Weill Cornell Medicine
Research Integrity
Human Research Compliance

IRB NEWS

Sept 15, 2022

News & Announcements

Submitting a New IRB Application?

As of 9/15/2022, all new applications must utilize the new **IRB Initial Review Application** (IRA). Forms, templates, and guidance are available on the Forms, Templates, & Guidance page on our web site.

Why the new application?

The IRA has been designed to capture the essential information needed by the IRB in their assessment of whether the protocol satisfies the regulatory criteria, facilitating faster turn-around times for protocol review.

How does this benefit the researcher?

In addition to decreasing the overall wait time from submission to approval, use of the IRA enables 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.

How do I use the IRA?

We recommend utilizing our Consultation Service for assistance in preparing your new initial submission utilizing the new IRB Initial Review Application. Click the request button now or find it at any time on any page of our website, to book a consult!

News from the Regulatory Agencies

The **NIH Offices of Science Policy (OSP) and Extramural Research (OER)** recently co-hosted a two-part webinar series focused on implementing the NIH Data Management and Sharing (DMS) Policy, and it's now available for viewing on the NIH Data Scientific Data Learning Page.

- The first webinar, ***Understanding the New NIH Data Management and Sharing (DMS) Policy***, took place on 08/11/22 and focused on DMS policy expectations, the applicability of the policy, how to prepare a Data Management and Sharing Plan, and considerations for responsible data sharing.
- Part two, ***Diving Deeper into the New NIH Data Management and Sharing Policy***, took place on 09/22/22 and dove deeper into specific topics and questions they've heard from the community, such as privacy protections for sharing data from human participants.

For more information visit: NIH's Data Management and Sharing Policy Overview
and/or NIH's FAQs for its library of answers to frequently asked questions about the DMS policy.

Upcoming Trainings

HRC METS: Single IRB and Reliance

Thursday, November 17, 2022
11:00am – 12noon

Please join us for our next METS session presented by our very own Single IRB Administrator and Reliance Manager, German Jimenez! The goal of Single IRB review is to enhance and streamline the IRB review process for multi-site research so that research can proceed without compromising ethical principles and protections for human

research participants. This presentation will help provide education to WCM investigators, study teams and research administrators on the concept of a Single IRB model in multi-site research.

After this educational session, you will be able to:

1. Understand what Single IRB review is
2. Recognize what types of studies must comply
3. Explain the overall process for obtaining Single IRB review
4. Plan for Single IRB review for a multi-site research study

Registration is required to attend
Please register here

Future METS:

- **12/15/22**: Tips and Tricks for Successful IRB Submissions and Reviews
- **1/12/23:** Cultural Competency and the Responsible Conduct of Research
- **2/16/23**: Data Security in Research: PHI, Email, HIPAA, and You
- **TBA**

For more information or recordings of past METS, please visit our website

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ClinicalTrials.gov Quarterly Training

Thursday, November 3, 2022
1:30pm – 3:00pm

Registration is required to attend.
Please register here with your WCM email address.

This training will include:

- An overview of federal regulations, NIH policy, and journal requirements
- How to properly register and maintain a ClinicalTrials.gov record
- Results entry overview
- Q & A session

ClinicalTrials.gov Training on Demand

Unable to make the regularly scheduled ClinicalTrials.gov training? Email us with your training or help request or view a video of a prior training here.

Future Quarterly Training Dates

All training dates occur on a Thursday from 1:30pm – 3:00pm

- February 2, 2023
- May 4, 2023
- August 3, 2023
- November 2, 2023

For more information, please visit our website

Policy Alert!

The Office of Human Research Compliance (HRC) is pleased to deliver our latest batch of policy documents. HRC is working on policies to improve transparency and clarify expectations between the IRB and the research community. Policies allow for common reference point for all stakeholders engaged in human research at WCM and from these policies, HRC will be publishing guidance documents to further clarify best practices for ethical conduct of research. HRC will be releasing several more policies in the coming months and please note that these policies are living documents that will be revised regularly to ensure that they not only reflect any updates to IRB processes, but also to ensure that they reflect processes the support successful conduct of ethical research.

- 200.1 Staff Processing of Submissions.pdf

- 201.1 Exempt Review.pdf
- 202.1 Initial Expedited Review.pdf
- 203.1 Initial Full Board Review.pdf
- 204.1 Changes to Approved Research.pdf
- 205.1 Continuing Review.pdf
- 206.1 Study Closure.pdf
- 207.1 IRB Meeting Conduct.pdf
- 300.1 Research Supported by the Department of Defense

For the complete list of policy documents we have published to date, please visit our Policies and Procedures page

Did You Know?

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:

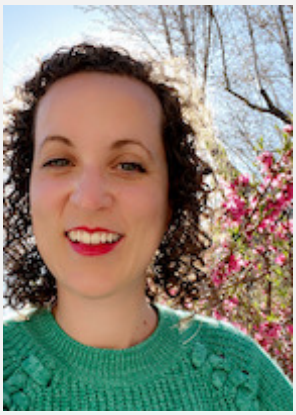
Mondays: 11:00am – 1:00pm
Thursdays*: 10:00am – 12:00pm, and 2:00pm – 4:00pm

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.

Team Member Spotlight

Meet a member of our Human Research Protections Operations Team! Brooke is one of our three QA Managers who have been tasked with evaluating and improving our internal processes as part of our IRB Transformation. The policy documents we have published in the past 10 months have been spearheaded by Brooke, who brings her deep knowledge of regulatory compliance to serve our community!



Cecilia Brooke Cholka, PhD CIP
Human Research QA and Education Manager
Brooke is a Certified IRB Professional and has 10 years of experience in research administration; she is also a co-founder and co-facilitator of the SBER Network, a professional community for social, behavioral, and educational research IRB professionals. As part of her passion for IRB, she has presented at several national conferences including Advancing Ethical Research (AER) Conference, Social, Behavioral, and Educational Research (SBER) Conference, AAHRPP Annual Conference, and is a contributing author to the third edition of *IRB Management and Function* by Bankert, Gordon, Hurley, and Shriver (Eds). In addition to her work in IRB, she has a PhD in Health Communication and has 17 years of research experience. In her time off, she hikes with her schnauzers, sings a cappella in four-part harmony, and enjoys traveling.

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