



## News & Announcements

### The New IRB Initial Review Application is live!

We are excited to announce that the New IRB Initial Review Application is now active. This Application will allow research teams to work on drafting their protocols outside of the WRG-HS system, thereby delaying the start of the 90-day submission completion clock that begins at initial intake.

**This form will capture the essential information needed by the IRB in their assessment of whether the protocol satisfies the regulatory criteria.**

Forms, templates, and guidance are available on our web site: <https://research.weill.cornell.edu/institutional-review-board/irb-policies-and-procedures/form-templates-guidance>

#### We want your feedback!

We will be holding IRB Town Hall sessions in the next month or two to hear your feedback and allow us to address any questions you might have after utilizing the Initial Review Application. Please look out for an email from us announcing the dates soon!

### September HRC METS, Take 2

We have rescheduled our September METS, cancelled due to a Zoom outage yesterday, for Thursday, September 29<sup>th</sup> – we hope you can join us:

#### **IRB 101: Regulating Research** **Ethics and the Responsible Conduct of Research**

Thursday, September 29<sup>th</sup>, 2022  
11:00am until 12noon

Please join us as we present a brief history of the evolution of human subjects protections in research and the general ethical principles guiding research regulations. We will also provide an overview of the various regulations that govern the responsible conduct of human subjects research and when they apply. This is an excellent opportunity for research team members to learn about the role of the IRB in ensuring that all human subjects research conducted within an organization meets the applicable guidelines and regulations governing the research.

**Registration is required!**  
Please register [here](#)

#### Future METS:

- 10/13/22: FDA-Regulated Research (Registration is open! Click [here](#))
- 11/17/22: Single IRB and Reliance
- 12/15/22: Tips and Tricks for Successful IRB Submissions and Reviews

## Did You Know?

### If you are using Protected Health Information (PHI) in your research and you need a HIPAA waiver:

Your study must meet the OHRP requirements set forth in 45 CFR 164.512(i)(2)(ii), which states that a waiver or alteration of HIPAA can be sought only if the following criteria are met:

- A) The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
- 1) an adequate plan to protect the identifiers from improper use and disclosure;
  - 2) an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
  - 3) adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;
- B) The research could not practicably be conducted without the waiver or alteration; and
- C) The research could not practicably be conducted without access to and use of the protected health information.

The protected health information for which use or access is sought is necessary for the research purposes."

### We Offer Our Consultation Services

We offer consultation hours to assist investigators, study coordinators, residents, and students with pre-review and other questions about IRB submissions.

Thirty-minute appointments are offered via Zoom during the following times:

**Mondays:** 11:00am – 1:00pm

**Thursdays\*:** 10:00am – 12:00pm, and 2:00pm – 4:00pm

Researchers may use their 30-minute session to receive assistance in:

- Determining the feasibility of a project and possible regulatory implications
- Pre-reviewing your draft IRB application, including your protocol and consent form
- General questions about the IRB and other regulatory requirements.

Click the button below now or find it at any time on any page of our website, to book a consult!



*\*Consultation services will not be available on Thursday, 9/22*

## Team Member Spotlight

### Meet Your IRB Navigator!

If you have ever used our consultation service or asked for help navigating the IRB submission process, it is almost certain you have interacted with Yefrenia. She is our Sr. IRB Navigator and "the face" of the IRB for many of you, so we felt it was time you met the person behind the help!



## Yefrenia Henriquez Taveras

*Sr. IRB Navigator/Clinical Research Program Manager*  
Human Research Protections Operations Team

I am a Public Health & Research Compliance Specialist with 12+ years of advanced-level expertise in socio-behavioral and biomedical research, strategic oversight, operational delivery, and regulatory compliance. Currently serving as the Senior IRB Navigator for WCM's Human Research Compliance office, I work directly with research departments and faculty members to facilitate the completion of necessary regulatory and compliance processes surrounding WCM's active and growing clinical research portfolio.

Outside of WCM, I am currently pursuing a Doctorate in Healthcare Quality & Analytics, and during my free time, I enjoy reading the latest science fiction book, watching an 'oldie but goodie' horror flick, traveling, baking and volunteering my translation services to community-based organizations.



Have general questions about the IRB, or need help with your submission? [Email the IRB Team!](#)



Would you like to set up training for your lab or department? [Email the Operations Team!](#)

For more information, visit us at <https://research.weill.cornell.edu/irb>