

Welcome!

- The session will begin shortly; if you are joining us on Zoom, please take a moment to make sure your microphone is muted.
- The presentation portion of this session will be recorded.
- Not registered? Please register now using the QR code.



Working with Columbia

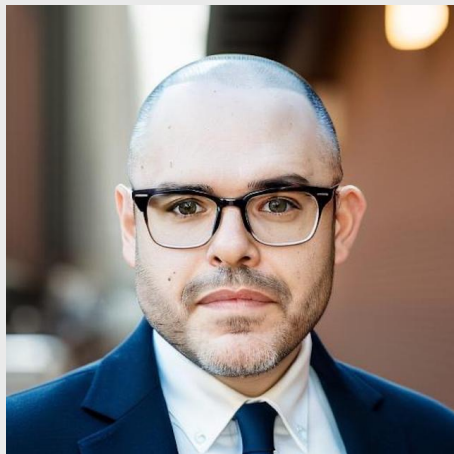
IRB submission considerations when
both sites are engaged



Rui Ferreira, MA, CIP
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Rui Ferreira, MA, CIP



9+ years of experience in human research protections,

10 years of research experience in quantitative neurophysiological and neurocognitive endophenotypes in schizophrenia with associated publications and conference presentations

Joined WCM in 2021

Topics

Overview: NewYork-Presbyterian (NYP) Collaborative Affiliations

Human Subjects Research at Weill Cornell Medicine (WCM)
Columbia University Medical Center (CUMC)

Single IRB (sIRB) Considerations



New York Presbyterian:



Affiliated, yes, but separate legal entities

Federal Wide Assurance (FWA)

Per DHHS 45 CFR Part 46.103:



FWA is a commitment by an institution and its researchers to comply with federal regulations for human subjects research.



Obtained from the Office for Human Research Protections (OHRP).



Mandatory for institutions and researchers engaged in DHHS-supported or conducted research.



IRB review is required for **research**
involving **human subjects**



What is Research?

45 CFR 46.102(I)

- **Research** means a **systematic** investigation including research development, testing and evaluation, **designed** to develop or contribute to **generalizable knowledge**.

FDA definition 50.3(c) and 50.3(j)

- **Clinical investigation** means any experiment that involves a test article and one or more human subjects, and that either requires prior submission to the FDA or when the results will be used to support an application for a research or marketing permit.
- **Test article** means any drug (including a biological product), medical device, food additive, color additive, electronic product, or any other article subject to FDA oversight.



What is Human Subjects Research?

A **living** individual **about whom** an investigator obtains:

- Data through intervention or interaction with the individual, OR
- Identifiable private information

Per the FDA, subject means a human who participates in an investigation:

- Either as a recipient of the new test article or as a control.
 - A subject may be a healthy human or a patient with a disease. [21 CFR 312.3(b)]
- Either as an individual on whom or on whose specimen a test article is used or as a control.
 - A subject may be in normal health or may have a medical condition or disease. [21 CFR 812.3(p)]



What is Engagement?

An Institution becomes “engaged” in human subjects research when its employees or agents for the purposes of a non-exempt research project obtain:

1. Data about the subjects of the research through intervention or interaction with them;
2. Identifiable private information about the subjects of the research; or
3. The informed consent of human subjects for the research.



WCM IRB is the IRB of Record For:

- **NewYork-Presbyterian Hospital – Cornell Campus**
- **Gracie Square Hospital**
- **Lower Manhattan Hospital**
- **Westchester Behavioral Health**



NYP-WCM FWA#:
00033325



Weill Cornell Medical
College FWA#:
00000093



CUMC IRB is the IRB of Record For:

- NewYork Presbyterian Hospital-168th Street Campus
- Allen Hospital
- NYP Westchester
- Hudson Valley Hospital



NYP-Columbia
FWA#: 00003831



Human Subjects Research at WCM and CUMC



What do I do when a collaborative Human Subjects Research (HSR) project with CUMC is proposed?



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
irb@med.cornell.edu

Consult with the WCM IRB



Weill Cornell Medicine

WCM/CUIMC Collaborative Study Evaluation Form

Study Details:

Study Title:

WCM PI:

CUIMC PI:

WCM Protocol #:

WCM Protocol Status: Approved, Exempt, Under IRB Review, Other

CUIMC Protocol #:

CUIMC Protocol Status: Approved, Exempt, Under IRB Review, Other

Study Summary:

Submit a Collaborative Study Evaluation Form



Weill Cornell Medicine

What is evaluated when research is proposed at both sites?

Investigators
involved

Research
activities


Funding


Study status




Possible outcomes:

 Neither site is engaged in research - no IRB submission required

 Only one site is engaged in research - submit to only one IRB

 Both sites are engaged in research - submit to both IRBs

 Both sites are engaged in research - submit to only one IRB
(WCM/Columbia/3rd party)

Example Scenarios:

1. A WCM investigator engaged in HSR has asked their colleague at CU for help recruiting participants from a CU site

2. Investigators at WCM and CU are collaborating on a secondary data analysis study that is only receiving coded/deidentified private information or specimens

4. Investigators at WCM and CU are collaborating on a survey study with all recruitment and data collection happening at CU. WCM is only working with de-identified data

3. WCM and CU Investigators are proposing HSR as part of a federally funded study

5. WCM and CU Investigators are proposing HSR as part of a non-federally funded study



Example Scenarios:

WCM: Engaged. Submission to the WCM IRB required.

CUMC: Likely qualifies as exempt. Follow CUMC IRB requirements.

WCM: Likely qualifies as exempt. Submission to WCM IRB is recommended.

CUMC: Engaged. Submission to the CUMC IRB required.

WCM: Not engaged, Submission to WCM IRB is recommended.

CUMC: Not engaged, consultation with CU IRB recommended.

sIRB mandate applies and both sites are expected to establish reliance.

Both sites would be engaged and may qualify for either sIRB or standalone subs at each site.



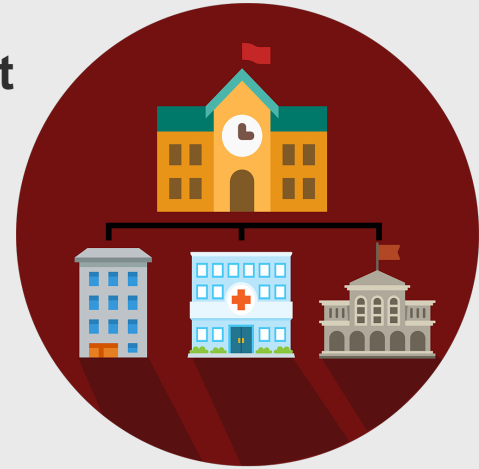
Single IRB Considerations



sIRB:

The single IRB (sIRB) mandate is a requirement that applies to:

- Federally supported studies
- Involving multiple sites
- Conducting collaborative non-exempt human subjects research



Requires all sites involved to rely on one IRB for federal regulatory oversight of the research



Takeaways

Secondary Title



Takeaways:



When research is proposed at both WCM and CUMC, reach out to the WCM IRB to confirm the best course of action



To avoid unnecessary burden at either site, begin discussions as early as possible in the study development process



Resources

- **WCM/CUMC Evaluation Form**
https://weillcornell.azure1.qualtrics.com/jfe/form/SV_08mDhEwZKj3FGS2
- **WCM IRB Website**
hrp.weill.cornell.edu
- **IRB Consultation Service**
https://weillcornell.azure1.qualtrics.com/jfe/form/SV_8B8nCOcC8q7pUN0
- **WCM IRB Office**
irb@med.cornell.edu



Contact Us



IRB Member
Portal



Forms,
Templates &
Guidelines



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Research Protections**
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Weill Cornell Medicine

Contact Us



Scan the QR code to
request a consult
during our on-site
Tuesday, 1/9 through
Thursday 1/11



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