Weill Cornell Medicine

ClinicalTrials.gov Updates

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Human Research Compliance

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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	• Criminal proceedings and civil penalties (up to $10,000/day) • Loss of HHS funding • Noncompliant records Identified on ClinicalTrials.gov	• 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

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Qualtrics Decision Tool Now Available

ClinicalTrials.gov Decision Tool

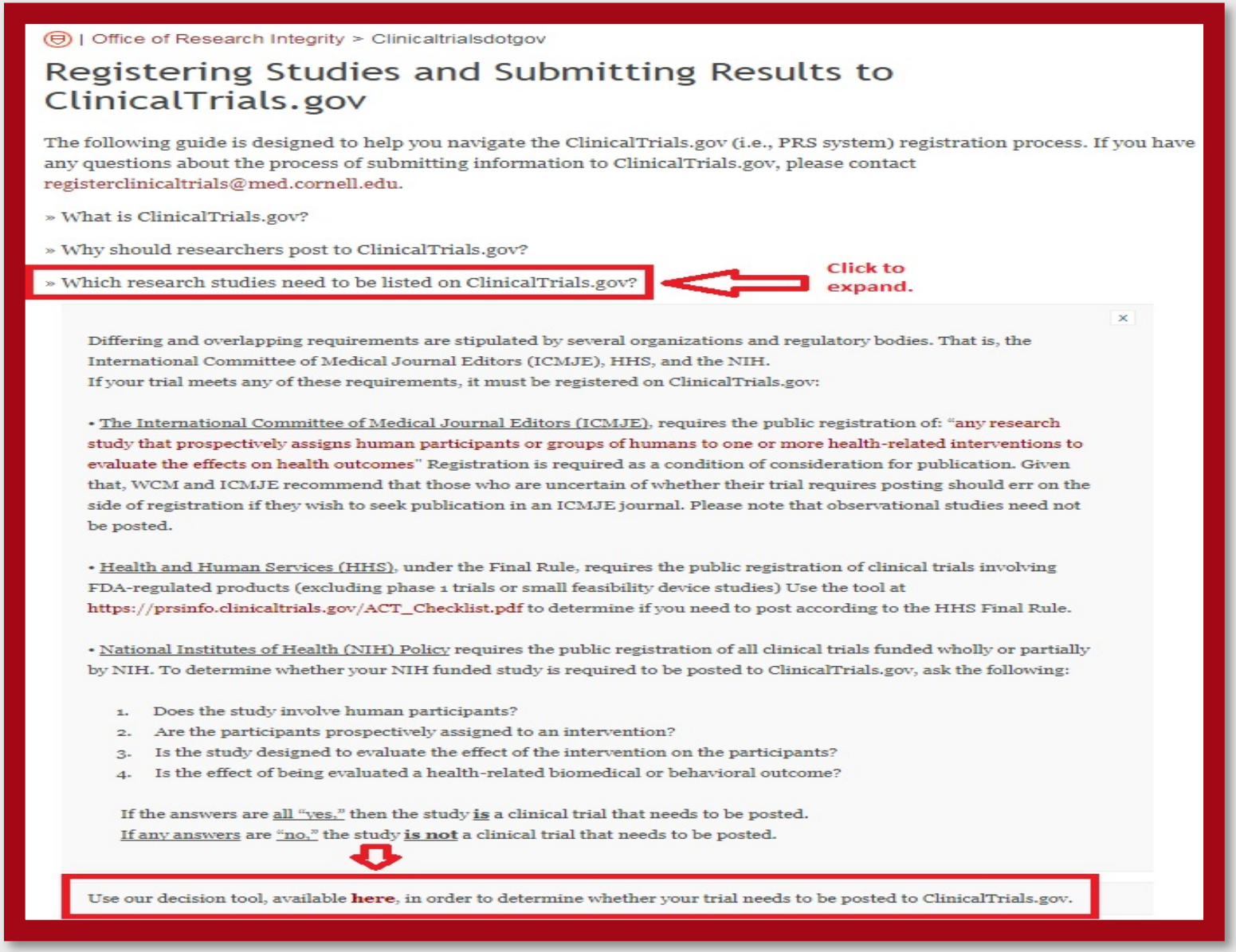
- Navigate to “Which research studies need to be listed on ClinicalTrials.gov?” to access the link, or email us at registerclinicaltrials@med.cornell.edu.

- 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



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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

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My research study is:

Interventional

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

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

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My research study is:

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

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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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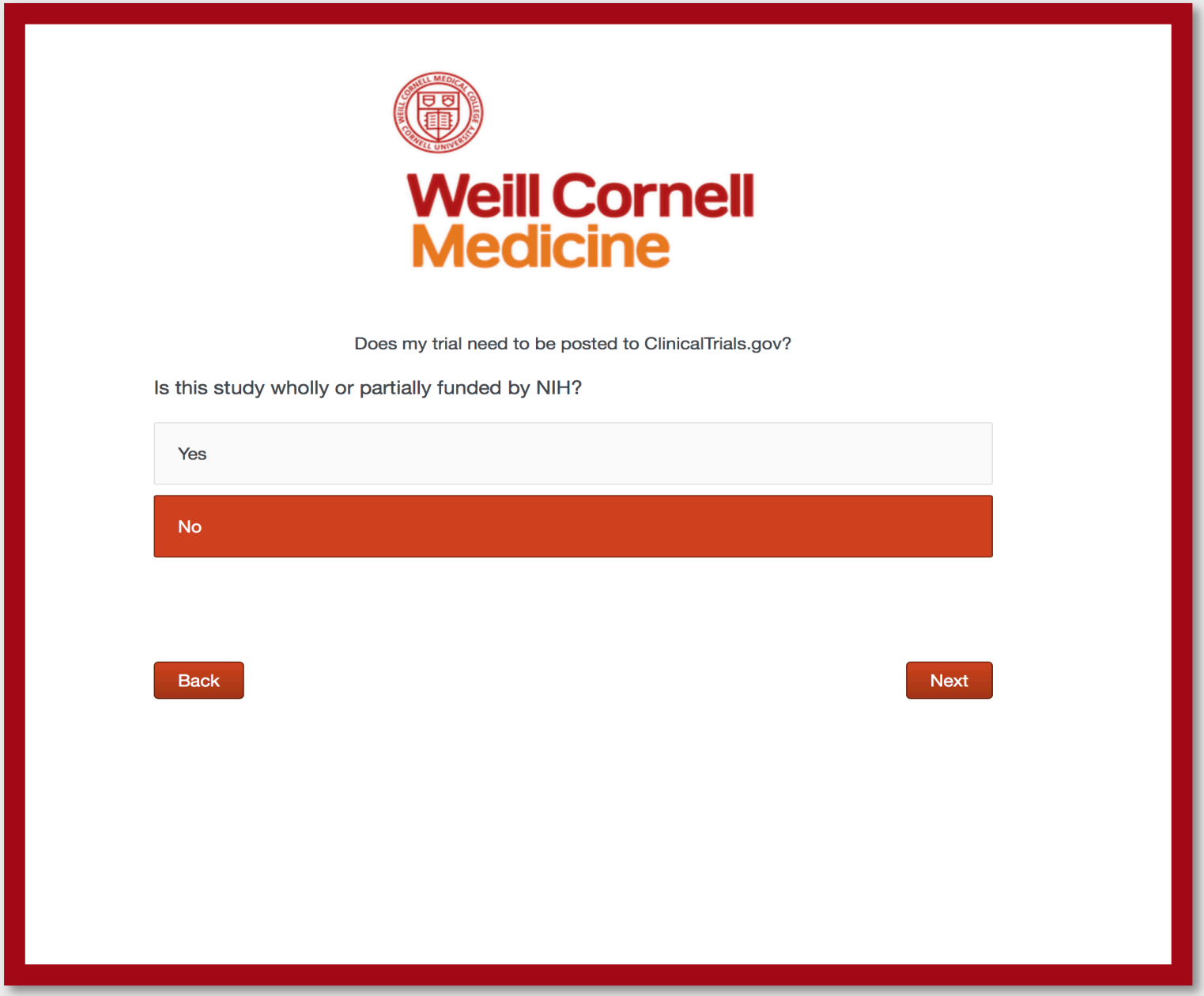
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Does my trial need to be posted to ClinicalTrials.gov?
Is this study wholly or partially funded by NIH?
Yes
No
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Does my trial need to be posted to ClinicalTrials.gov?

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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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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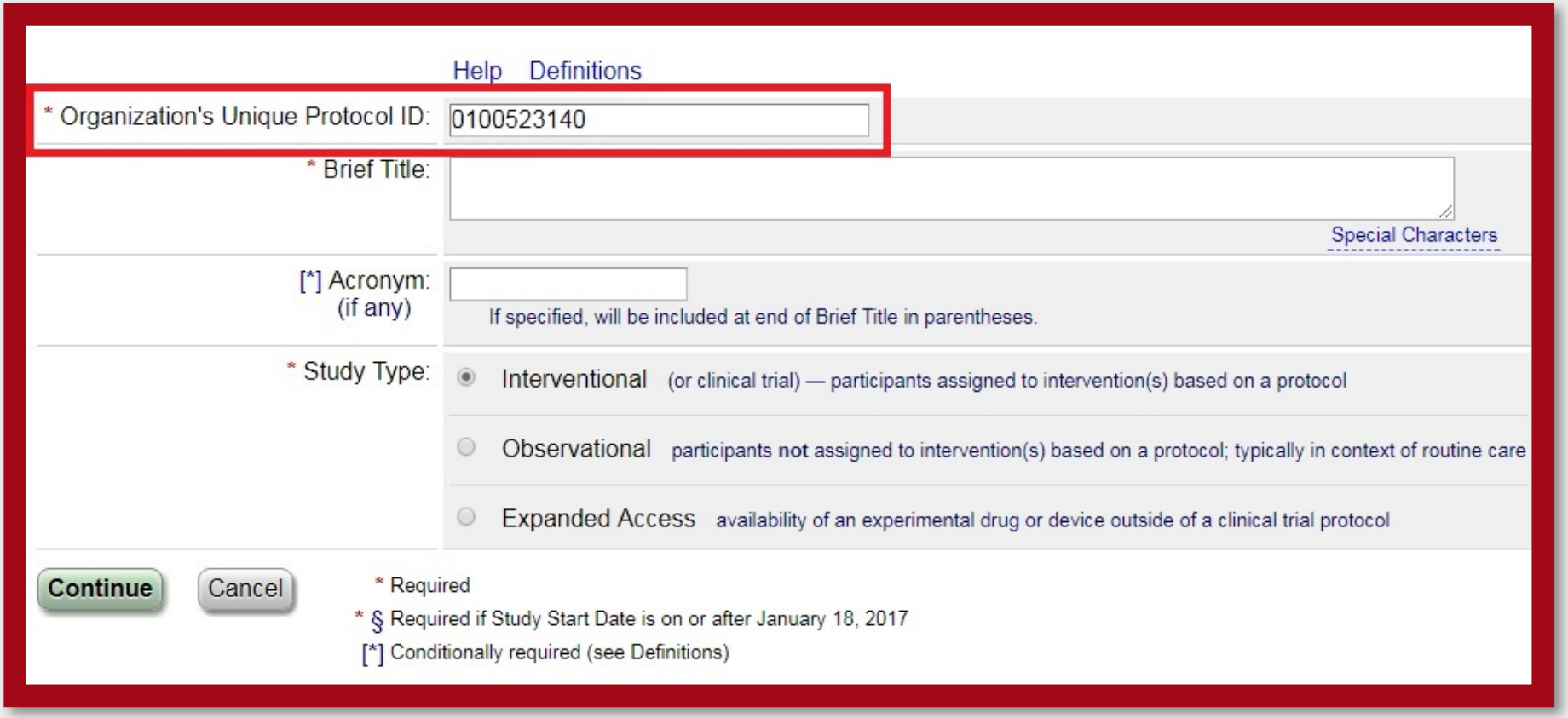
Registration Requirements

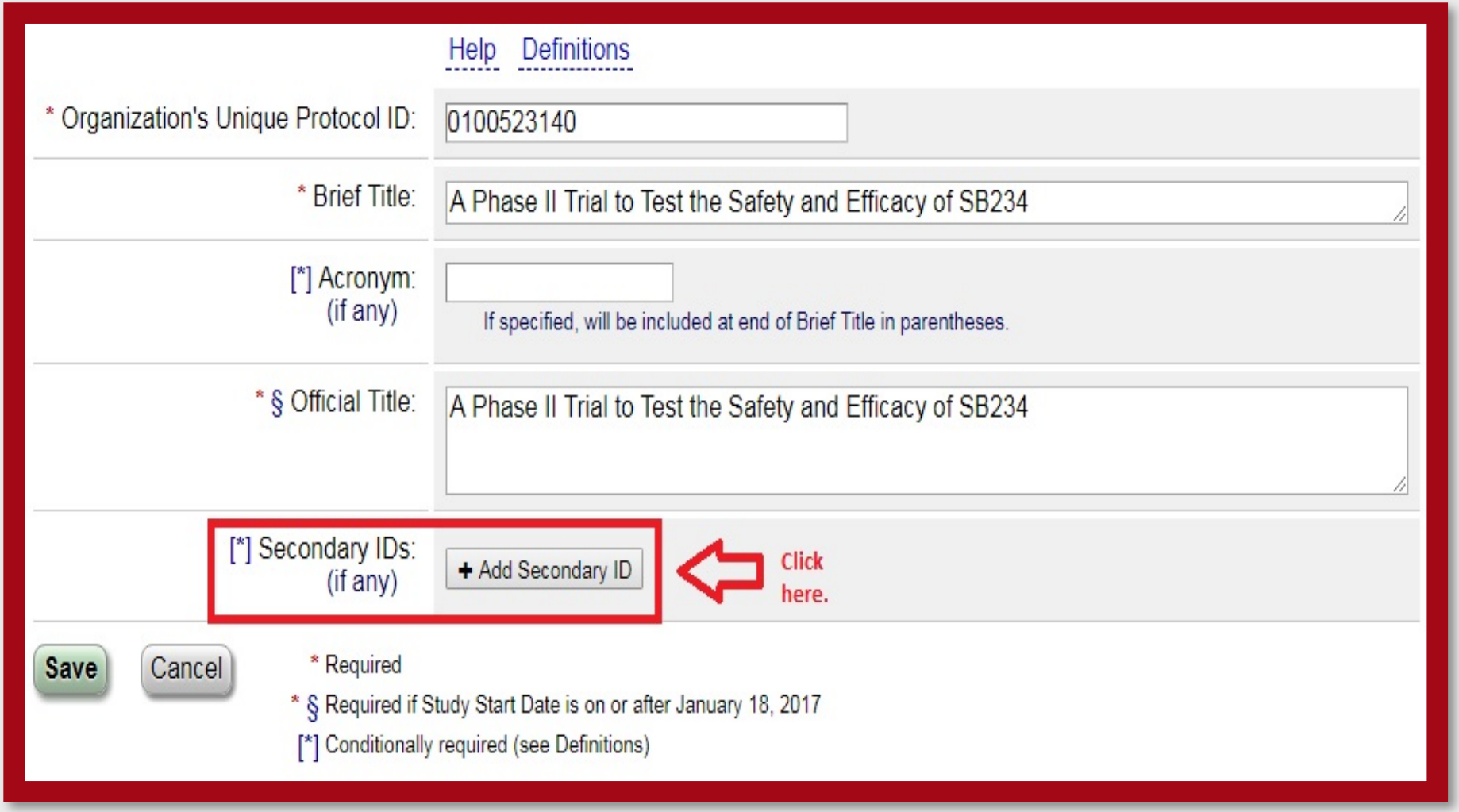
Requirements at the Time of Registration

- 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

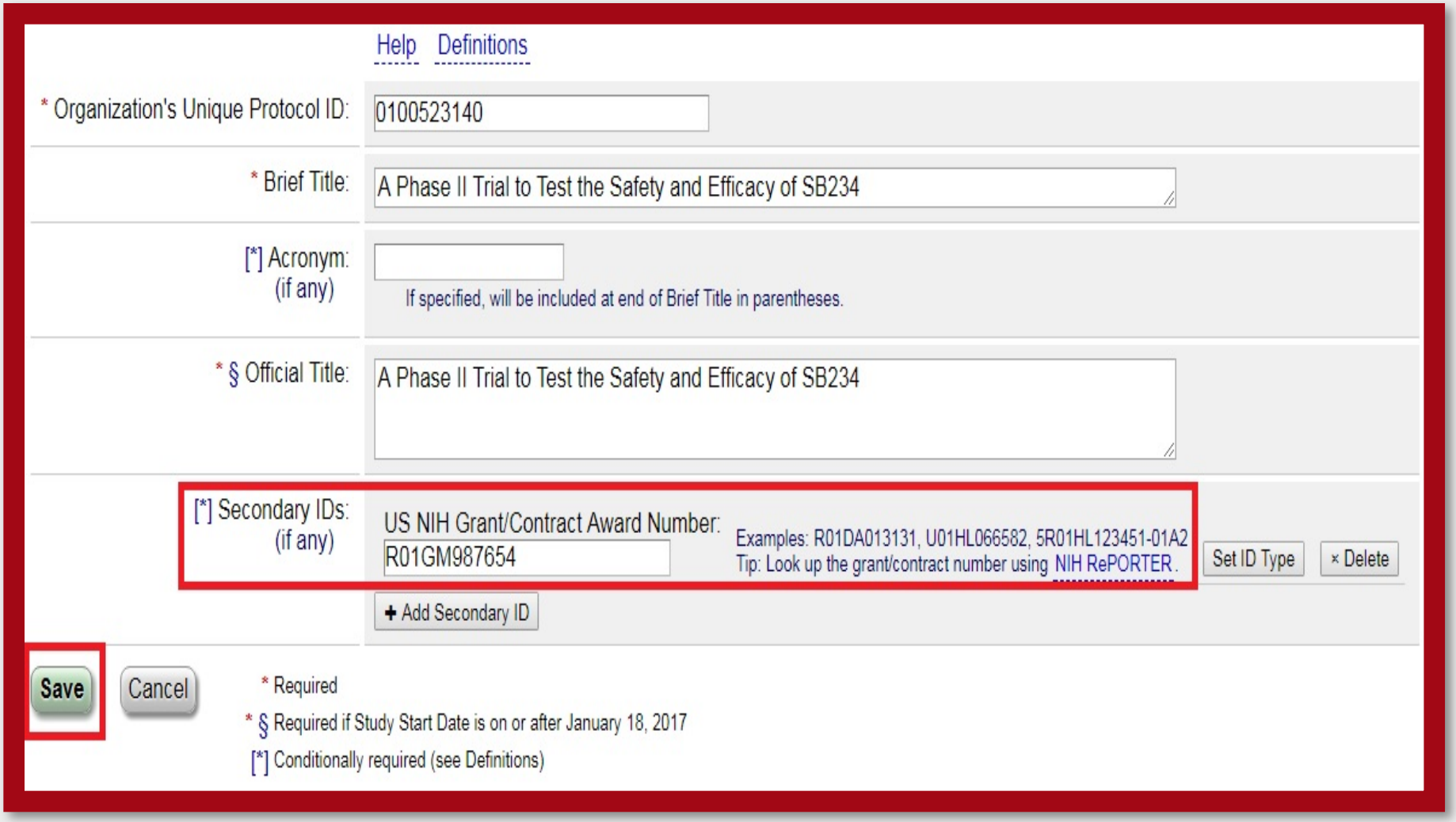


To Add NIH Grant #, Click Add a Secondary ID

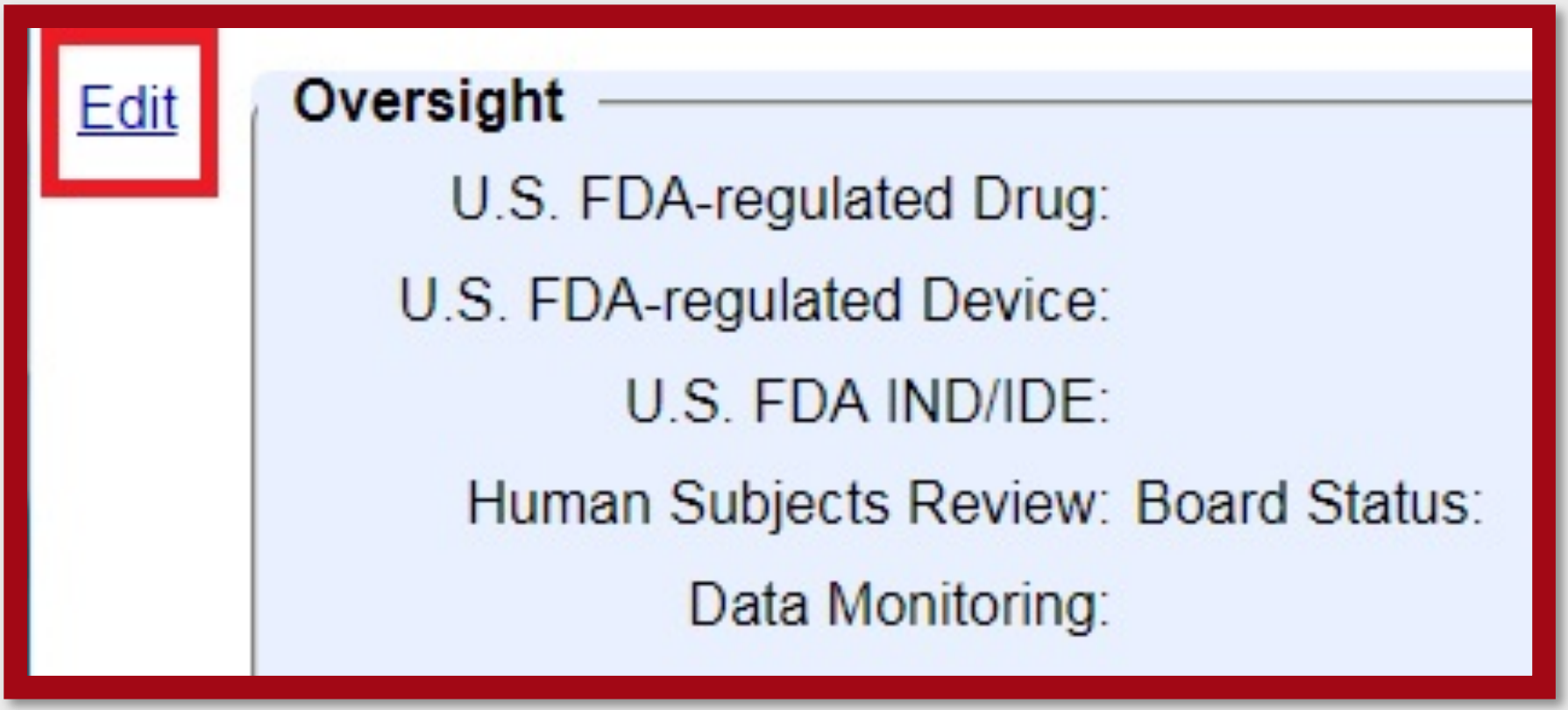


Select US NIH Grant/Contract Award Number, then Click Add

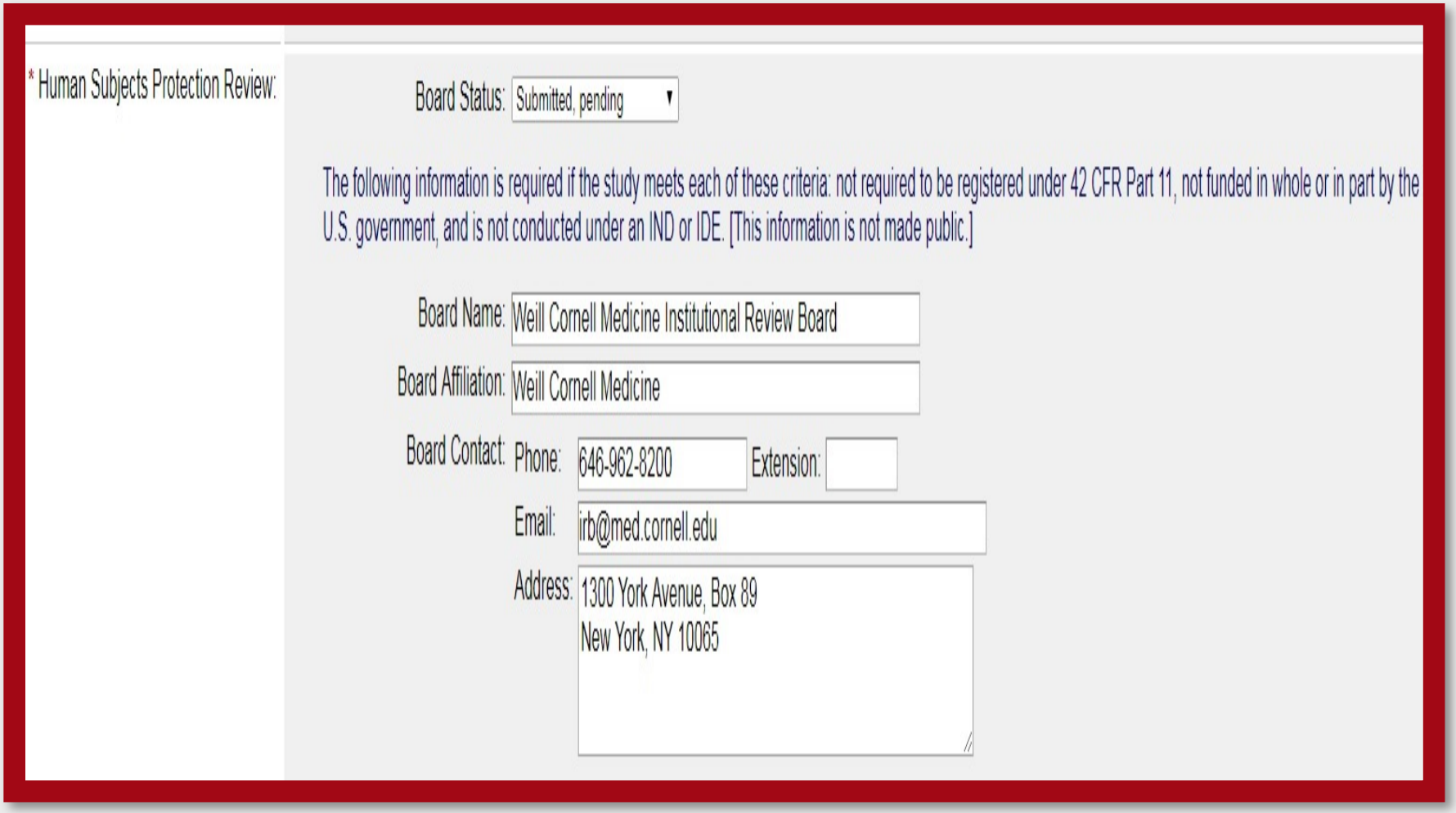
Enter NIH Grant #, then Click Save



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



Enter IRB Information As Follows



When to Update Your Record

UPDATE EVERY 12 MONTHS TO:	
• Update the Record Verification Date (The date the protocol information was last verified.)	• Review the Primary Completion Date and Study Completion Date, update if necessary
UPDATE WITHIN 30 DAYS OF A CHANGE TO:	
• Overall Recruitment Status • Primary Completion Date • Study Start Date • Intervention 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	• Individual Site Status • Human Subjects Protection Review Board Status • Study Completion Date • Responsible Party and RP Contact Information • Changes in the protocol that are communicated to subjects • Device 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

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