Weill Cornell Medicine
Research Integrity

A message from the office of Human Research Protections

IRB NEWS

October 15, 2023

News & Announcements

Are you using Digital Health Interventions (DHI) in your research?

The decision to use a digital health intervention (DHI) requires consideration of multiple factors before using for research. Please make sure you are familiar with the guidance recently published by the WCM Compliance & Privacy Office: Using Digital Health Interventions Guidance for WCM Faculty, available on their Privacy Policies/Guidance & Best Practices web page.

Engaging in a multi-site study requiring the use of a single IRB?

Decisions about whether Weill Cornell Medicine will enter into a Reliance Agreement, whereby the WCM IRB will rely on an external IRB, or will review for other institutions, are handled on a protocol-specific, case-by-case basis once those requests have been submitted. To initiate a reliance request for IRB, complete the WCM reliance request form.

For more information, please visit our Single IRB Reliance page, where you can find answers to frequently asked questions, our recently published sIRB and Reliance SOP, and download the Non-WCM sIRB Submission Checklist.

Registration is open for a special presentation by the MRCT Center

The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard invites us to a special presentation:

Amplifying Participant Voices: Crafting Respectful, Inclusive, and Understandable Patient Materials

October 23, 12noon – 1pm EST

As we celebrate Health Literacy Month, we invite you to join us on October 23 from 12-1 PM ET to explore practical and actionable strategies for incorporating participant perspectives to craft patient-facing materials that are accessible, culturally competent, and easy to understand - the key tenets of health literacy. This inclusive approach is pivotal in fostering trust, enhancing engagement, empowering patients, improving communication, and addressing knowledge gaps. By honing the relevance and effectiveness of health information, we pave the way for improved health outcomes and enriched participant experiences.

Register here

Did You Know?

Conducting a clinical trial at WCM? The Data Safety and Monitoring Committee (DSMC) is here to help!

The Weill Cornell Medicine Data and Safety Monitoring Committee (WCM DSMC) is an independent committee within the institution that is available to the research community to act as a monitoring entity for clinical trials. It performs a regular review of cumulative data to evaluate research subject safety, rates of accrual, and efficacy of experimental intervention. Based on its review, the WCM DSMC provides investigators with recommendations for protocol modification, continuation or termination. The intensity and frequency at which the WCM DSMC monitors a study is commensurate with the study's risks and needs.

We have recently upgraded the DSMC page on our website with an expanded FAQ section and updated guidance documents! For more information, please visit us at http://hrp.weill.cornell.edu.

Topic of the Month: Single Patient IND

Single Patient IND: Expanding Access to Investigational Drugs

Expanded access is a potential pathway for a patient with an immediately life-threatening condition or serious disease or condition, to gain access to an investigational medical product to treat their condition outside of a clinical trial.

A single patient IND allows a single patient to access an investigational drug that is not yet approved for use by the FDA. Single-patient INDs can be emergent (there is little or no time for IRB review) or non-emergent. In the rare emergent situation when there is insufficient time for IRB review prior to the use of the investigational drug, the treating physician may proceed with the emergency use and notify the IRB within 5 working days from the time of use. In all other scenarios, IRB review must occur prior to use of the investigational drug. Note, by checking "10b" on the FDA 3926 form (emergent or nonemergent), you may request a waiver of convened IRB review and approval. If approved by the FDA, the IRB Chair/delegate will concur the expanded access request and full IRB review and approval will not be needed. Note, informed consent is required and a template for "Single Patient Investigational Treatment" can be found on our website.

The treating physician should contact the WCM IRB (IRB@med.cornell.edu) before use of the investigational drug for assistance with determining when there is or is not sufficient time for the IRB to review the request prior to treatment use. You may also use WCM's Researcher Checklist: Obtaining Expanded Access IND for Treatment of Individual Patients for guidance.

Do you have an IND (or an IDE)? Check out ReGARDD!

ReGARDD (Regulatory Guidance for Academic Research of Drugs and Devices) has resources for you! ReGARDD resources are compiled by a group of regulatory affairs specialists from several institutions under a project funded by the NIH Clinical and Translational Science Awards (CTSA) Program. Check out their educational videos here: https://www.regardd.org/videos. And take a look around their website for other great resources!

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://hrp.weill.cornell.edu.