

Welcome to our March METS

- Please make sure your microphones are muted
- There will be a Q&A session after this presentation
 - Please reserve your questions until then

OR

- Put any/all questions in the chat and we will address them after the presentation
- This session will be recorded



Submitting an IRB Application

A Step-by-Step Guide



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

<https://research.weill.cornell.edu/irb>

Institutional Review Board ▶

Home ▶	IRB Members Portal ▶	Research Team Resources ▶	Human Research Compliance ▶	Research Participant Resources ▶	Educational Resources ▶	Policies & Procedures ▶	Glossary, Terms, & FAQs ▶	IRB Staff Portal ▶
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Research Team Resources

This section is designed to provide you with the basic keys to help get your IRB submission started. Familiarizing yourself with these basics will ultimately save you time and reduce effort as you continue on with your study.

Getting Started

If you are wondering if you have to submit your study to the IRB for review, or if you need assistance in the preparation of your submission, this page is designed to help get you started. Familiarizing yourself with the points below will be helpful in facilitating the submission process.

Research Team Resources ▶

- [Research Team Training & Education](#)
- [Submitting to the IRB](#)
- [Project Guidance](#)

For an overview of the WCM IRB, please join us at next month's METS



Weill Cornell Medicine

Institutional Review Board ▶

About Us ▶	Human Research Compliance ▶	Research Team Resources ▶	Research Participant Resources ▶	Educational Resources ▶	Forms, Templates, & Guidance ▶	Policies & Procedures ▶	Glossary, FAQs, & Medical Terms ▶	IRB Member Portal ▶	Staff Portal ▶
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Human Research Compliance Monthly Education and Training Series (HRC METS)

The Office of Human Research Compliance is pleased to offer a monthly education and training series for our stakeholders. The goal of this program is to provide a rotating series of sessions that will assist you in making sure your team receives the information they need to navigate the IRB process. Sessions are scheduled on a Thursday in the middle of each month, and registration is required to attend.

We hope you can join us for our next session:

Submitting an IRB Application: A Step-by-Step Guide

Thursday, March 16, 2023
11:00am until 12noon

The focus of this session is to provide a step-by-step walk through of the IRB submission process, beginning with accessing the Weill Research Gateway-Human Subjects (WRG-HS) and Oncore, through the certification of your application. We will discuss the new IRB Review Application Forms, the required Key Information Section for Informed

Educational Resources ▶

- [HRC METS](#)
- [CITI Access Information](#)
- [HRC Training and Educational Videos](#)

Helpful Links

- [Office Directory](#)
- [IRB Member Resources](#)
- [Research Team Resources](#)
- [Research Participant Resources](#)
- [Forms, Templates & Guidance](#)
- [Single IRB](#)

How Do I Get Started?



First Things First: Access to WRG-HS & -CT

- WRG Access Form submitted by Department DA
- Modules to have access to:
 - Human Subjects (HS)
 - Clinical Trials (CT)
- Select **add** for both **regulatory coordinator** and **clinical research associate**

WRG Departmental Access Request Form

Employee Name: Employee CWID:

This form is to request access and training to the Weill Research Gateway (WRG). Select "Add" or "Remove" next to each security position to request an update for the noted user. Once completed, submit this form to the Department Administrator (DA) or Department Designee (DD) within your department. The DA or DD will need to submit this form in the Weill Business Gateway (WBG) under the System Access tab. **All training must be complete prior to granting access.** RAC Support will notify the user that their System Access request is complete. For information on how to submit a System Access request, please reference the following Help File: https://helpfiles.med.cornell.edu/ram/folder-3_11_222112?mode=EU

Sponsored Programs/Proposals Access – (pages 1 and 2)
Clinical Trials/Human Subjects Access – (pages 3)
Research Safety Access (Environmental Health & Safety) – (page 4)

SPONSORED PROGRAMS/PROPOSALS ACCESS

Proposal Administrator
Proposal Administrator provides access to the Proposal Development module without budget permissions, allowing a user to initiate a submission, complete all sections except the budget, and submit for route. Common role pairing: PI Delegate; PI Budget Preparer. Prerequisite for access: Basics Training

Indicate "Add" or "Remove"

PI Budget Preparer
PI Budget Preparer allows one to edit budgets of proposal for which he/she is listed as the Principal Investigator. Prerequisites for access: Basics Training and Budget Training

Indicate "Add" or "Remove"

Budget Administrator
Budget Administrator provides access to the Proposal Development module with budget permissions and visibility, allowing user to initiate a submission, complete all sections, and submit for route. This role is inclusive of the Proposal Administrator functions. Prerequisites for access: Basics Training and Budget Training

Indicate the required department

Department Department

CLINICAL TRIALS/HUMAN SUBJECTS

Human Subjects Research Responsibilities

Select the tasks that the employee will be performing in Human Subjects and/or Clinical Trials: (checkboxes or indicated an "add/delete" next to each selection.

Regulatory Coordinator

- Creating, editing or submitting Institutional Review Board (IRB) applications
- Creating, editing or submitting Protocol Review and Monitoring Committee (PRMC)

Clinical Research Associate

- Enrollment of participants/subjects onto studies
- Management of participant/subject data

Prerequisite for access: Study Activation and/or Subjects Enrollment Training

Indicate "Add" or "Remove"

Regulatory Coordinator

Clinical Research Associate:

Personnel salaries on budgets.

ct

ct

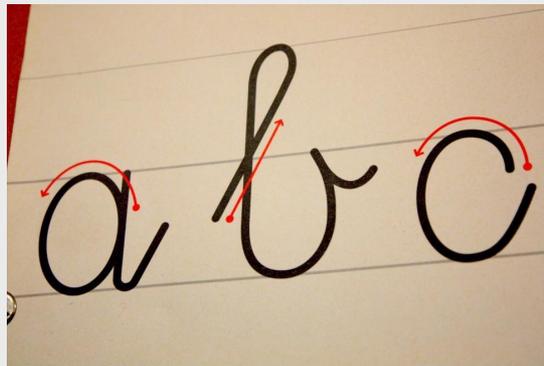
ct

Page 1



Submitting to the WCM IRB

1. Personnel training verification
2. Conflict of Interest (COI) certification
3. Submission Documents
 - ✓ Protocol template
 - ✓ Initial Review Application
 - ✓ Supplemental Forms
 - ✓ Consent
 - ✓ Other Documents
4. Intake form
5. PRMC review or its equivalent
6. IRB application
7. Personnel approval and certification



1. Confirm Personnel Training

- **Key Personnel = Any individual engaged in research with human subjects**
- **CITI Modules:**
 - Biomedical Research Investigators and Key Personnel (3 yrs)
 - Good Clinical Practice (3 yrs)
 - Conflict of Interest (4 yrs)

See Training and Education requirements on the [Research Team Training & Education](#) page of IRB site

Research Team Training & Education

Education is a key component in the protection of human subjects in research. It is essential that **all key personnel** engaged in human subjects research understand the regulations that govern research that involve the use of information and specimens obtained from human subjects. All WCM investigators, research coordinators, and research staff who are engaged in research involving living human subjects, human tissue samples, or identifiable private information must complete the required Human Subjects Protection (HSP) training mandated by the terms of our Federal Wide Assurance before they can submit their protocols in WRG-HS.

- Please refer to the [CITI Access Information Page](#) for instructions on how to access the required courses
- To log into CITI directly, click [here](#)

What constitutes "Key Personnel"?	+
Human Subjects Protection Training	+
Conflict of Interest Training	+
Good Clinical Practice (GCP) Education	+

The WCM IRB will not issue approval for a research protocol if any key personnel has not satisfied the education requirement.

2. Confirm COI Certifications

- All personnel listed on the IRB application must have completed Conflicts Survey on file
 - Including those with no interests to disclose
- COI disclosures must be submitted when additional investigators join a study
- Minimum once annually
- Changes must be reported within 30 days

Find the “COI Annual Disclosure Survey” button on the Conflicts of Interest website

Conflicts of Interest ▶

About Us Policies, Guidelines & Forms External Activities Open Payment Program Glossary, FAQs, & Responsible Parties WCM-Qatar

At Weill Cornell Medicine (WCM), we recognize that conflicts of interest (COI) and commitment can arise from our research endeavors. It is our mission to understand and assess how the many facets of our employees, students, and trainees' lives - including their professional activities and personal interests - may interact with their engagement in research and clinical work here at WCM.

We are also committed to our continual monitoring of how WCM's various interests - including financial commitments, intellectual properties, and personal engagement of our officials - may give rise to institutional conflicts of interest related to our research and other activities.

The WCM Conflict of Interest Office is responsible for implementing the policies and processes related to these areas, along with partnering offices and committees across the Institution. The Office seeks to be a resource to all individuals and units across campus as they navigate multiple responsibilities and activities, particularly related to sponsored and human subjects research. The goal is to manage all relationships appropriately, pursuant to the applicable institutional policies.

COI Office ▶

- About Us
- Office Directory
- News & Announcements
- COI Annual Disclosure Survey

Helpful Links

- Office Directory
- COI Annual Disclosure Survey
- Policies, Guidelines, and Forms
- Consulting & Other Activities

Need help?
Call the COI Hotline
(646) 962-8200
Option 5

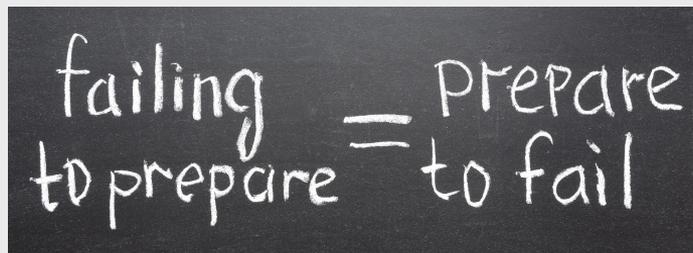
Office of the Research Dean
Weill Cornell Medicine
1300 York Ave.
New York, NY 10065
ResearchDean@med.cornell.edu

Where would you like to go today?

- COI Annual Disclosure Survey
- Announcements
- Policies, Guidelines, & Forms
- COI Training & Education
- Start-up Activities
- External Activities
- WCM-Qatar COI
- FAQs

3. Prepare Submission Documents

- ✓ JCTO Protocol Template, if applicable
- ✓ IRB Review Application
- ✓ Supplemental Forms
- ✓ WCM Informed Consent Form
- ✓ Other documents



failing = prepare
to prepare = to fail



JCTO Protocol Templates

TITLE:

IRB Protocol #:
Version Date:
Funding Source(s): (if applicable)

Principal Investigator: Name
 Address
 Telephone
 Fax
 E-mail address

Co-Investigators: Name
 Address
 Telephone
 Fax
 E-mail address

 Name
 Address
 Telephone
 Fax
 E-mail address

Statistician:
(if applicable)
Name
Address
Telephone
Fax
E-mail address

Participating Sites: List all participating sites (include site name, PI, and contact information).

Joint Clinical Trials Office (JCTO) Protocol Templates:

- Observational Correlative Studies
- Therapeutic Studies
- Tissue Use/Chart Reviews

For questions about these templates, please contact the JCTO or visit their website: <https://jcto.weill.cornell.edu/>





IRB Review Application (IRA)

- Streamlines/focuses the collection of all IRB-required ethical and regulatory information
- Reduces duplicative information found in previous WRG-HS application
- Available on WCM IRB website for easier updates with no impact in WRG
- Versions:
 - Biomedical IRA
 - Biorepository IRA
 - SBER and Records IRA



Use this IRB Review Application if you have completed the [Therapeutic Studies JCTO Protocol template](#) and/or have a study which will use a device/drug or implement a clinical trial. If you are initiating a biorepository, complete the IRB Review Application – Biorepository. Please delete the instructions and sample text after you complete each section. Do not delete the section headings; if the heading does not relate to your research insert N/A.

First time users of this form are encouraged to set-up a walkthrough [consultation with the IRB](#). Contact irb@med.cornell.edu or trpc@med.cornell.edu with any questions.

You may also view the [Therapeutic JCTO Protocol Guidance Document](#) for additional information to assist with completing this application.

Title:	
Version Date:	
Funding Source(s):	
Principal Investigator:	
Study Sponsor:	
IND/IDE Number:	
Participating Sites/Collaborators:	
IRB (WRG number):	

Background/Purpose/Study Aims:

Briefly and clearly state the overall purpose of the study in a few sentences.

Provide a non-technical explanation in lay terms to justify why the research needs to be done and what its relevance will be. Describe the relevant prior scientific or scholarly literature and gaps in current knowledge. Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge. If applicable, describe any relevant preliminary data. Include references at the end of this protocol.

List research objectives, specific aims, and state the hypotheses to be tested.

Describe the primary and secondary endpoints, including safety endpoints.

Study Population:

Describe the participant population such as age range, gender, and ethnic background. List the inclusion/exclusion criteria (characteristics that people must have to be included in or excluded from participating in the research). Justify the reasons for exclusions. Note that if you have inclusion/exclusion criteria, please explain the screening process in the Screening Procedures section. If your study is aimed at addressing issues that affect a certain community or group, set-up a [consultation with the IRB](#) to review what is required. The IRB will work with you to confirm if the target community needs to be involved in the design and conduct of the study.



Supplemental Forms

The term "drug product" references investigational and approved drugs (including radiolabeled), biological products, and dietary supplements. For each drug product used for this research, add product labeling, package insert, Investigator Brochure and clinical protocol (as applicable).

Submit a copy of all FDA or sponsor documents related to this drug including Investigational New Drug (IND) documentation.

In the protocol, address the risks associated with the use of the drug and how those risks will be minimized. Note that the FDA considers epinephrine alkaloids to pose a significant and unreasonable risk and research involving these drugs must be justified. Include in the protocol and consent form (or other document as appropriate) how participants will be instructed in the use of the drug product. If the drug is a radiolabeled, add approval from institutional radiation committee. If the drug is considered a biological product, add approval from institutional biosafety committee. Drug products to be used solely in vitro, must comply with shipping labels requirements (see [21 CFR 312.150](#)). The PI must adhere to requirements at [21 CFR 312 Subpart D](#).

1. Drug Information.

Drug name:

Drug manufacturer:

Product formulation:

Dose and strength:

Route of administration:

Is the drug a controlled substance? Note: drugs subject to the Controlled Substances Act must be stored in a securely locked, substantially constructed cabinet or enclosure.

Yes, classification:

No.

Is the drug investigational or FDA approved?

Investigational

FDA approved

2. Describe the procedures for dispensing the drug including who will dispense and how it will be dispensed.

If someone other than the PI or a pharmacist is dispensing the drug, describe how the PI will train and evaluate to ensure that it is provided as required for the research.

3. Describe where the drug will be stored and how it will be secured (including limited access):

4. Specify who is prescribing the drug, including contact information:

5. Describe the plan for unused drug including skipped doses as well as following discontinuation, termination, suspension, or completion of the investigation:

6. Does the drug have an IND? Yes No

7. Are you requesting an IND exemption?

Yes. Answer the following questions.

No. Skip the following questions.

For each device used for this research, complete one form and add device labeling, package insert, instruction manual, Investigator Brochure and clinical protocol (as applicable). Submit a copy of all FDA or sponsor documents related to this drug including Investigational Device Exemption (IDE) documentation and device risk determinations. In the protocol, include the risks associated with the use of the device and how those risks will be minimized. Also, address how participants will be instructed in the use of the device and upload corresponding documents.

All clinical investigations of devices must have an approved IDE or be exempt from the IDE regulations. Investigations that are exempted from 21 CFR 812 are described in [§ 812.2\(c\)](#) of the IDE regulations. Significant Risk (SR) device projects are governed by the Investigational Device Exemptions (IDE) regulations ([21 CFR Part 812](#)). Non-Significant Risk (NSR) device projects have fewer regulatory controls than SR projects and are governed by the abbreviated requirements (21 CFR [812.2\(b\)](#)). The major differences are in the approval process and in the record keeping and reporting requirements. If a researcher proposes the initiation of a claimed NSR device project to the IRB, and if the IRB agrees that the device project is NSR and approves the project, the project may begin without submission of an IDE application to FDA.

Exempt and abbreviated IDE requirements do not in any way exempt you from complying with FDA requirements including the requirements for informed consent and initial and continuing review conducted by the IRB. You must monitor the research and report to the IRB and FDA noncompliance, adverse events, and unanticipated problems. If abbreviated IDE requirements apply, you will maintain records and reporting according to the requirements at 21 CFR [812.140](#) and [150](#). You will not promote or test market an investigational device until after FDA has approved the device for commercial distribution; charge participants for a device beyond recovering costs; unduly prolong the research; nor represent that an investigational device is safe or effective for the purposes for which it is being investigated.

1. Device Information

Device name:

Device model number:

Device manufacturer:

If there is no brochure, describe the device (this can include important components, properties, and/or principles of operation):

Is the device FDA approved for the proposed use? Yes No

Does the device have an Investigational Device Exemption (IDE)?

Yes, specify IDE #: No

2. Describe how the device is stored securely:

3. Describe how the device is labeled (note that the device must be labeled as an investigational device, see FDA guidance):

4. Describe who has access to the device:

5. Will participants be charged for the device? Yes No

6. Describe how will the device be provided or delivered to participants:

7. Describe how will unused devices be disposed of following discontinuation, termination, suspension, or completion of the investigation, include details if the device is surgically implanted:

The term, "specimen," applies to blood, other bodily fluids, excreta, and tissues. When more than one type will be collected, clarify which type is being addressed for a specific item. When applicable, upload material transfer agreements and other supporting documentation.

1. What types of specimens will be collected for this research? Check all that apply.

Blood and blood fractions; plasma, serum, buffy coat, red blood cells

Bodily products; teeth, hair, nail clippings

Bodily fluids or excreta; sweat, urine, feces

Saliva and buccal cell

Sub-cellular components such as DNA or RNA

Cells or tissues from any part of the body

Other, specify:

2. Are you drawing blood?

Yes, answer the following questions.

No, go to the next question.

Will participants be healthy, nonpregnant adults who weigh at least 110 pounds/ 49.9 kg and will the amount drawn be no more than 550 ml in 8 weeks and collected no more often than twice per week?

Yes No

If participants will be unhealthy or pregnant adults, or children, will the amount drawn be less than 50 ml or 3 ml per kg in 8 weeks and will collection occur no more often than twice per week?

Yes No

3. Will specimen samples contain Personally Identifiable Information (PII)?

Yes No

4. How will specimens be obtained? Check all that apply:

Blood, by finger, ear, or heel stick

Blood, by venipuncture

Biopsy

From samples obtained for diagnostic or therapeutic procedures

Hair or nail clippings in non-disturbing manner

Deciduous teeth at time of extraction or during required extraction

Permanent teeth during required extraction

Sweat or other excreta or external secretions

Uncannulated saliva

Placenta removed at delivery

Amniotic fluid obtained when membrane ruptures before or during labor

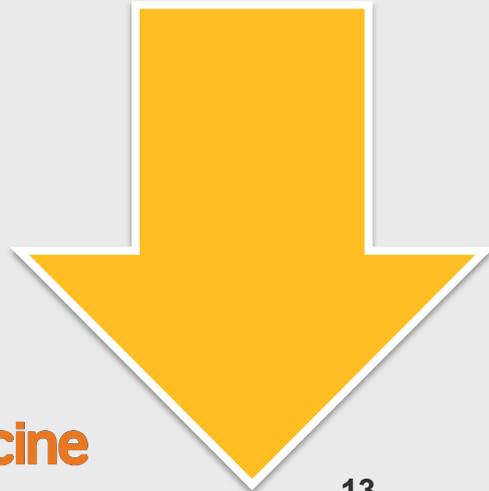


How does the IRA streamline the submission process?



IRAs will now account for information about:

- General Study Design
- Retrospective and/or Prospective
- Cost, Reimbursement, or Compensation
- Risks and Risk Minimization
- Benefits
- Privacy and Confidentiality
- Informed Consent, Minor Assent, and Parental/Guardian Permission



WRG-HS's initial application will now ONLY collect:

- Personnel (WCM/NYP)
- Non-Affiliated (Non-WCM/NYP) Personnel
- Review & Approval
- Sponsors and Entities
- Attachments



Institutional Review Board



Forms, Templates, & Guidance

*This page is being continually updated; please check back often!

Forms & Applications

IRB Review Application (IRA) Forms

For all **new initial applications** submitted to WRG-HS, a supplemental IRB Review Application (IRA) must be attached. Please select and fill in the applicable IRB Review Application (IRA) linked below. Once complete, please upload it to WRG as part of your new submission.

- [Biomedical IRA](#): Use this IRB Review Application if you have completed the Therapeutic Studies JCTO Protocol template and/or have a study which will use a device/drug or implement a clinical trial.
- [Biorepository IRA](#): This IRB Review Application template is **only** to be used for the establishment of a biorepository (storage and maintenance) for potential future use, not testing and research.
- [Social-Behavioral and Educational Research \(SBER\) and Records IRA](#): Use this IRB Review Application if you have completed the Non-Therapeutic Studies or Tissue Use/Chart Review JSTO template, the Education Protocol Template and/or have a study which will use conduct social, behavioral, or educational research.

Supplemental Forms

- [Drug Form](#): Used for any study involving drugs/dietary supplements
- [Device Form](#): Used for any study involving medical devices (as [defined by the FDA](#))
- [Specimen Form](#): Used for any study collecting or using Human biological specimens for research (e.g., organ tissue, plasma, urine, feces, cells). This may include specimens collected as part of routine care for use as part of the research. This includes medical waste.





WCM Informed Consent Form

- **WCM Template: "WCM Informed Consent Template (with Key Information section)"**

- available on the IRB web page: Forms, Templates, & Guidance

Weill Cornell Medicine Institutional Review Board
 Research Integrity
 Human Research Compliance

Instructions for the Informed Consent and HIPAA Authorization for Research Template

- This template, developed by Weill Cornell Medicine's Institutional Review Board (IRB), has been created to assist the Principal Investigator (PI) in the design of their informed consent form (ICF). It is important that PIs adapt their own ICFs to the outline and requirements of their particular study. Ensure descriptions and added details are written in plain language that is clear, easy to understand, and in a way that facilitates comprehension.
- Do not be concerned by the length of this template. It is long because it contains guidance and explanations which are for you and which you will not include in the informed consent forms that you develop and provide to participants in your research.
- Consider the method or mode of communication and informed consent process with potential participants. For example, when using email communication consider informing participants that email is not secure way to communicate about your health or to share private information given there are many ways for unauthorized users to access email.
- In this template:
 - Square brackets *[containing red bold and italicized text]* are instructional to you.
 - Once the instructions are followed, the *[bold and italicized text]* should be deleted from the template before proceeding.
 - Square brackets containing *[red text]* are intended as template language to include, if applicable to your study, or to remove, if not applicable to your study.
 - If the template language is applicable to your study, remove the square bracket and make the font color black.
 - When you've completed the creation of the ICF, there should be no red text remaining.
 - Please ensure that you update the header and footer.
- Prior to submitting to the IRB, convert to PDF first, then delete this instructional page.

TEMPLATE ON THE FOLLOWING PAGE

[Institution Name]
 Informed Consent and HIPAA Authorization for Research

Project Title:	
Research Project/Protocol #:	
Principal Investigator:	<i>[If there is more than one consent for the study, please indicate the type of consent here (E.g., Screening Consent; Group B Consent). Otherwise, delete this row.]</i>
<i>[Arm/Group]</i>	
Subject Name or number:	
<i>[MRN]</i>	<i>[If you will not be obtaining the MRN, please delete this row.]</i>

[If this study involves minors, and this is a parent consent, or if it involves an LAR signing on behalf of the subject, please include one of the following introductory statements as it applies to your study:]
[If for Parental/Guardian Permission:]
 Please note that references to "You" or "your" refer to your child [the child] who will be participating in the study for whom you are providing consent.
[If use of an LAR:]
 This consent form is written to address a research subject. If you will be providing permission as the legally authorized representative of a subject, the words "you" and "your" should be read as "the subject" and "subject's".
 Please note, are you currently or have been (within the last 6 months) a participant in any other research study at Weill Cornell Medicine, New York Presbyterian Hospital or elsewhere? If so, please inform the research team.

Weill Cornell Medicine
[Sponsor#, Amend# and date]
 Consent Template, Version March 2022

IRB Protocol # *[Insert protocol #]*
 Consent version date: *[MM/DD/YYYY]*

Page 2 of 9



Elements of the Informed Consent Form



What the Key Information Section Is

- **The first thing your participant sees during the Informed Consent process**
- **Should include the most crucial information needed to decide on participation**
- **It is NOT a summary**
- **It does NOT have all elements of the Informed Consent**
- **It does NOT include exclusion criteria***
- **It does NOT have to look identical to our template**

For more on Informed Consent, watch:

**Weill Cornell
Medicine**

Informed Consent in Research

Regulatory Requirements and Ethical Considerations



Kaori Kubo Germano, Ph.D.
Human Research Compliance

HRC METS
Thursday, August 17th, 2022



Weill Cornell Medicine



Other Documents

- **Letters of Support**
- **Other IRB Approvals**
- **Data Transfer Agreements**
- **Certificates of Confidentiality**
- **Assent Document**
- **HIPAA Authorization**
- **Recruitment Materials**
- **Surveys/questionnaires/data collection tools/interview scripts/questions**



4. Submit an IRB Intake

1. Log in to the Weill Research Gateway with your CWID and password
2. Click the **Human Subjects** link in the left navigation menu



Weill Cornell Medicine | WRG Welcome Kaori Germano

Home My Profile My Items Search For Items Calendar Mailbox Action Items SASP

Sponsored Programs

Human Subjects

Research Safety

Conflicts Of Interest

SPIN

Clinical Trials

CITI Training

Online Research Binder

Important Announcement

Please note: Thursday, February 23rd, beginning at 5:00PM, WRG will be down for maintenance. During this time, users will see a "Temporarily unavailable" message when accessing WRG.

Assignments

Open

Drag a column header and drop it here to group by that column

<input checked="" type="checkbox"/>	Module	Record Number	Record Owner	Object	Assignment Type	Record Status	Subject	Assigned
No results found.								

4. Submit an IRB Intake

3. Click the **Create New Protocol** button

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Home My Profile My Items Search For Items Calendar Mailbox Action Items SASP

Sponsored Programs
Human Subjects
Research Safety
Conflicts Of Interest
SPIN
Clinical Trials
CITI Training
Online Research Binder

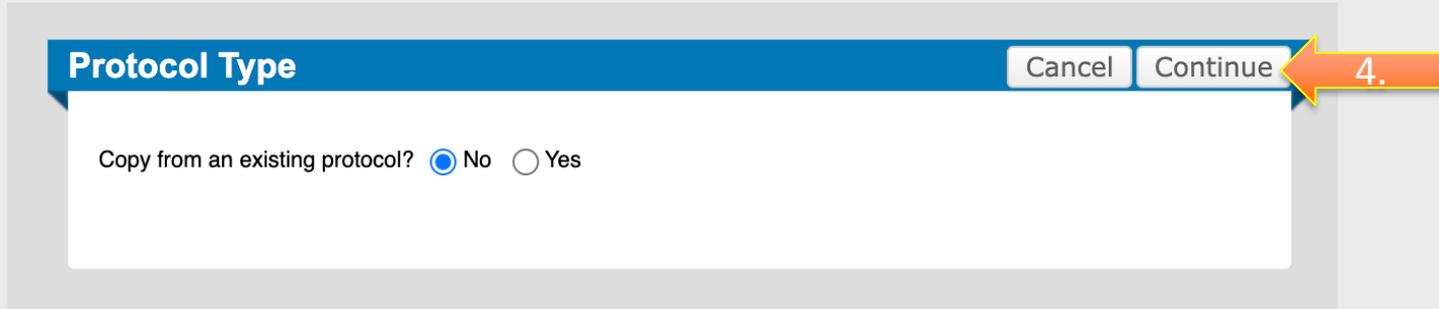
Human Subjects

3. [Create New Protocol](#) [Reviews Management](#)
[WRG User Guide](#) [Standard Reporting](#)
[Adhoc Reporting](#)
[Amend or Renew Protocol](#)

Department Resources
[IRB](#)
[JCTO](#)
[Researcher's toolbox \(intranet only\)](#)

4. Submit an IRB Intake

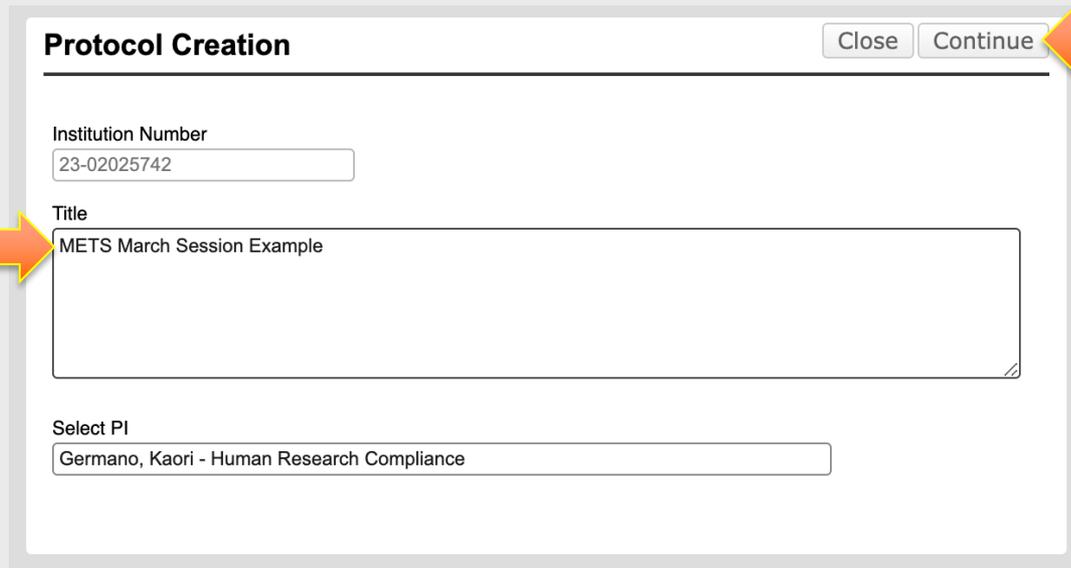
4. Copy from Existing Protocol should default to **No**. Keep that as is and click **Continue**.



The screenshot shows a form titled "Protocol Type" with a blue header. Below the header, there is a question: "Copy from an existing protocol?" with two radio button options: "No" (which is selected) and "Yes". To the right of the question, there are two buttons: "Cancel" and "Continue". An orange arrow with the number "4." points to the "Continue" button.

4. Submit an IRB Intake

5. Enter a **Title** for this protocol. The Title should match the name of your study.



The screenshot shows a web form titled "Protocol Creation". At the top right are "Close" and "Continue" buttons. An orange arrow labeled "6." points to the "Continue" button. Below the title bar, there are three input fields: "Institution Number" with the value "23-02025742", "Title" with the value "METS March Session Example", and "Select PI" with the value "Germano, Kaori - Human Research Compliance". An orange arrow labeled "5." points to the "Title" input field.

6. Click continue.

4. Submit an IRB Intake

7. Click the **Intake** form

Record Number: 23-02025742
Done Save

METS March Session Example
Kaori Kubo Germano - Human Research Compliance

Human Subjects Protocol
Edit Mode
Change Project Info

Submissions (1) Linkages Summaries Attachments (3) Communications Approved Docs Access ?

Home > Submissions

Submissions New Submissions cannot be added to this Protocol.

Type	Submission Number	Investigator Submitted On Date	Management Submitted On Date	Internal ID	Determination Date	Determination Date From	Determination Date To	Access Log
Intake	23-02025742-01	N/A	N/A	N/A	In Progress	N/A	N/A	Log Delete

4. Submit an IRB Intake

8. Click on the Intake Form

Record Number: 23-02025742
Submission Type: Intake
PI: Germano, Kaori

Submissions (1) | Linkages | Summaries | Attachments (3) | Communications | Approved Docs | Access

Home > Submissions > Intake > Submission

Record Number: 23-02025742
Submission Type: Intake
PI: Germano, Kaori

- Not Started
- In Progress
- Completed
- Not Applicable

*** You can check SASP for additional details anytime

Submission Number: 23-02025742-01 Created on: 23-Feb-2023 Status: In Progress

Document/Form	Add	Type	Status	
HS - Protocol Initiation Form (Intake)			Incomplete	Submit (Mandatory Form)

4. Submit an IRB Intake

9. Answer all questions

Review

General

[Save](#)

Submission Number

Submitted on 

Coordinator

Internal ID Number

Exemption Categories [Set](#)

Expedited Categories [Set](#)

Review Activities [Set](#)

Created On 23-Feb-2023

Created By Kaori Kubo Germano

Description



4. Submit an IRB Intake

6. Please select the type of application you are submitting to the IRB for review (If an external IRB will serve as the IRB of record please select option E. Non-WCM Review and Approval (Central IRB or Single IRB)).

- ✓
- a. IRB Application (Full, Expedited, or Exempt)
- b. HUD/HDE
- c. Emergency Use of an investigational test article
- d. Expanded Access (aka Compassionate Use or Single Patient Access)
- e. Non-WCM Review and Approval (Central IRB or Single IRB)
- f. Human Subjects Research Determination Request



6. Please select the type of application you are submitting to the IRB for review (If an external IRB will serve as the IRB of record please select option E. Non-WCM Review and Approval (Central IRB or Single IRB)).

a. IRB Application (Full, Expedited, or Exempt) ✓

Initial IRB Protocol Application (Full, Expedited, or Exempt): Greater than minimal risk or minimal risk that involves human subjects.

4. Submit an IRB Intake

10. When you've answered all questions, click the **Save** button

11. Then the **Complete** button, both of which are at the top of the page.

The screenshot displays the Weill Cornell Medicine Protocol Initiation Form (Intake) interface. At the top right, there is a navigation bar with buttons for 'Close', 'Print', 'Form History', 'Save', and 'Complete'. Two orange arrows point upwards from the bottom of the page towards the 'Save' and 'Complete' buttons, labeled '10.' and '11.' respectively. Below the navigation bar, the title 'Protocol Initiation Form (Intake)' is centered, followed by the text 'Updated By: Kaori Kubo Germano 23-Feb-2023 04:50:57 PM'. A red horizontal line separates the header from the main content area. Below the line, there is a 'Review' section. The main content area is titled 'General' and contains a 'Save' button in the top right corner. Below the 'Save' button, there are input fields for 'Submission Number' (containing '23-02025742-01'), 'Submitted on' (with a calendar icon), and 'Coordinator'.

4. Submit an IRB Intake

12. Back on this page the status will now read, **Complete**; click **Submit**

Record Number: 23-02025742
METS March Session Example
Kaori Kubo Germano - Human Research Compliance

Done Save

Human Subjects Protocol
Edit Mode
Change Project Info

Submissions (1) Linkages Summaries Attachments (3) Communications Approved Docs Access

Home > Submissions > Intake > Submission

Record Number: 23-02025742
Submission Type: Intake
PI: Germano, Kaori

- Not Started
- In Progress
- Completed
- Not Applicable

Submit Intake

Submit to PRMC PRMC Pre-Review PRMC Approval

Submit Initial Certification IRB Pre-Review Assign to Agenda IRB Approval

*** You can check SASP for additional details anytime

Submission Intake Submission Number: 23-02025742-01 Created on: 23-Feb-2023 Status: In Progress

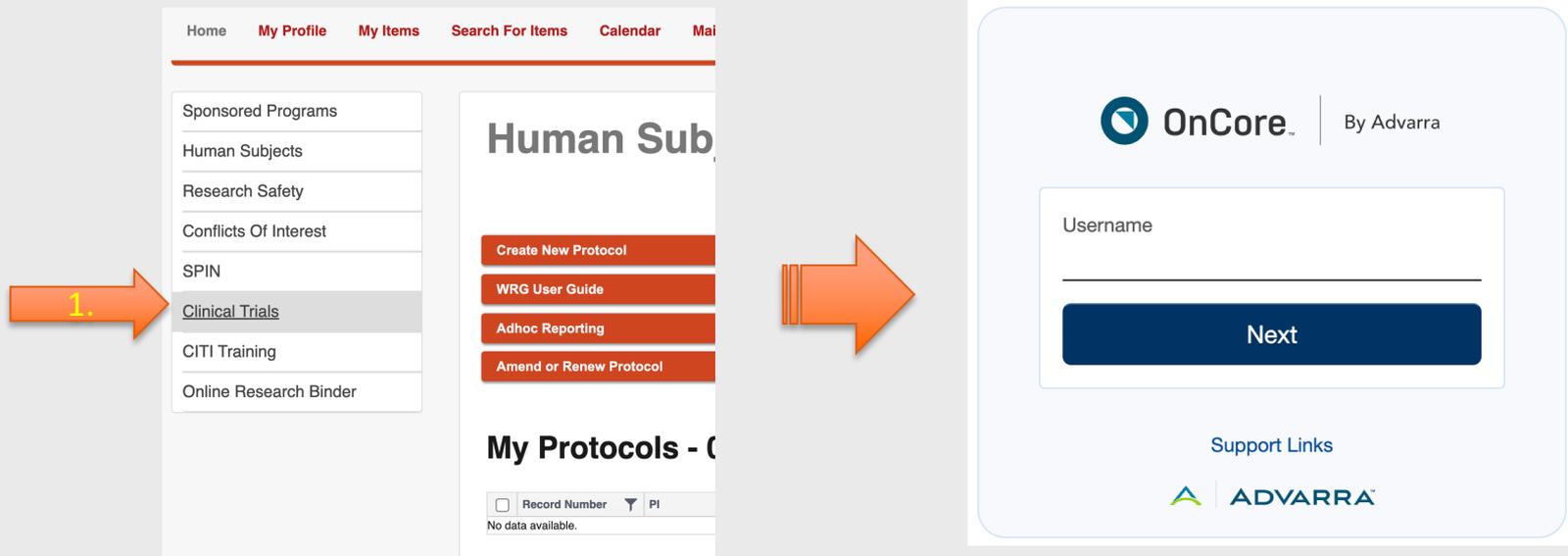
Document/Form Add Type Status

HS - Protocol Initiation Form (Intake) Incomplete

12. Submit (Mandatory Form)



5. Submit a PRMC Application



The image illustrates the first step of submitting a PRMC application. On the left, a screenshot of the OnCore web application shows the 'Human Subjects' menu. An orange arrow labeled '1.' points to the 'Clinical Trials' option. On the right, a screenshot of the OnCore login page shows the 'Username' input field and the 'Next' button. The OnCore logo and 'By Advarra' text are visible at the top of the login page.

For step-by-step instructions visit JCTO's [Navigating the PRMC](#) page

About the PRMC

- **Independent of the IRB**
 - Obtain PRMC approval *prior to* submitting to the IRB
- **For inquiries:**
 - General PRMC:
generalprmc@med.cornell.edu
 - Cancer PRMC:
cancerprmc@med.cornell.edu
- **90-day submission clock begins at initial intake**

If the study relates to cancer research, Disease Management Team (DMT) approval is also required, preferably before PRMC submission

Joint Clinical Trials Office (JCTO)

Protocol Review & Monitoring Committee (PRMC)

Reviewer Checklist

The Protocol Review & Monitoring Committee (PRMC) emphasizes the following while reviewing proposals:

Scientific Merit:

- There is a clearly stated purpose or question to address that will be the focus of the project.
- Adequate background information is provided.
- Experimental design is sufficiently detailed.
- Testing procedures address the research question.
- Statistical analysis is appropriate.
- Outcome measures are clearly defined.
- Comprehensive literature review is provided.

Feasibility:

- A comprehensive budget is provided.
- The outlined timeline is realistic.
- Research procedures are clearly defined.
- Rationale for the study is provided.
- Applicant team's expertise is adequate to manage the project.
- Applicant team's resources are sufficient to complete the project, both in terms of personnel and facilities.
- Safety/facility considerations are addressed.

Study Significance:

- The importance of participation in this project for the PI is clearly stated.
- Participation in the project is expected to improve the PI's standing in the research community.
- Participation is integral to ongoing research as part of the PI's research program.
- Project serves programmatic needs.
- The impact of the project on the field is clearly stated and significant.

Informed Consent:

- Not applicable, this study appropriately requests a waiver of informed consent.
- Study drugs or devices are identified.
- Drug or device status with the FDA is clearly stated.
- Known risks of the drug or device are clearly stated.
- Known risks seem reasonable in relation to potential benefits to subject or to the importance of knowledge that may result from the research.

Joint Clinical Trials Office (JCTO)

in the protocol or Non-Technical



6. Submit an Initial Application

Proceed to this step ONLY once PRMC approval has been obtained

Step I: Locate your protocol

Weill Cornell Medicine | WRG

Welcome Kaori Germano

Home My Profile My Items Search For Items Calendar Mailbox Action Items SASP

Quick Find

Sponsored Program

Human Subject

Research S

Conflicts Of Interest

SPIN

Clinical Trials

CITI Training

Online Research Binder

Important Announcement

Note: Thursday, February 23rd, beginning at 5:00PM, WRG will be down for maintenance. During this time, users will see a "Temporarily unavailable" message when accessing WRG.

Assignments

Drag a column header and drop it here to group by that column

<input type="checkbox"/>	Module	Record Number	Record Owner	Object	Assignment Type	Record Status	Subject	Assigned
No results found.								

6. Submit an Initial Application

Proceed to this step ONLY once PRMC approval has been obtained

Step I: Locate your protocol

Results found: 2 Switch Owner You ▾ Export to Excel

Drag a column header and drop it here to group by that column

<input type="checkbox"/>	Record Number	Record Type	Record Owner	Record Primary Department	Record Title	Record Primary Sponsor	Record Status
▶	kkg4003	Conflict of Interest	Germano, Kaori Kubo	Human Research Compliance	Case for Kaori Germano		No conflicts reported
▶	23-0000574	Human Subjects	Germano, Kaori	Human Research	METS March Session Example		In Progress

23-0000574 (circled in yellow) Edit (circled in yellow)

- View ▶ Intake (23-Feb-2023 In Progress)
- Info ▶
- Forward
- Delete
- Bookmark Record



6. Submit an Initial Application

Step II: Add an Initial IRB Application to your Submission Package

The screenshot displays the IRB submission management interface. At the top, it shows the record number 23-02025742 and the project name 'METS March Session Example' by Kaori Kubo Germano. There are 'Done' and 'Save' buttons, and a 'Change Project Info' button. Below this is a navigation bar with tabs for Submissions (1), Linkages, Summaries, Attachments (3), Communications, Approved Docs, and Access. The main content area shows a breadcrumb 'Home > Submissions' and a table of submissions. A dropdown menu is open over the 'Intake' submission, listing various actions like 'Initial', 'Amendment', and 'Continuing Review'. A yellow arrow points to the 'Initial' option in the dropdown.

Record Number
23-02025742

METS March Session Example
Kaori Kubo Germano - Human Research Compliance

Human Subjects Protocol
Edit Mode

Change Project Info

Submissions (1) Linkages Summaries Attachments (3) Communications Approved Docs Access ?

Home > Submissions

Submissions

Type	Submission Number	Investigator Submitted On Date	Management Submitted On Date	Internal ID	Determination Date	Determination Date	Determination Date
Intake	23-02025742-01	N/A	N/A	N/A	In Progress	N/A	N/A

- Initial
- Amendment
- Continuing Review
- Reportable Events
- Closure Report
- Admin Amendment
- Post-Approval Monitoring Annual Report

6. Submit an Initial Application

Step III: Fill out and submit your Initial IRB Application

Record Number: 23-02025751
Submission Type: Initial
PI: Germano, Kaori

Legend:
○ Not Started
⌚ In Progress
✓ Completed
⊖ Not Applicable

Progress: Submit Intake (Completed) → Submit to PRMC (Not Started) → PRMC Pre-Review (Not Started) → PRMC Approval (Not Started) → **Submit Initial (In Progress)** → Certification (Not Started) → IRB Pre-Review (Not Started) → Assign to Agenda (Not Started) → IRB Approval (Not Started)

*** You can check SASP for additional details anytime

Submission: **Initial** Submission Number: 23-02025751-02 Created on: 24-Feb-2023 Status: In Progress

Document/Form	Type	Status	Submit
IRB Application	Protocol	Incomplete (Mandatory Form)	<input type="button" value="Submit"/>
Guidance - IRB Review Application Therapeutic JCTO Protocol Guidance.docx	Protocol	Completed (Mandatory Form)	

6. Submit an Initial Application

Step III: Fill out and submit your Initial IRB Application

Weill Cornell Medicine

Close Print Form History Save Complete

IRB Application - The Effectiveness of a Monthly Educational Training Series on Regulatory Compliance

Record Number: 23-02025751
PI: Germano, Kaori Kubo
Updated By: Kaori Kubo Germano 24-Feb-2023 01:43:34 PM

Review

General

Submission Number	<input type="text" value="23-02025751-02"/>
Submitted on	<input type="text"/>
Coordinator	<input type="text"/>
Internal ID Number	<input type="text"/>
Exemption Categories	Set
Expedited Categories	Set
Review Activities	Set
Created On	24-Feb-2023
Created By	Kaori Kubo Germano
Description	<input type="text"/>

Reviews Method Board

6. Submit an Initial Application

Step III: Fill out and submit your Initial IRB Application

Record Number: 23-02025751
Submission Type: Initial
PI: Germano, Kaori

- Not Started
- In Progress
- Completed
- Not Applicable

Submit Intake Submit to PRMC PRMC Pre-Review PRMC Approval Submit Initial Certification IRB Pre-Review Assign to Agenda IRB Approval

*** You can check SASP for additional details anytime

Submission: Initial Submission Number: 23-02025751-02 Created on: 24-Feb-2023 Status: In Progress

Document/Form	Type	Status	Actions
IRB Application	IRB Application	Completed	PDF Submit (Mandatory Form)
Guidance - IRB Review Application Therapeutic JCTO Protocol Guidance.docx	Other Research Documents	Completed	(Mandatory Form)
Guidance - IRB Review Application Therapeutic JCTO Protocol Guidance.docx	Protocol	Completed	(Mandatory Form)
Guidance-IRB Review Application - Non-Therapeutic and Chart Review JCTO Protocol Guidance.docx	Main Consent	Completed	(Mandatory Form)

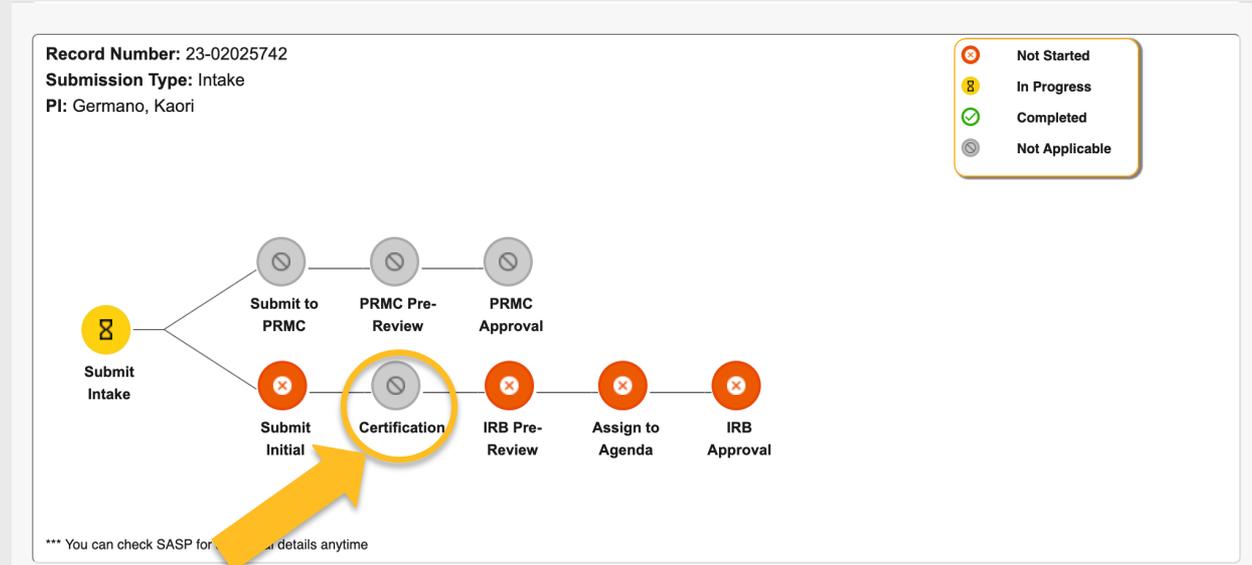
7. Certify Your Application

This is confirmation of the study personnel's agreement to be part of your study!

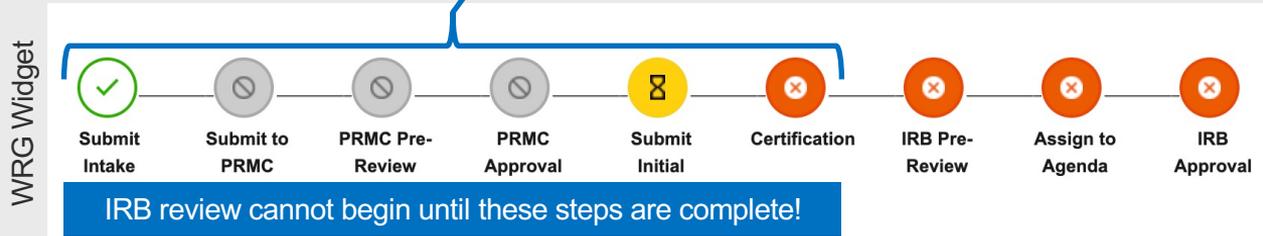
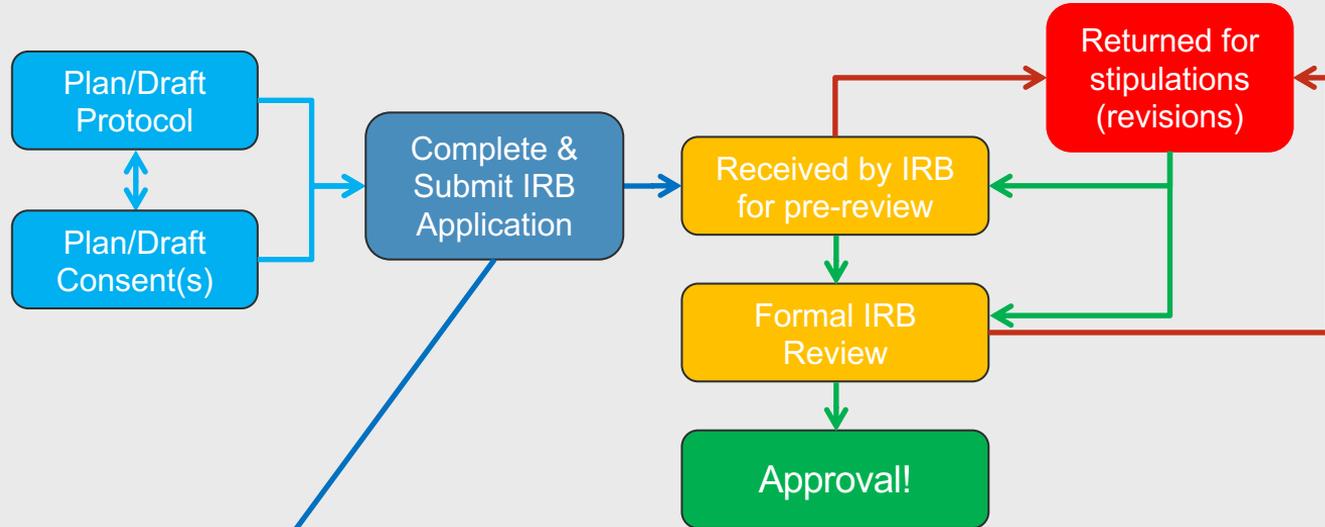
The screenshot displays the Weill Cornell Medicine | WRG portal interface. The top navigation bar includes links for Home, My Profile, My Items, Search For Items, Calendar, Mailbox, and Action Items. A yellow arrow points to the 'Action Items' link, which is circled in yellow. Below the navigation bar, there is a 'Quick Find' search box. On the left side, a sidebar menu lists various categories: Sponsored Programs, Human Subjects (highlighted), Research Safety, Conflicts Of Interest, SPIN, Clinical Trials, CITI Training, and Online Research Binder. The main content area features an 'Important Announcement' section with a speaker icon and a 'Certification' modal window. The modal window contains the following text: 'I confirm my role as Principal Investigator, that my department chair approves of this study being conducted, and that I have adequate resources to conduct this activity. All information included in this application is accurate. In addition, I have completed/updated my Conflicts of Interests survey in accordance with Cornell University policy 4.14 - Conflicts of Interests and Commitment and Cornell University policy 1.7 - Financial Conflict of Interest Related to Research to reflect any applicable relationships to this protocol. By signing below, as Principal Investigator I further certify that no investigators listed on this study have a conflict related to the conduct, design, review, safety monitoring or analysis of this study.' Below the text are two radio buttons labeled 'Accepted' and 'Declined', and a 'Continue' button. A 'Close' button is located in the top right corner of the modal window.

7. Certify Your Application

Hover over 'Certification' to see which certification is missing



IRB Review and Decision



For Tips and Tricks for a Successful Submission, watch:

**Weill Cornell
Medicine**

Tips and Tricks: *Successful IRB Submission and Review Process*



Yefrenia Henriquez Taveras, MPH, MHA, CHES
Clinical Research Program Manager & Sr. IRB Navigator
Human Research Compliance Office

Thursday, February 23, 2023
<https://research.med.cornell.edu/irb>

Resources

- [ITS Study Activation Guides](#)
- [JCTO Researcher's Toolbox](#)

Study Activation Guides

In order to obtain access to the Human Subjects and Clinical Trials modules, please work with your department to submit a WRG Access Request form. While a few of the videos contained in the course may appear in the articles below, you must complete the coursework in the Learning Management System (LMS) in order to be granted system access.

- [Video: Study Activation Process Overview](#)
- [How To: Submit an Intake Form](#) [↗](#)
- [Overview: The Study Activation Status Page \(SASP\)](#) [↗](#)
- [How To: Submit your Protocol to the PRMC in ePRMS](#) [↗](#)
- [How To: Submit your Initial IRB Application](#) [↗](#)
- [How To: Approve + Certify on an IRB Application](#) [↗](#)
- [How To: Complete Items on your Task Lists](#) [↗](#)
- [How To: Submit Study Lifecycle Events \(Amendments, Continuing Reviews, etc.\)](#) [↗](#)



Welcome to the JCTO Researcher's Toolbox. Here you will find various tools and templates that may be utilized throughout the process of study activation and during the conduct of your study. To expand each section, please click on the orange "+" next to the category.

Please note, to ensure compatibility please download all excel files using [Google Chrome](#) [↗](#) as your browser.

BRANyplus	+
ClinCard Reference Materials	+
Research Systems Forms and Guidance	+
Protocol Review and Monitoring Committee (PRMC) Tools and Templates	+
Clinical Translational Core Lab (CTCL) Materials	+
Contract and Budget Tools and Templates	+
Investigational Pharmacy	+
Investigator Initiated Protocol Templates	+
Regulatory Tools and Templates	+
Subject Recruitment Tools and Templates	+
TWIST (Training Workshops for Investigators and Study Teams)	+
Training and Education Tools and Templates	+

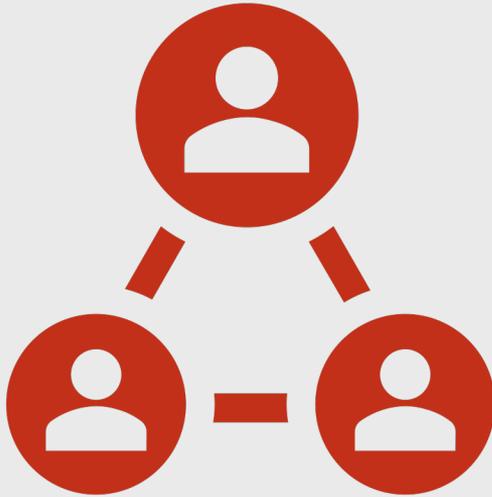
Contact Information

Joint Clinical Trials Office
Weill Cornell Medicine /
NewYork-Presbyterian
1300 York Avenue,
Box 305
New York, NY 10065
Phone: (646) 962-8215
Fax: (646) 962-0536

Abbreviation Library



Helpful contacts



- *BRANYplus-related questions:* branyplus@med.cornell.edu
- *JCTO-related questions:* jctoperations@med.cornell.edu
- *PRMC-related questions:* generalprmc@med.cornell.edu (non-cancer studies); cancerprmc@med.cornell.edu
- *Single IRB/reliance-related questions:* singleirb@med.cornell.edu
- *Oncore, WRG-CT-related questions:* jctoctms@med.cornell.edu
- *WRG-related issues/questions:* wrg-support@med.cornell.edu





Weill Cornell Medicine