Weill Cornell Medicine
Research Integrity
Human Research Compliance

April 15, 2023

IRB NEWS

News & Announcements

Reminder: Sign up for the next ClinicalTrials.gov Training

Join Lauren Odynocki, Sr. Compliance Analyst and ClinicalTrials.gov Administrator, as she covers regulatory requirements and practical, nuts-and-bolts information about how to successfully register trials, maintain public records, and post results.

Thursday, May 4th, 2023
1:30pm – 3:00pm
Registration required: Register with your WCM email address here

Conducting an industry-sponsored, industry-initiated trial?

Industry-sponsored/initiated trials are ***NOT*** eligible for BRANYplus; they **must** go to the industry-sponsored designated commercial IRB **or**, if no IRB has been designated, BRANY (***NOT*** BRANYplus). Please **STOP all BRANYplus steps and complete the correct reliance request form in Qualtrics**

Once received, we will be able to determine if Weill Cornell Medicine IRB can rely on BRANY, or if a different type of submission to our IRB is more appropriate.

Please also see the reliance request guidance document available on the IRB website for more details of the WCM workflow, or you can email us at singleirb@med.cornell.edu with any questions!

Attention: Researchers with NIH-Funded Clinical Trials

The NIH has ramped up its enforcement actions for noncompliance with the requirement to publicly post summary results on ClinicalTrials.gov within 12 months of the completion of data collection. Noncompliance can affect release of NIH funds and, if a study is FDA-regulated, can result in significant fines.

Follow These 5 Tips to Stay Compliant

1. Know that results are due for NIH-funded clinical trials within 12 months of the completion of primary outcome data *collection*, not analysis.
2. Within 30 days of completing data *collection* for primary outcome measures, update your ClinicalTrials.gov record's "primary completion date" at https://register.clinicaltrials.gov so the ClinicalTrials.gov Program can immediately advise you of the results submission deadline and provide you with guidance
3. Review what summary results are required by clicking here
4. View our institutional resources at https://research.weill.cornell.edu/clinicaltrialsgov
5. Request a help session or additional guidance by emailing us at registerclinicaltrials@med.cornell.edu

Other News from the Regulatory Agencies

From the National Institutes of Health:

Explore the recordings, slide sets, and transcripts from the NIH's recently held conference:

- **Human Subjects Research: Policies, Clinical Trials & Inclusion 12/7/2022** (view: transcript)

        - An Overview of NIH Policies on Clinical Trials (view: slides)
        - Including Diverse Populations in NIH Research (view: slides)
        - Using the Human Subjects System (HSS) (view: slides)
    - **Human Subjects Research: Policies, Clinical Trials & Inclusion 12/6/2022** (view: transcript)
        - How do I Know if a Research Study is Human Subjects Research (view: slides)
        - What You Need to Know About FWAs and IRBs (view: slides)
        - An Overview of NIH Policies on Human Subjects Research (view: slides)
        - Essentials of sIRB Requirements (view: slides)

From The Office of Human Research Protections:

Explore educational videos provided by the OHRP:

- Doing Research with Data and Biospecimens under the Common Rule Part 1 – What Researchers Should Know (view slides)
- Doing Research with Data and Biospecimens under the Common Rule Part 2 – How Does that Work with Repositories and Future Use? (view slides)
- Before Saying "I Do" to the Common Rule: Figuring out "Engagement" (view slides)
- Respecting Persons – From Basic Requirements to Embracing Participant-Centered Informed Consent (view slides)

Did You Know?

We have a growing library of Training and Educational Videos for use by research teams during onboarding of new staff members:

101 Courses: the Basics

- IRB101: An Introduction to the WCM IRB (Click here for the pdf handout)
- REGS101: ClinicalTrials.gov (Click here for the pdf handout)

HRC Trainings

- ClinicalTrials.gov Quarterly Training 2/2/2022 (Click here for the pdf handout)

IRB Guidance: Tips, Tools, and Informational Videos

- The New IRB Initial Review Application (Click here for the pdf handout)
- IRB Guide: Checking Readability Scores (Click here for the pdf handout)
- The Key Information Section: A 2018 Common Rule Requirement for the Informed Consent Form (download a pdf handout here)

Previous METS

- IRB101: The Informed Consent Form: Elements of the Informed Consent Form, Checking Readability, and Ensuring Understanding (Click here for the pdf handout)
- IRB101: Regulating Research: Research Ethics and the Responsible Conduct of Research (Click here for the pdf handout)
- FDA Regulated Research: An Overview (Click here for the pdf handout)
- Single IRB: An Overview (Click here for the pdf handout)
- Tips & Tricks for a Successful IRB Submission and Review (Click here for the pdf handout)
- Cultural Competence and the Responsible Conduct of Research (Click here for the pdf handout)
- Data Security in Research: PHI, Email, HIPAA, and You (Click here for the pdf handout)
- Submitting an IRB Application: A Step-by-Step Guide (Click here for the pdf handout)

If there is a topic you are interested in that is not listed above, let us know by emailing hrpo@med.cornell.edu!

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