News & Announcements

Conducting an industry-sponsored, industry-initiated study?

Industry-sponsored and industry-initiated studies must utilize a commercial IRB.

- The WCM IRB suggests using the commercial IRB used by the Sponsor.
- For studies where the Sponsor does not designate a commercial IRB, studies will be directed to BRANY.*

*Remember to build the cost of BRANY into your budgets!
Refer to the JCTO Budget Development & Cost web page for details.

Conducting an investigator-initiated study?

Please join our very own Senior Human Research Compliance Specialists, Lauren Odynocki and Kelly Ann Balem, RN, CPN, at tomorrow’s TWIST presented by the JCTO:

Study Activation: Resources for Investigator-Initiated Studies

Wednesday, February 15th, 2023
11:00am until 12noon

Study start-up for Investigator-Initiated Studies (IIS) can seem overwhelming. This month’s TWIST will help study teams understand some of the resources at WCM for IISs. Join us as we review the requirements related to posting a study on ClinicalTrials.gov (“CT.gov”). Learn about the types of studies that utilize the Data Safety Monitoring Committee (DSMC) and how to submit to have a study reviewed. Understand how to develop a data capture system using REDCap or REDCap Cloud.

https://weillcornell.zoom.us/j/94088238364
+1 646 876 9923 US
+1 646 931 3860 US
Meeting ID: 940 8823 8364

Working with Protected Health Information?

Please join us for this month’s METS:

Data Security in Research: PHI, Email, HIPAA and You

Thursday, February 16, 2023
11:00am until 12noon

In this session, we review the IRB’s role as Privacy Board by exploring the different regulatory pathways to utilizing Protected Health Information (PHI) in research according to the Health Insurance Portability & Accountability Act (HIPAA) of 1996. Discussion will include how to determine when your research needs a full or partial HIPAA waiver as opposed to prospective HIPAA Authorization from subjects, and other scenarios.
We’ll also discuss what you can do to protect research subjects’ PHI when transmitting it via email and how to report to the IRB in the event of an accidental disclosure.

Registration is required; please register [here](#).

**Future METS**
- 3/16/23: Submitting Your Study to the IRB: A Step-by-Step Guide (register [here](#))
- 4/13/23: IRB101: An Introduction to the WCM IRB (register [here](#))
- 5/18/23: The Informed Consent Form: Regulatory Requirements and Ethical Obligations (register [here](#))

**Did You Know?**

The Research Team Resources page on the IRB web site has all the information you need to prepare your IRB submission! On this page you will find answers to common questions such as, “How do I know if I am conducting research with human subjects?” and “Does the NIH Single IRB Policy apply to my research?” The subpages include information on:

- Research Team Training & Education – this page outlines what training is required of study team members and appropriate sources of information or links to the trainings themselves
- Submitting to the IRB – this page has all the information you need to prepare and submit your study for IRB review, with helpful sections such as, “How do I get started? A step-by-step guide,” which outlines each step toward a successful IRB submission.
- Project Guidance – this page outlines the elements the IRB looks for when reviewing research (both initial and continuing reviews)
- FDA-Regulated Research Guidance – this page provides guidance on determining whether or not FDA regulations apply to your study, and guidance documents to assist you in preparing your submission.
- Forms, Templates, & Guidance – here is where you will find the IRB Review Application (IRA) forms, supplemental forms, and guidance documents to utilize in your submission.

And of course if there are any questions that aren’t addressed on our site, you can always reach out to us for a consultation by clicking the “Request a Consultation” button below (this button also appears on every page throughout our web site).

For more information, visit us at [https://research.weill.cornell.edu/irb](https://research.weill.cornell.edu/irb)