

ClinicalTrials.gov Updates

Gabrielle Gaspard
Assistant Director
Human Research Compliance



Posting Requirements for ClinicalTrials.gov

Reporting Requirement	ICMJE Policy (effective in 2005)	FDAAA Final Rule Regulations (2007 and 2016)	NIH Policy (Issued in 2016)
Scope	Clinical Trials (any)	Applicable Clinical Trials	Clinical Trials NIH-Funded
What	Registration	Registration & Results Reporting	Registration & Results Reporting
Phase	All	Not Phase 1 or small feasibility device studies	All
Intervention Type	All	Drug, biologic, & device products regulated by the FDA	All (e.g., including behavioral interventions)
Funding Source	Any	Any	NIH
Initial Registration	Prior to enrollment of first participant	Not later than 21 days after enrollment of first participant	Not later than 21 days after enrollment of first participant
Results Reporting	N/A*	Within 12 months of primary completion date	Within 12 months of primary completion date
Enforcement	Refusal to publish	<ul style="list-style-type: none"> Criminal proceedings and civil penalties (up to \$10,000/day) <ul style="list-style-type: none"> Loss of HHS funding Noncompliant records Identified on ClinicalTrials.gov 	<ul style="list-style-type: none"> Suspension or termination of grant or contract funding Can be considered in future funding decisions Noncompliant records Identified on ClinicalTrials.gov





ClinicalTrials.gov Policy

- Enumerates regulation-based institutional expectations and resources with regard to registration and results postings, record updates, and more.
- Details noncompliance outcomes at the institutional and grant/federal level.
 - Civil penalties, loss of NIH funding; inability to publish in ICMJE journals; withholding of IRB approval for any study under a given Principal Investigator.
- Provides Dissemination Plan language for investigators submitting NIH FORM E.
- Provides a data sharing statement for manuscripts submitting to ICMJE journals that report results.
 - As of 7/1/18 manuscripts submitted to ICMJE journals that report results of clinical trials must contain a data sharing statement.



Dissemination Plan Template Language

- Investigators submitting NIH FORM E must utilize dissemination plan language provided by Human Research Compliance in their application.

The WCM Clinicaltrials.gov administrator will facilitate the Principal Investigator's dissemination of study results through ClinicalTrials.gov registration and reporting.

X (insert your name or PI designee) will be responsible for handling ClinicalTrials.gov requirements for this project according to WCM clinicaltrials.gov SOP. (insert your name or PI designee) will register the trial prior to enrolling the first subject. Once a record is established, (insert your name or PI designee) will confirm accuracy of record content; resolve problems; and maintain records including content update and modifications. (insert your name or PI designee) will also be responsible for results reporting and Adverse Events reporting at the conclusion of the project.

- ***Add specifics related to this trial.***



When is Registration Required under NIH Policy?

All 4 questions must be answered “yes” in order to meet the NIH definition of “clinical trial”

1. Does the study involve human participants?
2. Are the participants prospectively assigned to an intervention?
3. Is the study designed to evaluate the effect of the intervention on the participants?
4. Is the effect being evaluated a health-related biomedical or behavioral outcome?



NIH Definition

- ***Prospectively assigned*** refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects to one or more arms (e.g., intervention, placebo, or other control)
- ***Intervention*** is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints.
 - E.g., Drugs, small molecules, compounds, surgical techniques, delivery systems such as face-to-face interviews, strategies to change health-related behavior (e.g., diet, cognitive therapy), treatment strategies, prevention strategies, diagnostic strategies
- ***A health-related biomedical or behavioral outcome*** is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical or behavioral status or quality of life.
 - Positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression)
 - positive or negative changes to psychological or neurodevelopmental parameters (e.g, mood management intervention for smokers; reading comprehension and/or information retention)
 - Positive or negative changes to health-related behaviors or quality of life or disease processes



Qualtrics Decision Tool Now Available



ClinicalTrials.gov Decision Tool

- Navigate to “Which research studies need to be listed on ClinicalTrials.gov?” to access the link, or email us at registerclinicaltrials@med.cornell.edu.
- Note: Survey responses will be anonymously recorded to assess how often the research community is making use of this resource.
- If still unsure of whether your trial requires registration, consult Human Research Compliance at registerclinicaltrials@med.cornell.edu.
- <http://researchintegrity.weill.cornell.edu/clinicaltrialsdotgov.html/>



View From Website

 | Office of Research Integrity > Clinicaltrialsdotgov

Registering Studies and Submitting Results to ClinicalTrials.gov

The following guide is designed to help you navigate the ClinicalTrials.gov (i.e., PRS system) registration process. If you have any questions about the process of submitting information to ClinicalTrials.gov, please contact registerclinicaltrials@med.cornell.edu.

» What is ClinicalTrials.gov?

» Why should researchers post to ClinicalTrials.gov?

» Which research studies need to be listed on ClinicalTrials.gov?

Click to expand.

Differing and overlapping requirements are stipulated by several organizations and regulatory bodies. That is, the International Committee of Medical Journal Editors (ICMJE), HHS, and the NIH.

If your trial meets any of these requirements, it must be registered on ClinicalTrials.gov:

- The International Committee of Medical Journal Editors (ICMJE), requires the public registration of: “any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes” Registration is required as a condition of consideration for publication. Given that, WCM and ICMJE recommend that those who are uncertain of whether their trial requires posting should err on the side of registration if they wish to seek publication in an ICMJE journal. Please note that observational studies need not be posted.

- Health and Human Services (HHS), under the Final Rule, requires the public registration of clinical trials involving FDA-regulated products (excluding phase 1 trials or small feasibility device studies) Use the tool at https://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf to determine if you need to post according to the HHS Final Rule.

- National Institutes of Health (NIH) Policy requires the public registration of all clinical trials funded wholly or partially by NIH. To determine whether your NIH funded study is required to be posted to ClinicalTrials.gov, ask the following:

1. Does the study involve human participants?
2. Are the participants prospectively assigned to an intervention?
3. Is the study designed to evaluate the effect of the intervention on the participants?
4. Is the effect of being evaluated a health-related biomedical or behavioral outcome?

If the answers are all “yes,” then the study is a clinical trial that needs to be posted.

If any answers are “no,” the study is not a clinical trial that needs to be posted.

Use our decision tool, available [here](#), in order to determine whether your trial needs to be posted to ClinicalTrials.gov.





Weill Cornell Medicine

Does my trial need to be posted to ClinicalTrials.gov?

Please note that, if yours is a multi-center trial that is sponsored by another entity (e.g., non-NIH government funded, pharmaceutical, etc.), then that entity is responsible for creating the ClinicalTrials.gov record, with Weill Cornell listed as a sub-site under their main ClinicalTrials.gov record.

My research study is:

Interventional

Observational (assignment of medical intervention is not at the discretion of the investigator)

Next





Weill Cornell Medicine

Does my trial need to be posted to ClinicalTrials.gov?

Please note that, if yours is a multi-center trial that is sponsored by another entity (e.g., non-NIH government funded, pharmaceutical, etc..) then that entity is responsible for creating the ClinicalTrials.gov record, with Weill Cornell listed as a sub-site under their main ClinicalTrials.gov record.

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Interventional

Observational (assignment of medical intervention is not at the discretion of the investigator)

Next





Weill Cornell Medicine

Does my trial need to be posted to ClinicalTrials.gov?

Observational studies do not need to be posted on ClinicalTrials.gov.

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Next





Weill Cornell Medicine

Does my trial need to be posted to ClinicalTrials.gov?

Please note that, if yours is a multi-center trial that is sponsored by another entity (e.g., non-NIH government funded, pharmaceutical, etc.) then that entity is responsible for creating the ClinicalTrials.gov record, with Weill Cornell listed as a sub-site under their main ClinicalTrials.gov record.

My research study is:

Interventional

Observational (assignment of medical intervention is not at the discretion of the investigator)

Next





Weill Cornell Medicine

Does my trial need to be posted to ClinicalTrials.gov?

Does your study involve the evaluation of one or more FDA-regulated drug, biological, or device products?

Yes

No

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Weill Cornell Medicine

Does my trial need to be posted to ClinicalTrials.gov?

Is this study wholly or partially funded by NIH?

Yes

No

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Weill Cornell Medicine

Does my trial need to be posted to ClinicalTrials.gov?

Does your study assign participants, with or without comparison or control groups, to study the relationship between a health-related intervention and a health outcome?

Health-related interventions are those used to modify a biomedical or health-related outcome; examples include drugs, surgical procedures, devices, behavioral treatments, educational programs, dietary interventions, quality improvement interventions, and process-of-care changes.

Health outcomes are any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events.

Yes

No

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Weill Cornell Medicine

Does my trial need to be posted to ClinicalTrials.gov?

This study must be registered on ClinicalTrials.gov. The Principal Investigator must obtain an account by emailing registerclinicaltrials@med.cornell.edu with name, CWID and phone number to initiate the registration process.

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Registration Requirements



Requirements at the Time of Registration

- The protocol's IRB number must be used as the record's "Unique Protocol ID".
- If NIH funded, the "Secondary ID" must include the NIH Grant #.
- The "Responsible Party" in the "Sponsor/Collaborators" section must be listed as "Sponsor" – This will be automatically be selected.
- Sponsor must be "Weill Cornell Medicine of Cornell University".
- The PI or designee must be the record owner.
- All notes, warnings, and errors in the record need to be cleared to the best of the submitter's ability.
- The "Oversight" section must contain accurate information pertaining to the IRB as received at the time that CT.gov user access is granted.



Enter the IRB Protocol # as the Unique Protocol ID When Registering

[Help](#) [Definitions](#)

* Organization's Unique Protocol ID:

0100523140

* Brief Title:

[*] Acronym:
(if any)

If specified, will be included at end of Brief Title in parentheses.

* Study Type:

☒ Interventional (or clinical trial) — participants assigned to intervention(s) based on a protocol

☐ Observational participants not assigned to intervention(s) based on a protocol; typically in context of routine care

☐ Expanded Access availability of an experimental drug or device outside of a clinical trial protocol

Continue

Cancel

* Required

* § Required if Study Start Date is on or after January 18, 2017

[*] Conditionally required (see Definitions)

[Special Characters](#)



To Add NIH Grant #, Click Add a Secondary ID

[Help](#) [Definitions](#)


* Organization's Unique Protocol ID:

* Brief Title:

[*] Acronym:
(if any)
If specified, will be included at end of Brief Title in parentheses.

* § Official Title:

[*] Secondary IDs:
(if any)

 Click here.

* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)



Select US NIH Grant/Contract Award Number, then Click Add

Select Secondary ID Type:

1st click this

☒ US NIH Grant/Contract Award Number

☐ Other Grant/Funding Number

☐ Registry Identifier

☐ EudraCT Number

☐ Other Identifier

Then click this

Enter NIH Grant #, then Click Save

[Help](#) [Definitions](#)

* Organization's Unique Protocol ID:	<input type="text" value="0100523140"/>
* Brief Title:	<input type="text" value="A Phase II Trial to Test the Safety and Efficacy of SB234"/>
[*] Acronym: (if any)	<input type="text"/> <small>If specified, will be included at end of Brief Title in parentheses.</small>
* § Official Title:	<input type="text" value="A Phase II Trial to Test the Safety and Efficacy of SB234"/>
[*] Secondary IDs: (if any)	<div><div>US NIH Grant/Contract Award Number: <input type="text" value="R01GM987654"/></div><div>Examples: R01DA013131, U01HL066582, 5R01HL123451-01A2 Tip: Look up the grant/contract number using NIH RePORTER.</div></div> <div><input type="button" value="+ Add Secondary ID"/> <input type="button" value="Set ID Type"/> <input type="button" value="× Delete"/></div>

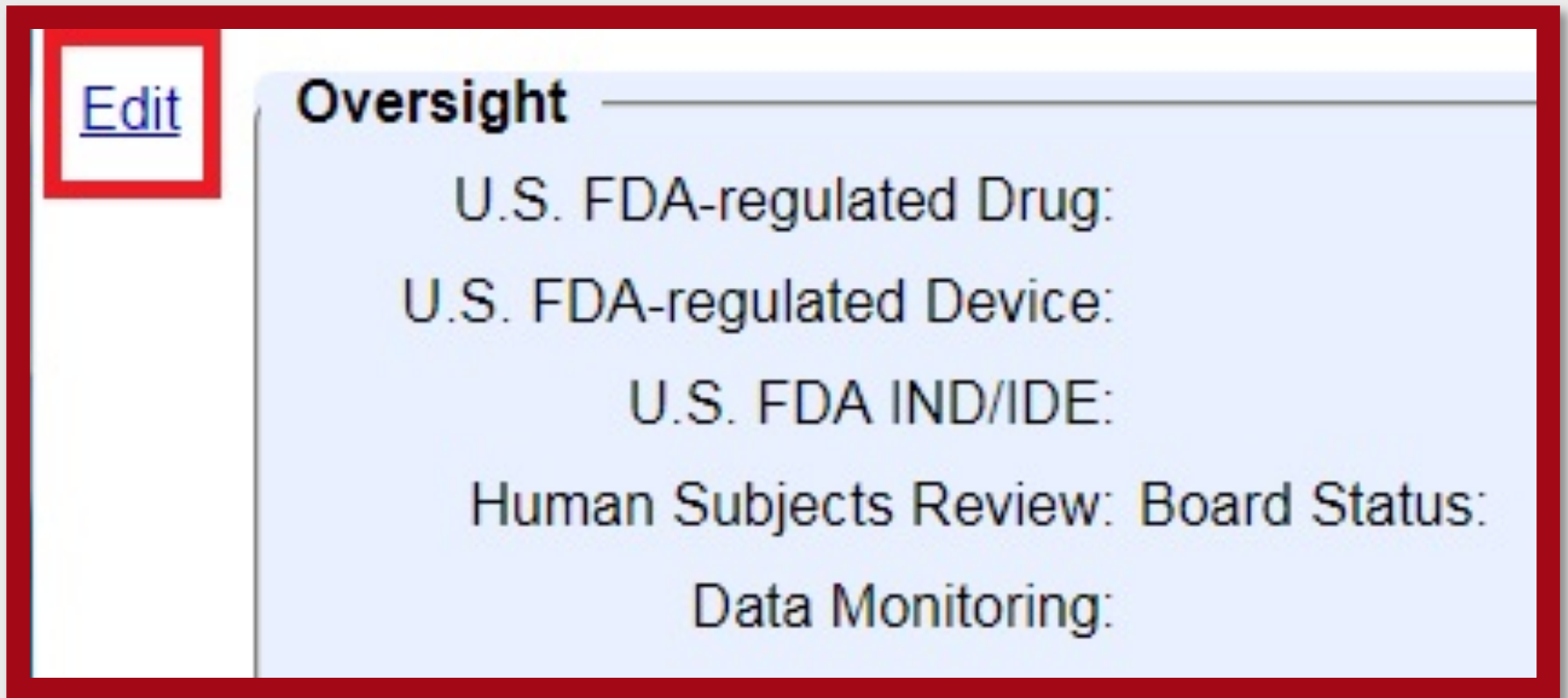
* Required

* § Required if Study Start Date is on or after January 18, 2017

[*] Conditionally required (see Definitions)



Click the “Edit” Link to Input IRB Information Into the Oversight Section



The screenshot shows a web interface with a red border. On the left, there is a white box containing a blue, underlined link labeled "Edit". To the right of this box is a light blue area titled "Oversight" in bold black text. Below the title, there are several lines of text, each followed by a colon, indicating input fields: "U.S. FDA-regulated Drug:", "U.S. FDA-regulated Device:", "U.S. FDA IND/IDE:", "Human Subjects Review: Board Status:", and "Data Monitoring:". The entire form is enclosed in a thick red rectangular frame.

[Edit](#)

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

U.S. FDA IND/IDE:

Human Subjects Review: Board Status:

Data Monitoring:

Enter IRB Information As Follows

* Human Subjects Protection Review:

Board Status: Submitted, pending ▼

The following information is required if the study meets each of these criteria: not required to be registered under 42 CFR Part 11, not funded in whole or in part by the U.S. government, and is not conducted under an IND or IDE. [This information is not made public.]

Board Name: Weill Cornell Medicine Institutional Review Board

Board Affiliation: Weill Cornell Medicine

Board Contact: Phone: 646-962-8200 Extension:

Email: irb@med.cornell.edu

Address: 1300 York Avenue, Box 89
New York, NY 10065



When to Update Your Record

UPDATE EVERY 12 MONTHS TO:	
<ul style="list-style-type: none">Update the Record Verification Date (The date the protocol information was last verified.)	<ul style="list-style-type: none">Review the Primary Completion Date and Study Completion Date, update if necessary
UPDATE WITHIN 30 DAYS OF A CHANGE TO:	
<ul style="list-style-type: none">Overall Recruitment StatusPrimary Completion DateStudy Start DateIntervention names (must update to a non-proprietary name within 30 days after a non-proprietary name is established)Availability of Expanded Access (if WCM is the manufacturer and sponsor of the ACT)Expanded Access Status and Expanded Access Type	<ul style="list-style-type: none">Individual Site StatusHuman Subjects Protection Review Board StatusStudy Completion DateResponsible Party and RP Contact InformationChanges in the protocol that are communicated to subjectsDevice Product Not Approved or Cleared by U.S. FDA (update within 15 days after change in approval or clearance status)



For Help: Contact

ClinicalTrials.gov

- Email register@clinicaltrials.gov with your NCT #
 - The PRS Team at ClinicalTrials.gov provides detailed assistance in response to targeted questions about filling out modules at the time of registration.
- Guidance

The “Help” dropdown at <http://register.clinicaltrials.gov> has resources for filling out each section:

 - Modules Guidance
 - Definitions for each data element in each section
 - Description of ClinicalTrials.gov review criteria for results

WCM ClinicalTrials.gov Administrator

- registerclinicaltrials@med.cornell.edu or call 646-962-4065
- <http://researchintegrity.weill.cornell.edu/clinicaltrialsdotgov.html>
- A WebEx session with the PRS Team at ClinicalTrials.gov can be arranged by the WCM ClinicalTrials.gov Administrator upon request





Weill Cornell Medicine