Welcome!

• The session will begin shortly; if you are Zooming in, please take a moment to make sure your microphone is muted.
• The presentation portion of this session will be recorded.
• Please hold your questions until the end of this session.
• Not registered? Please register now using the QR code.
Navigating WRG-HS
A Step-by-Step Guide

Cynthia Franco  IRB Manager
Kortney Rogers  IRB Analyst

https://research.weill.cornell.edu/irb
Cynthia Franco, MHA

15+ years of experience in human research protections

Joined WCM in December 2006
Kortney Rogers, MHA

2 years of experience in human research protections

Joined WCM in January 2022
Kala Moe Kastanis

Over 1 year of experience with the Research Administrative Computing (RAC) team

Joined WCM in August 2022
Kristine Pangilinan, BSN

15 years of experience in human research protections

Joined WCM in September 2008
Margaret Mackenzie, MM

9+ years of experience in human research protections

Joined WCM in October 2014
Reba Yohannan

5+ years of experience in human research protections

Joined WCM in April 2018
How Do I Get Started?
Submit Intake Form
Locate Your Protocol
Submit PRMC Application
Submit an Initial Application
Complete Certification
Where is my IRB protocol
Helpful Resources
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.

For an in-depth presentation on Submitting an IRB Application, please watch our METS presentation from March 2023
Next Steps

1. Submit Intake in WRG-HS
2. Submit applicable scientific review (e.g., PRMC, CTSC, etc.)
3. Submit Initial application in WRG-HS
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

See “**HowTo: Submit an Intake Form (Study Activation)**” on ITS site
3. Click the Create New Protocol button

See “HowTo: Submit an Intake Form (Study Activation)” on ITS site
4. Copy from Existing Protocol should default to No. Keep that as is and click Continue
5. Enter a Title for this protocol. The Title should match the name of your study.

6. Click Continue.
7. Click on the Intake submission link

For an in-depth presentation on Submitting an IRB Application, please watch our METS presentation from March 2023.

See “HowTo: Submit an Intake Form (Study Activation)” on ITS site.
8. Click on the link to the Intake Form

See “HowTo: Submit an Intake Form (Study Activation)” on ITS site
9. Answer all the questions and upload necessary documents
10. When you've finished the form, click the Save button
11. Then click the Complete button

See “How To: Submit an Intake Form (Study Activation)” on ITS site
12. On the Intake submission page, the status will now read Complete

Click Submit
Locate Your Protocol
Search the protocol number in Quick Find, My Items, or Search for Items.

See “How To: Submit an Intake Form (Study Activation)” on ITS site.
Example 1: Quick Find

Click the protocol number, hover over Edit, and click Master Record.

See “HowTo: Submit an Intake Form (Study Activation)” on ITS site
Example 2: My Items

Find the protocol number in your "My Protocols" list. Click the protocol number, hover over Edit, and click Master Record.

See “HowTo: Submit an Intake Form (Study Activation)” on ITS site
Submit PRMC Application
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*
Submit a PRMC Application

For step-by-step instructions visit JCTO’s Navigating the PRMC page
Submit an Initial Application
1. Add an Initial Submission to the protocol

See “HowTo: Submit an Intake Form (Study Activation)” on ITS site
2. Click on the link to the IRB application

See “HowTo: Submit an Intake Form (Study Activation)” on ITS site
3. Answer all the questions in the form and upload the necessary documents.
Types of Documents That May Need to be Uploaded

• Add drug and/or device information by making the appropriate selection for question 7, and clicking the red Add button.

• Upload the IRB Review Application (IRA) for question 9 by clicking the gray icon. The forms can be found at the link within the question.

See “HowTo: Submit Your Initial IRB Application”** on ITS site
IRB Review Application (IRA) forms and supplemental forms can be found on our website.
Consent Templates and Checklists can be Found on our Website
4. When you've finished the form, click the Save button

5. Then click the Complete button

See “How To: Submit Your Initial IRB Application” on ITS site
Based on the answers selected in the application, upload icons will appear for required documents. Upload all required documents.

See “HowTo: Submit Your Initial IRB Application” on ITS site
6. Submit your Initial IRB Application

See “HowTo: Submit Your Initial IRB Application”** on ITS site
Complete Certification
7. Click on Action Items
8. On your assignments list, find the item with the protocol number and "Certification is required" as the subject. Click on the protocol number.

Note: Each study team member must complete certification. This is confirmation of the study personnel’s agreement to be part of your study!

See “HowTo: Certify on an IRB Application or Other Submission Type” on ITS site
9. Click Review
10. Select Reviewed in the Review Status dropdown
11. Click Approved
12. Click Accept

See “HowTo: Certify on an IRB Application or Other Submission Type” on ITS site
Tip: To see who still needs to certify, hover over the Certification step in the Submission Progress bar!

See “HowTo: Certify on an IRB Application or Other Submission Type” on ITS site
Where is my Protocol?
1. Locate your protocol by searching the record number in Quick Find, My Items, or Search For Items
2. Click on the protocol number, hover over View, and click on the Initial submission.
3. Select Assignments from the left list to view who the submission is currently assigned to.
Helpful Resources
• Opening a ticket with WRG Support:
  o Call 646-962-2169 or 212-746-4878 and select option 3.
  o Email wrg-support@med.cornell.edu
  o ITS Helpdesk: wcmcprd.service-now.com/myhelpdesk
• Human Research Protections
• ITS Study Activation Guides
• JCTO Researcher’s Toolbox
• METS (Monthly Education & Training Series)
Questions?
Scan the QR code to request a consult during our on-site Tuesday, 1/9 through Thursday 1/11