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New Initial IRB Review Process:

Initial Review Application (IRA) + Abbreviated WRG-HS Application

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Human Research Compliance Office

Thursday, September 1, 2022
https://research.med.cornell.edu/irb

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IRB Initial Review Application (IRA): Overview

An IRB-specific tool completed as part of the abbreviated WRG-HS initial application form

Streamlines and focuses the collection of all IRB-required ethical and regulatory information in one place increasing IRB compliance needs

Greatly reduced duplicative collection of information found in the previous WRG-HS application

Resides on the WCM IRB website allow for easier updates with no impact on WRG

3 study-specific versions:

- **Biomedical IRA**: Used in association with the Therapeutic JCTO Protocol template and/or for studies that will use a device/drug or implement a clinical trial.
- **Biorepository IRA**: Used for the establishment of a biorepository (storage and maintenance) for potential future use, not testing and research.
- **SBER and Records IRA**: Used in association with the Observational or Tissue Use/Chart Review JCTO template, the Education Protocol Template, and/or have a study that will conduct social, behavioral, or educational research.

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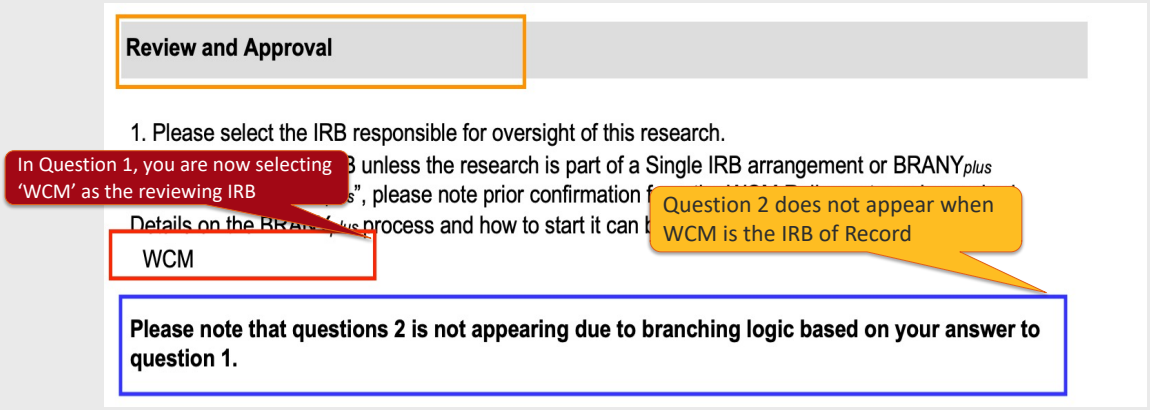
The New Abbreviated WRG-HS Initial Application



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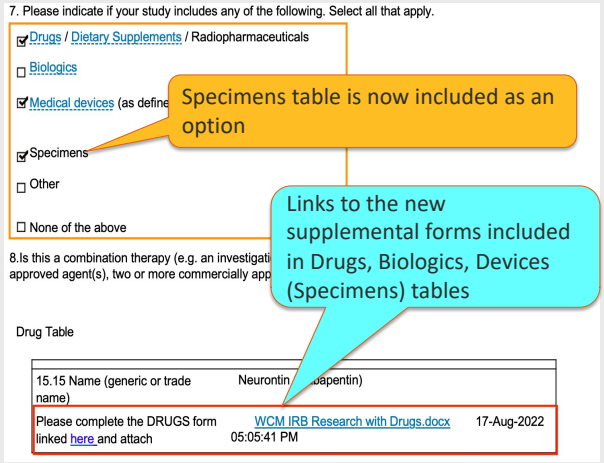
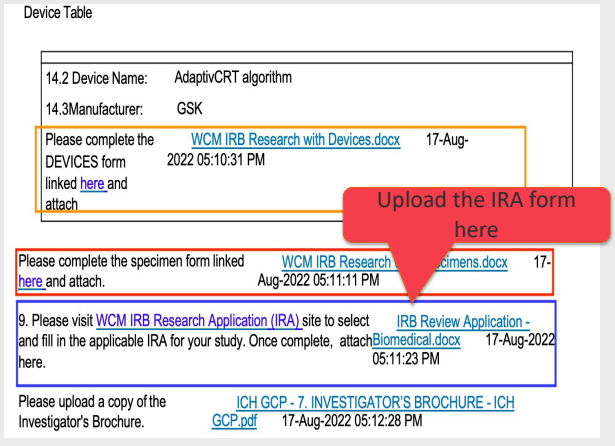
The New Abbreviated WRG-HS Initial Application, Cont.





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How does this change 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

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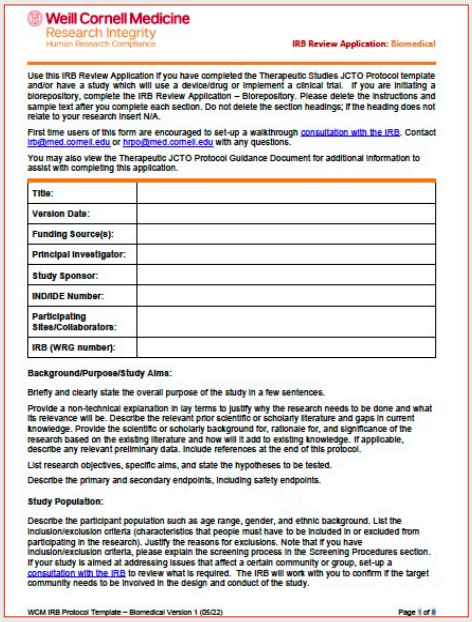
IRA and Abbreviated Initial Walk-Thru



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IRB Review Application: Biomedical

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.

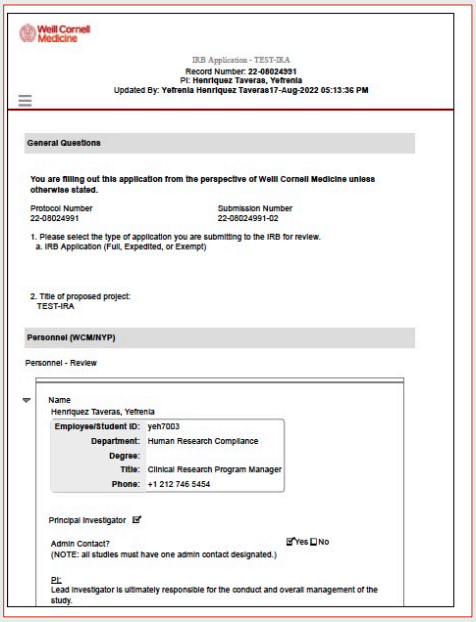
List research objectives, specific aims, and state the hypotheses to be tested.

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.

WCM IRB Protocol Template – Biomedical Version 1 (05/22) Page 1 of 8



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IRB Application - TEST-IRA
Record Number: 22-08024991
PI: Henriquez Taveras, Yefrenia
Updated By: Yefrenia Henriquez Taveras17-Aug-2022 05:13:36 PM

General Questions

You are filling out this application from the perspective of Weill Cornell Medicine unless otherwise stated.

Protocol Number: 22-08024991
Submission Number: 22-08024991-02

1. Please select the type of application you are submitting to the IRB for review.
a. IRB Application (Full, Expedited, or Exempt)

2. Title of proposed project:
TEST-IRA

Personnel (WCM/NYP)

Personnel - Review

Name
Henriquez Taveras, Yefrenia
Employee/Student ID: yeh7003
Department: Human Research Compliance
Degree:
Title: Clinical Research Program Manager
Phone: +1 212 746 5454

Principal Investigator ☑

Admin Contact? ☑Yes ☐No
(NOTE: all studies must have one admin contact designated.)

PI:
Lead investigator is ultimately responsible for the conduct and overall management of the study.

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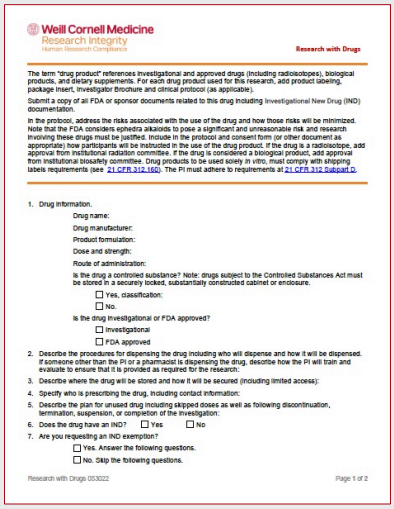
Other Supplemental Forms



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Research with Drugs

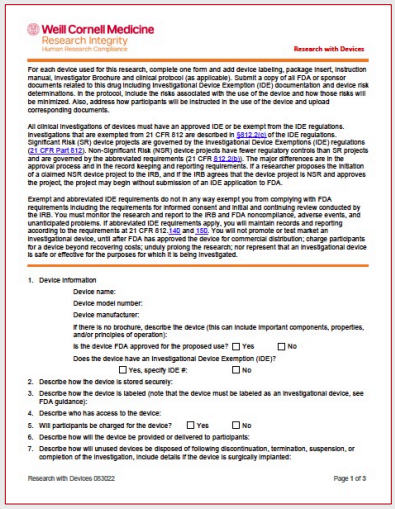
The term "drug product" references investigational and approved drugs (including radioisotopes), biological products, and dietary supplements. For each drug product used for this research, add product labeling, package insert, investigator brochure and clinical protocol (as applicable).

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 ephedra 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 radioisotope, 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 312.160). 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.

Research with Drugs 053022 Page 1 of 2



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Research with Devices

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 §12.2(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:

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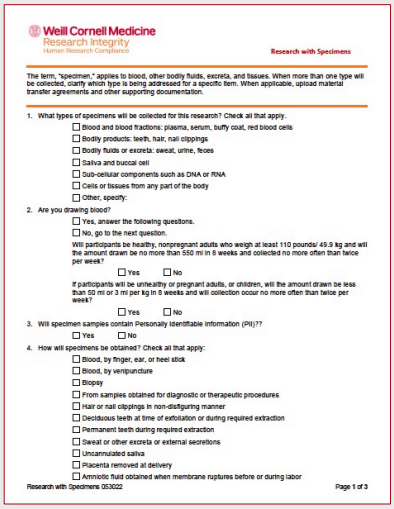

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Research with Specimens

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-disfiguring manner
   - ☐ Deciduous teeth at time of exfoliation or during required extraction
   - ☐ Permanent teeth during required extraction
   - ☐ Sweat or other excreta or external secretions
   - ☐ Unexamulated saliva
   - ☐ Placenta removed at delivery
   - ☐ Amniotic fluid obtained when membrane ruptures before or during labor

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Where do I find the IRAs and the other supplemental forms?

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

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 New Submissions must be attached to an IRB Review Appication (IRA). 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.
- SBER and Records IRA: Use this IRB Review Application if you have completed the Non-Therapeutic Studies or Tissue Use/Chart Review JSCO 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.

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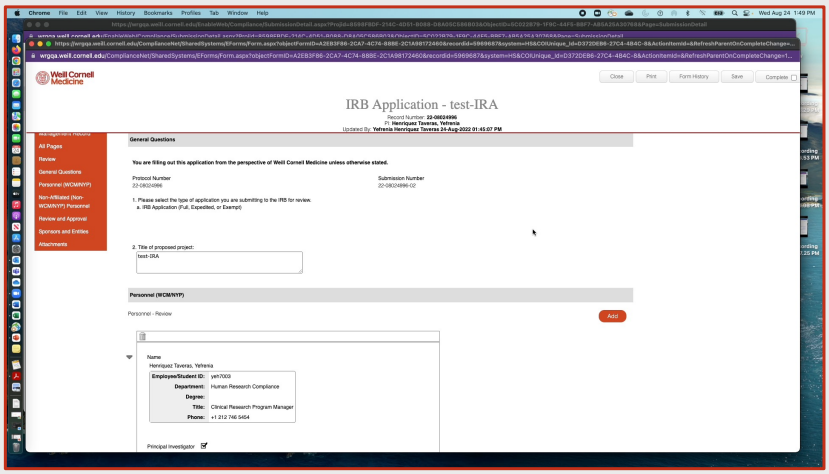
Abbreviated WRG-HS Initial + IRA mockup: WRG-HS



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Interim Abbreviated Application/IRA: Initial Application Implementation Efforts

- IRB meets with ITS' Research Admin team weekly
- Collected feedback from the IRB liaison working group (composed of heavy IRB/WRG-HS users)
- Conducted User Acceptance Testing (UAT) in collaboration with ITS' RA
- Provides the WCM research community with web-based resources, in-person consultations, and 2x week walkthroughs and training ahead of and post Go Live.

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FAQS

Q: Do the IRAs replace the protocol document?

A: No. The IRAs are forms specific to IRB review and determination and do not replace your protocol document. Note that your protocol document is used for other institutional requirements such as PRMC, CTSC, RSC, and/or IBC submissions.

Q: **Would I need to use the IRAs if submitting to BRANY via BRANYplus?**

A: No. the IRAs and other supplemental forms are to be used for studies where WCM is the reviewing IRB. If using BRANY, or any other external IRB as your reviewing IRB, then you'd continue to complete the corresponding protocol document only.

Q: When does the new requirement go into effect?

A: The IRAs will go live on September 15th, so any record created on or after this date will need to complete the IRAs as part of their submission.

Q: What if I've already started my intake/ initial prior to September 15th?

A: If created before September 15th, your record would still show the same sections and not the abbreviated version of it. In terms of the IRA requirement, submissions will be assessed on a case-by-case basis and IRA completion might be requested at the IRB's discretion.

Q. What if I am not certain which form to use, or have questions about completing it?

A: We invite you to make use of our consultation services, as well as reach out to our IRB listserv team for any further assistance.

Q: Would there be other training sessions available?

A: Yes! Training will also be available on Tuesday, 8/30, Tuesday, 9/6 Friday, 9/9, and lastly Monday, 9/12. Note that registration is required:

Date	Time	Registration
~~Wednesday 8/24~~	~~11:00am-12:00pm~~	~~register here~~
~~Thursday 8/25~~	~~12:00pm–1:00pm~~	~~register here~~
~~Tuesday 8/30~~	~~12:00pm–1:00pm~~	~~register here~~
Tuesday 9/6	12:00pm–1:00pm	register here
Friday 9/9	12:00pm–1:00pm	register here
Monday 9/12	12:00pm–1:00pm	register here

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Helpful Resources

or

Email:

WCM IRB Office: irb@med.cornell.edu

HRPO team: hrpo@med.cornell.edu

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Questions?

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