

Weill Cornell Medicine
Research Integrity

A message from the office of Human Research Protections

IRB NEWS

Special Year-End Edition: December 30, 2023

2023 YEAR IN REVIEW

Thank you from all of us in Human Research Protections

We are closing out this year with **much gratitude** to you, our WCM research community. Your continued support and feedback have allowed us to carry over the successes we achieved in 2022 through our IRB transformation initiative, into 2023:

- **9,701 IRB submissions processed**
- **Average completion times** for IRB submissions remained steady or decreased:
  - ✓ 56 days in 2023 for **Initial Full Committee** submissions, compared to 112 days in 2022, a **50% decrease**
  - ✓ 32 days in 2023 for **Initial non-Committee** submissions, compared to 40 days in 2022, a **20% decrease**
  - ✓ 13 days in 2023 for **Initial non-WCM** submissions, compared to 13 days in 2022, **remaining consistent**
  - ✓ 7 days in 2023 for **Amendments** submissions, compared to 10 days in 2022, a **30% decrease**
  - ✓ 13 days in 2023 for **Continuing Review** submissions, compared to 25 days in 2022, a **48% decrease**
- A **56% increase** in the number of **one-on-one consultation requests** filled, from 250 (2022) to 390 (2023)
- A **16% increase** in the average attendance at our **Monthly Education and Training Series (METS)**, from 99 (2022) to 115 (2023)

FDA Inspection: PASSED!

The FDA conducted a routine audit of our office in June. Due to our improvement initiatives implemented in the past year, we were able to quickly and comprehensively demonstrate our action plans and processes. Our prompt and thorough response resulted in a non-issuance of findings, the best possible outcome!

NEW IN 2023

Our Name Change

Moreso than Human Research Compliance, **Human Research Protections** *encapsulates the vital role we play in ensuring that all research teams adhere to the highest standards of ethical conduct and regulatory compliance, ultimately protecting the individuals who participate in our research.*

New Studies Working Group

The New Studies Working Group is a rotating group of IRB analysts who meet twice a week with staff regulatory experts to pre-review and discuss all new WCM IRB submissions. This group was formed to improve compliance and efficiency of review, as well as QA current workflow and processes to identify potential areas of improvement and resource needs.

Improved Single IRB/Reliance Process

The WCM Single IRB policy was updated to streamline the IRB review process for multisite research and to avoid administrative burden to our investigators. This policy provides clarity on the criteria for determining who can serve as IRB of Record and procedures for when an External IRB or WCM IRB will serve as Reviewing IRB for multisite research at WCM.

Informed Consent Template Library

- Assent Template
- Biomedical Consent
- Humanitarian Use Device Consent
- Informed Consent Addendum
- Intermediate-Size Investigational Treatment Consent
- Pregnant Partner Non-Subject Consent
- Pregnant Partner Research Subject Consent
- Repository Consent
- Social Behavioral Education Research Consent
- Single Patient Investigational Treatment Consent

New Guidance Documents/Templates

- Amending an Existing Protocol vs. Submitting a New One **Guidance**
- Assessing Capacity to Consent **Guidance**
- Determining Engagement **Guidance**
- Medical Education IRB Review Application (IRA) **Template**
- Not Human Subjects Research (NHSR) **Guidance**
- Single IRB Submission **Checklist**

Best Wishes for a Happy New Year!

All of us at HRP are looking forward to what the new year will bring us, and we hope you will continue to reach out to us and make us partners in your research endeavors. Remember you can find us any time at hrp.weill.cornell.edu!

Contact Us | IRB Member Portal

Forms, Templates & Guidelines | Request a Consultation

Weill Cornell Medicine Human Research Protections
575 Lexington Avenue
New York, NY 10022
Phone: (646) 962-8200