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Welcome!

- The session will begin shortly; if you are joining us on Zoom, please take a moment to make sure your microphone is muted.
- The presentation portion of this session will be recorded.
- Not registered? Please register now using the QR code.

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Understanding the IRB Review Application (IRA)

How to Craft a Thorough and Well-Structured IRA

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Joined Weill Cornell Medicine Human Research Protection Operations office in January 2022.

Earned her Bachelor of Arts degree at Hunter College and is pursuing her Graduate degree at Columbia University in Bioethics.

Today's Topics

- The IRB
- Evolution of our IRB Application
- IRA Sections and Corresponding Approval Criteria
- Resources

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The IRB

It's role and requirements

The Purpose an IRB

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Institutional Review Board (IRB)

Headed by scientists/nonscientists in any institution/agency conducting research with human participants

1. **Minimization of risks to participants**
2. **Reasonable risk in relation to benefits**
3. **Equitable selection**
4. **Informed consent**
5. **Documentation of informed consent**
6. **Data monitoring**
7. **Privacy and confidentiality**

IRB review is required for **research** involving **human subjects**

Applicable Regulations May Include

1. Declaration of Helsinki
2. Good Clinical Practice (GCP)
3. Food and Drug Administration (FDA) Regulations
4. Health Insurance Portability and Accountability Act (HIPAA)
5. Family Educational Rights and Privacy Act (FERPA)
6. International Conference on Harmonization (ICH) Guidelines
7. National Institutes of Health (NIH) Policies
8. State and Local Regulations
9. Institutional Policies and Standard Operating Procedures

Commonly Accepted Ethical Standards

- **Informed Consent**
- **Voluntariness**
- **Privacy and Confidentiality**
- **Beneficence**
- **Non-Maleficence**
- **Justice**
- **Respect for Persons**

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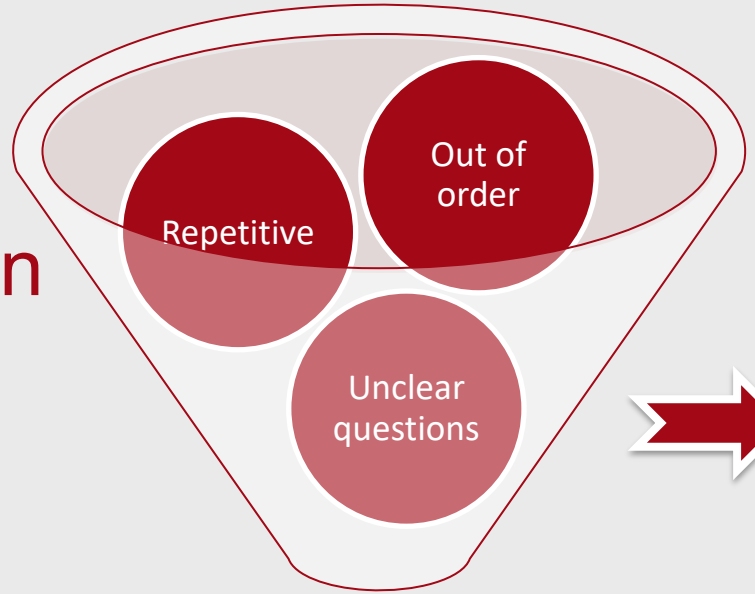
Evolution of our IRB Application

Our Old IRB Application



Many returns for clarifications

Upset researchers

Frustrated staff

Backlog

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How does the IRA streamline the submission process?

IRAs 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 now ONLY collects:

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

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IRA and Corresponding Approval Criteria

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 hrpo@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.

Generally, study populations in clinical research should (and often do) mirror the characteristics of the population affected by a particular illness or condition or reflect the characteristics of the population intended to use the product. As an important ethical principle, justice, and fairness in distribution of the opportunities and potential benefits of participation in research drive an affirmative commitment to diverse inclusion. Describe any activity to increase diversity in clinical research (click here to access a best practices resource).

Indicate specifically whether you will include or exclude any of the following special populations: (You may not include members of these populations as participants in your research unless you include them in the description of your participant population.). Justify any inclusion/exclusions of vulnerable populations.

Population	Included/Excluded?	Justification
Adults unable to consent	☐ Included ☐ Excluded	
Individuals who are not yet adults (infants, children, teenagers)	☐ Included ☐ Excluded	
Pregnant individuals	☐ Included ☐ Excluded	
Prisoners	☐ Included ☐ Excluded	
Adults with diminished capacity to consent	☐ Included ☐ Excluded	
Individuals who are not able to clearly understand English	☐ Included ☐ Excluded	

Vulnerable Populations:

(See list above and confirm details are in line with information under JCTO protocol section 4.6, if used) Outline how researchers are ensuring that appropriate steps are taken for their consent and additional safeguards that have been included to protect the rights and welfare of these participants. If your study involves pregnant individuals, fetuses, neonates of uncertain viability, or nonviable neonates, set-up a consultation with the IRB to review what is required. Reference IRB policies for information about various populations.

Recruitment Process:

Describe the plan (when, where, how) to identify potential participants, including database review and data sources if applicable. Indicate who will make initial contact and how, and if physicians or staff refer participants. Specify if any advertising/recruitment materials will be used, including verbal/electronic announcement of the research. Upload recruitment material(s) as supporting documents with your submission.

Screening Procedures:

Describe the screening process (how researchers will confirm that potential participants meet inclusion/exclusion criteria) and what will happen to screening/eligibility data for individuals who are not eligible to participate.

Background/Purpose/Study Aims:

Does this study constitute as research defined by the Revised Common Rule

"Research is as a *systematic investigation*, including research development, testing and evaluation, designed to *develop or contribute to generalizable knowledge*."

Study Population

- Age range, gender and ethnic background
- inclusion/exclusion criteria

IRB Approval
Criteria 46.111
Risks to subjects are minimized

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Vulnerable Populations

If you are not targeting the population, do NOT list it.

IRB Approval
Criteria 46.111
Informed consent

- Adults Unable to Consent
- Children/Minors
- [illegible] Individuals
- Prisoners
- Adults with Diminished Capacity
- Non-English Speakers

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Recruitment Process

- Describe the plan to identify potential participants

IRB Approval Criteria 46.111 Selection of subjects is equitable

Screening Procedures

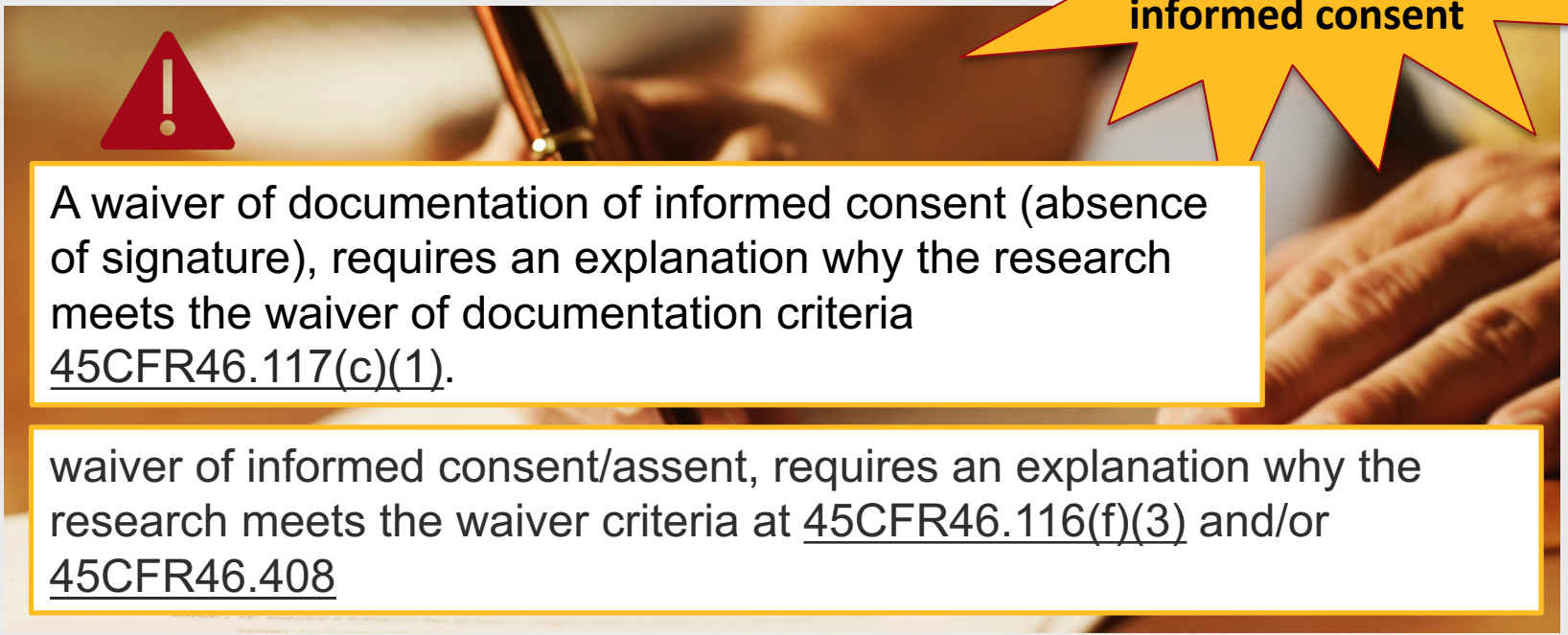
- Describe the screening process and
- Plan for screening/eligibility data for individuals who are not eligible

IRB Approval
Criteria 46.111
Data Monitoring

Informed Consent Process

Will you be obtaining consent or requesting a waiver?

46.116 General requirements for informed consent



A waiver of documentation of informed consent (absence of signature), requires an explanation why the research meets the waiver of documentation criteria 45CFR46.117(c)(1).

waiver of informed consent/assent, requires an explanation why the research meets the waiver criteria at 45CFR46.116(f)(3) and/or 45CFR46.408

Elements of Consent

- **Statement that it is research.**
- **Explanation of the purposes, duration, and procedures of the research and of the subject's participation.**
- **Description of any reasonably foreseeable risks.**
- **Description of any benefits to the subject or to others.**
- **Description of how confidentiality will be maintained.**
- **Information of whom to contact for answers about the research and research subjects' rights.**
- **Statement that participation is voluntary and that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.**

HIPAA Authorization

HIPAA only applies if you are accessing medical records from a covered entity

Authorization is required

You may request a waiver of authorization or a partial HIPAA Waiver (screening, recruitment only)

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Data Collection Procedures

Describe the project procedures, interventions, assessments, and participant activities

- What is Standard of Care?
- What is being done for research only?
- Are there any data collection documents attached?
- Were all research study materials attached for review?

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Dosing and Administraton

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Study Locations

- List name of all sites/locations
- If you will be receiving/sending data to and from another institution, indicate which institution

*Note, the IRB does not determine whether a Data Use Agreement is necessary.

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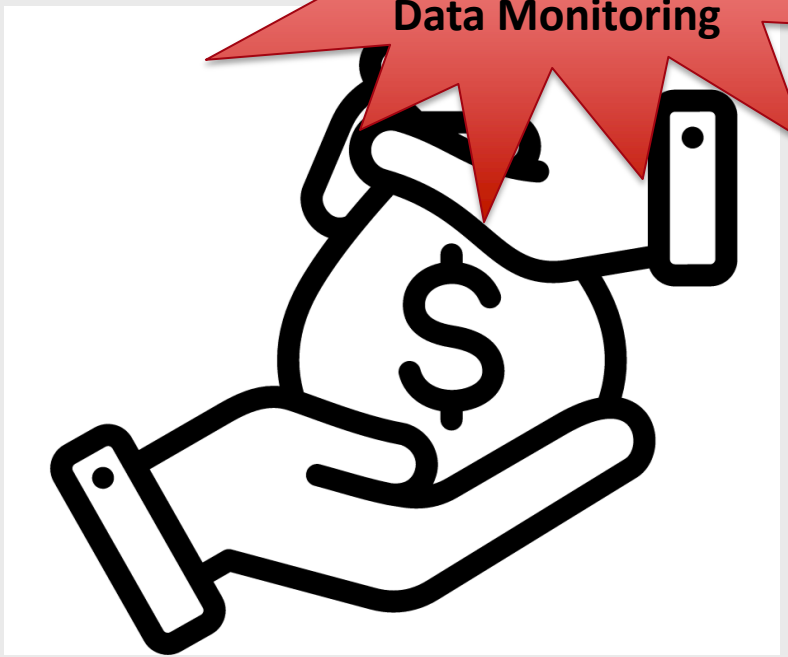
Participant Compensation



IRB Approval
Criteria 46.111
Data Monitoring

International Research

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Economic Burden to Participants

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Lifestyle Considerations

Risk to Participants

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Benefits to Participants

- The IRB considers only the benefits that may result from the research

Privacy of Participants

- Privacy concerns people, whereas confidentiality concerns data.

Data Management and Confidentiality

Considerations for securely storing data include:

- Paper records are locked in a secure location.
- Electronic records are stored on password protected or encrypted computer as appropriate based on sensitivity of data.
- Identifiers are stored separately from project data.
- For identifiable data, a coding process will be used to store data without identifiers, the link stored separately from all other project records.

Provisions to Monitor the Data to Ensure the Safety of Participants

- Who will monitor the data for safety concerns?
- What data will be reviewed?
- How often will the monitoring occur?
- What are the reporting mechanisms?

Data and Specimen Banking

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Sharing of Results with Participants

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Withdrawal of Participants

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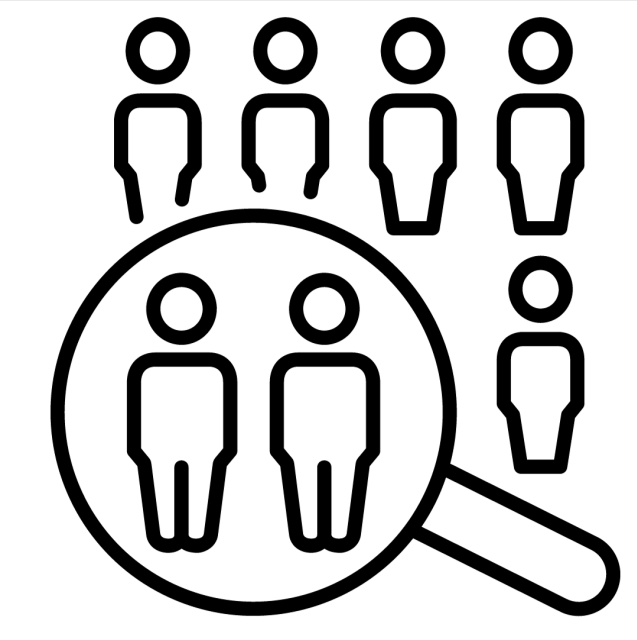
Sample Size



- Note, once IRB approves your study, you may not enroll beyond your sample size without first obtaining IRB approval.

Approach to Analysis

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Resources Available

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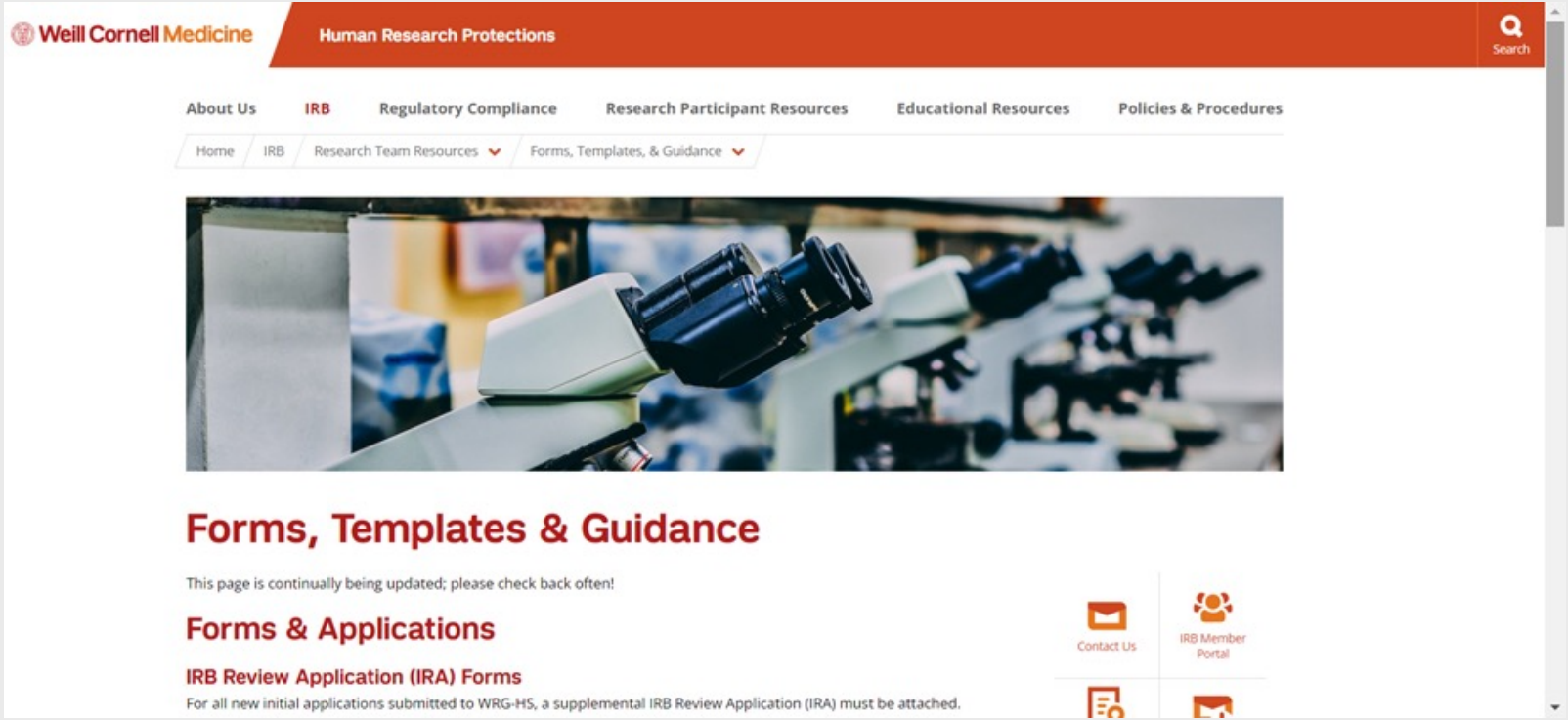
Forms & Applications

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.
- Medical Education IRA: Use this IRB Review Application if your study is minimal risk and qualifies under exempt category 1 only: *Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunities to learn required educational content or the assessment of educators who provide instruction.*
- 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 JCTO template, the Education Protocol Template and/or have a study which will use conduct social, behavioral, or educational research.

Where are the IRAs located?



Tips for Effective Communication with the IRB

Respond to feedback and address any concerns raised during the review process

Request a call with your pre-reviewer

Request a Consultation before your next IRB submission.

Third level copy

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Resources

Resources

Office of Human Research Protections website

https://hrp.weill.cornell.edu

Includes: Policies and Procedures
Submission Guidelines
Educational Materials
Staff Directory

Visit our Human Research Protections Monthly Education and Training Series (METS) page to watch recordings of our past METS presentations!

Need help? We are here for you!

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Contact Us

Scan the QR code to request a consult during our on-site
Tuesday, 1/9 through Thursday 1/11

Contact Us

IRB Member Portal

Forms, Templates & Guidelines

Request a Consultation

Weill Cornell Medicine Human Research Protections
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New York, NY 10022
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irb@med.cornell.edu

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