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
For an overview of the WCM IRB, please join us at next month’s METS.
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
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.
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
3. Prepare Submission Documents

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

failing to prepare = prepare to fail
JCTO Protocol Templates

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/
• 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:
  o Biomedical IRA
  o Biorepository IRA
  o SBER and Records IRA
Supplemental Forms
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 Appication (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 Template: "WCM Informed Consent Template (with Key Information section)"

☐ available on the IRB web page: Forms, Templates, & Guidance
Elements of the Informed Consent Form

1. WHAT IS IT ABOUT?
A statement about, and description of, the study

2. WHAT ARE THE RISKS?
A description of risks or discomforts to the subject

3. WHAT ARE THE BENEFITS?
A description of any benefits to the subjects

4. ARE THERE ALTERNATIVES?
A disclosure of appropriate alternative procedures or courses of treatment

5. WHO WILL KNOW?
A statement describing how confidentiality will be maintained

6. IS THERE COMPENSATION?
For greater-than-minimal risk studies, compensation and/or medical treatment

7. WHO IS THE CONTACT?
Contact information for questions or more information

8. IS IT MANDATORY?
A statement that participation is voluntary

9. WHAT HAPPENS AFTER?
A statement about what will be done with collected information
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:
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

See “*HowTo: Submit an Intake Form (Study Activation)*” on ITS site
4. Submit an IRB Intake

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

See “*HowTo: Submit an Intake Form (Study Activation)*” on ITS site
4. Submit an IRB Intake

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

See “HowTo: Submit an Intake Form (Study Activation)” on ITS site
4. Submit an IRB Intake

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

6. Click continue.

See “*HowTo: Submit an Intake Form (Study Activation)*” on ITS site.
4. Submit an IRB Intake

7. Click the **Intake** form

See “**HowTo: Submit an Intake Form (Study Activation)**” on ITS site
4. Submit an IRB Intake

8. Click on the Intake Form

See “HowTo: Submit an Intake Form (Study Activation)” on ITS site
4. Submit an IRB Intake

9. Answer all questions

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

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

See “HowTo: Submit an Intake Form (Study Activation)” on ITS site
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.
4. Submit an IRB Intake

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

For step-by-step instructions visit JCTO’s Navigating the PRMC page
About the PRMC

• Independent of the IRB
  o Obtain PRMC approval *prior to* submitting to the IRB

• For inquiries:
  o General PRMC: generalprmc@med.cornell.edu
  o 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.*
6. Submit an Initial Application

Proceed to this step ONLY once PRMC approval has been obtained

Step I: Locate your protocol

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

Proceed to this step ONLY once PRMC approval has been obtained

Step I: Locate your protocol

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

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

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

Step III: Fill out and submit your Initial IRB Application

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

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6. Submit an Initial Application

Step III: Fill out and submit your Initial IRB Application

See “HowTo: Submit Your Initial IRB Application” on ITS site
7. Certify Your Application

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
7. Certify Your Application

Hover over ‘Certification’ to see which certification is missing

See “HowTo: Certify on an IRB Application or Other Submission Type” on ITS site
IRB Review and Decision

IRB review cannot begin until these steps are complete!

Plan/Draft Protocol → Complete & Submit IRB Application → Received by IRB for pre-review → Formal IRB Review → Approval!

Returned for stipulations (revisions)

Plan/Draft Consent(s) → Complete & Submit IRB Application → Received by IRB for pre-review → Formal IRB Review → Approval!

Plan/Draft Protocol → Complete & Submit IRB Application → Received by IRB for pre-review → Formal IRB Review → Approval!

Plan/Draft Consent(s) → Complete & Submit IRB Application → Received by IRB for pre-review → Formal IRB Review → Approval!
For Tips and Tricks for a Successful Submission, watch:
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.)
Helpful contacts

- **BRANYplus-related questions:** branyplus@med.cornell.edu
- **JCTO-related questions:** jctooperations@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