Submitting an IRB application

The purpose of this information is to assist WCM faculty, staff and students who are planning to conduct projects that involve human subjects. You are urged to read this information carefully in order to avoid unnecessary delay in obtaining Institutional Review Board (IRB) or PRMC approval. For an overview of the IRB review process at WCM, please review the Human Research Compliance Monthly Education and Training Series (METS) presentation, "IRB101: Introduction to the WCM IRB"

If you have a question that is not answered below, or if you need to determine whether or not your project needs to be reviewed by the IRB, visit the IRB website at WCM IRB or contact our IRB Navigation Team by submitting a consultation request here.

How do I get started?

☐ 1. Get access to the Weill Research Gateway-Human Subjects (WRG-HS) and Oncore:

- Modules to have access to: ***Clinical Trials/Human Subjects***
- Your Department's DA needs to submit a WRG access request form
- Make sure that you are selecting "**add**" for both "**regulatory coordinator**" and "**clinical research associate**", under ***'Clinical Trials Access'***

☐ 2. Complete CITI training (Biomed, GCP; as well as Conflicts of Interest, if federally funded):

- Research Team Training and Education Requirements

☐ 3. Complete a Conflicts of Interest survey:

- Submitting your Conflicts Survey

☐ 4. Prepare your submission documents:

- **IRB Review Application** (IRA; Biomedical, Biorepository, or Social-Behavioral and Educational (SBER) and Records) and forms are available on our website
- **Supplemental Forms** are available on our website
- One of the following **Joint Clinical Trials Office (JCTO) protocol** templates:
  - Protocol template observational correlative
  - Protocol template therapeutic studies
  - Protocol template tissue use/chart reviews
- **WCM Informed Consent Form (ICF)** template available here
- **Other documents,** as applicable, to your research:
  - 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

☐ 5. Submit an IRB intake (via WRG-HS) and Protocol Review and Monitoring Committee (PRMC) application (via Oncore) for review. First step is to submit an intake form which allows WRG to create and assign a record to your protocol.

- How to submit an IRB intake form

After this, PRMC submission is recommended:

- How to submit to PRMC

Note: the PRMC is independent of the IRB. For questions about PRMC and PRMC reviews, please email the PRMC directly:

- *For **general** PRMC-related questions: generalprmc@med.cornell.edu.*
- *For **cancer** PRMC-related questions: cancerprmc@med.cornell.edu*

NOTE: There is a 90-day submission completion clock in WRG-HS that begins at initial intake. Please make sure you have all submission materials ready prior to submitting your intake form to avoid auto-closure of your submission due to inactivity!

☐ 6. Once PRMC has provided approval, and any potential modification requests have been addressed, then the PI should submit an Initial application to the IRB:

- How to submit an Initial IRB application

*** It is advised that within the application at least one key personnel besides the PI is designated as "admin contact" so that they may correspond with the IRB on behalf of the PI as needed**.*

☐ 7. Certify your application. Once an Initial IRB Application is submitted, the first step is for *ALL* key personnel on that application to certify and approve their participation in the study. You will be notified of this required step a couple of different ways:

- You'll receive an **Action Item** in WRG.
- You'll receive an **email notification** in your regular email pointing you to that Action Item:
  - How To Approve + Certify on an IRB Application

****Once certification has been completed by all study personnel, the application will then be routed to the IRB and an administrator will be assigned***.*

What about SASP?

The Study Activation Status Page (SASP) is a dashboard where you can monitor a set of tasks and required activities which need to be completed for each of your study protocols. Depending on the specifics of the research, some requirements are not necessary, while others are always required:

- Overview of The Study Activation Status Page (SASP)

Frequently Asked Questions & Resources

1. What are the steps for local IRB submission?
   - Please refer to the steps found here: Step-by-Step How to Submit to the IRB
2. Are you planning to use eConsent for the proposed research (*WCM currently supports two eConsent tools: REDCap and DocuSign*)?
   - Frequently Asked Questions about eConsent
3. Are you planning to compensate subjects for their participation in your project?
   - ClinCard SOP
   - ClinCard Request Form

4. Does your project involve live virtual sessions, such as interviews and focus groups, for which transcription would be needed?
    - How To Enable/Use the Zoom Live Transcription Services
5. Would you be using physician referrals as part of your recruitment methods?
    - Physician Email/Letter template
6. Do you need to register your study in CT.gov (ClinicalTrials.gov)?
    - CT.gov Decision Tool
    - CT.gov Guidance/FAQs
7. Is DSMB (Data Safety Monitoring Board) oversight appropriate for your proposed project?
    - DSMC Guidance & FAQ
    - DSMC SOP is available in the "Policies and Forms" expandable section of this page
8. Would you be collaborating/working with a researcher from another institution, or conducting research at another institution?
    - Single IRB + Reliance & sIRB Submission Process
    - IRB Reliance Request Form
    - PI Checklist Single IRB Submission
9. Would you be needing translation services?

    VITTORIO BUGATTI
    Translation Coordinator

    Telephone: 212.682.8585

    inlingua Metro New York
    551 Fifth Avenue
    New York, NY 10176

    email*:* translationsny@inlingua.com
10. What if I need to obtain an Expanded Access IND (SPIND or eIND) for the treatment of an individual patient?
    - Obtaining Expanded Access IND for Treatment of Individual Patient: Investigator Checklist
11. What if I am using BRANYplus? What are the steps for submission?
    - Please refer to the steps found here: Step-by-Step How to Submit to the IRB

Questions/Concerns?

For IRB questions/concerns, please reach out to the IRB Navigation team by submitting a consultation request here, and include the following information:

- ☐ WRG number (if available)
- ☐ Brief statement of issues
- ☐ Relevant deadlines
- ☐ Associated funding

Helpful contacts:

- Need consultation? Request IRB Consultation Hours
- JCTO-related questions: jctooperations@med.cornell.edu
- BRANYplus-related questions: branyplus@med.cornell.edu
- General PRMC-related questions: generalprmc@med.cornell.edu
- Cancer PRMC-related questions: cancerprmc@med.cornell.edu
- Single IRB/reliance-related questions: singleirb@med.cornell.edu
- Oncore, WRG-CT-related questions: jctoctms@med.cornell.edu
- CTS-related questions: ctsc@med.cornell.edu
- WRG-related issues/questions: wrg-support@med.cornell.edu