornell.edu/clinicaltrialsgov
• TEMPLATES – use them!