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Welcome!

- The session will begin shortly; 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.

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Grant & IRB Crossover

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Senior Manager, Sponsored Programs

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

Monia Mariani-Besch, MS, CRA

20+ years of experience in sponsored research administration

13 years of experience with sponsored research in academic settings, with focus on pre-award.

Joined WCM in 2020

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Today's Presentation

- Overview
- Grant Process
- HSR Considerations
- sIRB Requirements
- Pre-Post Score Planning

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Overview

Secondary Title

Office Roles

OSRA Grants

Responsible for:

- Addressing questions during proposal development, review, and submission process.
- Providing guidance and review feedback to PIs and departments based on sponsor guidelines, previous experience, and expertise.
- Handling submissions depending on sponsor and submission guidelines.

IRB

Responsible for:

- Ensuring that the rights and welfare of human subjects in research are protected.
- Ensuring all human subject research activities are conducted ethically, and in compliance with federal regulations, the requirements of applicable NYS and local laws, and institutional policies and procedures.
- Approving, modifying, and/or disapproving human subject research in accordance with the Common Rule and FDA regulations

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Grant Application Process

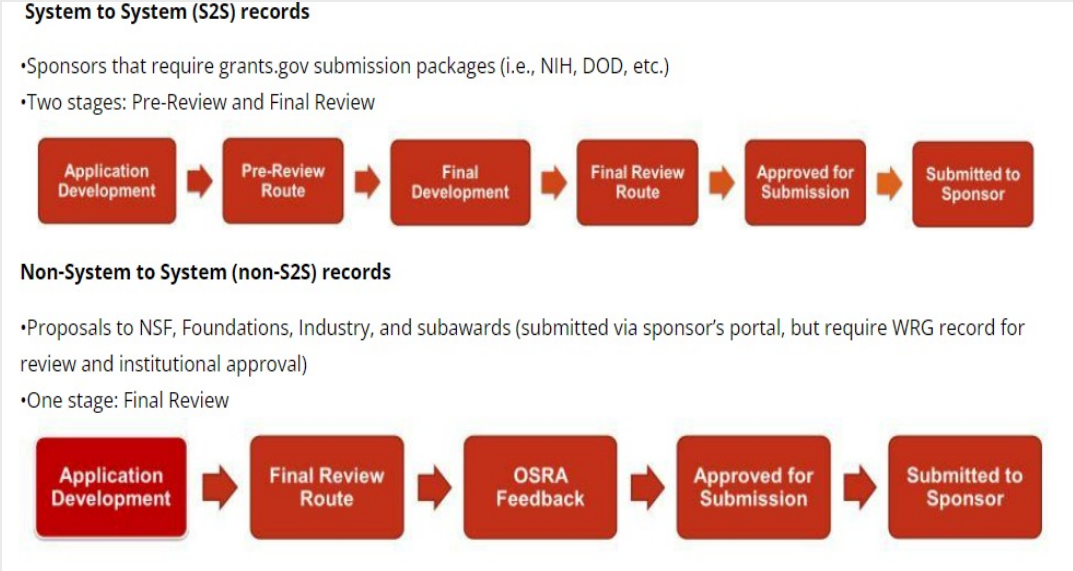
Grant Planning & Writing Stage

- **HS Study Record Development:**
  - Identify involvement of HS in the project, based on the NIH definition of HS research
  - Consulting with IRB in case of questions about HS determination and exemptions
  - If a multi-site project, verify if Singe IRB requirement applies and discuss who will serve as sIRB of record with the IRB office

- **Budget Development for sIRB**
  - Verify if HS needs of the project are properly covered in the budget
  - If Single IRB, ensure costs have been budgeted accordingly

Grant Review & Submission Stage

- ALL applications need to be submitted to OSRA via WRG for full review and approval prior to submission
- Draft application - **7 business days** of the submission deadline.
- Final application - **2 business days** of the submission deadline.



Engaging IRB prior to review stages is highly recommend!

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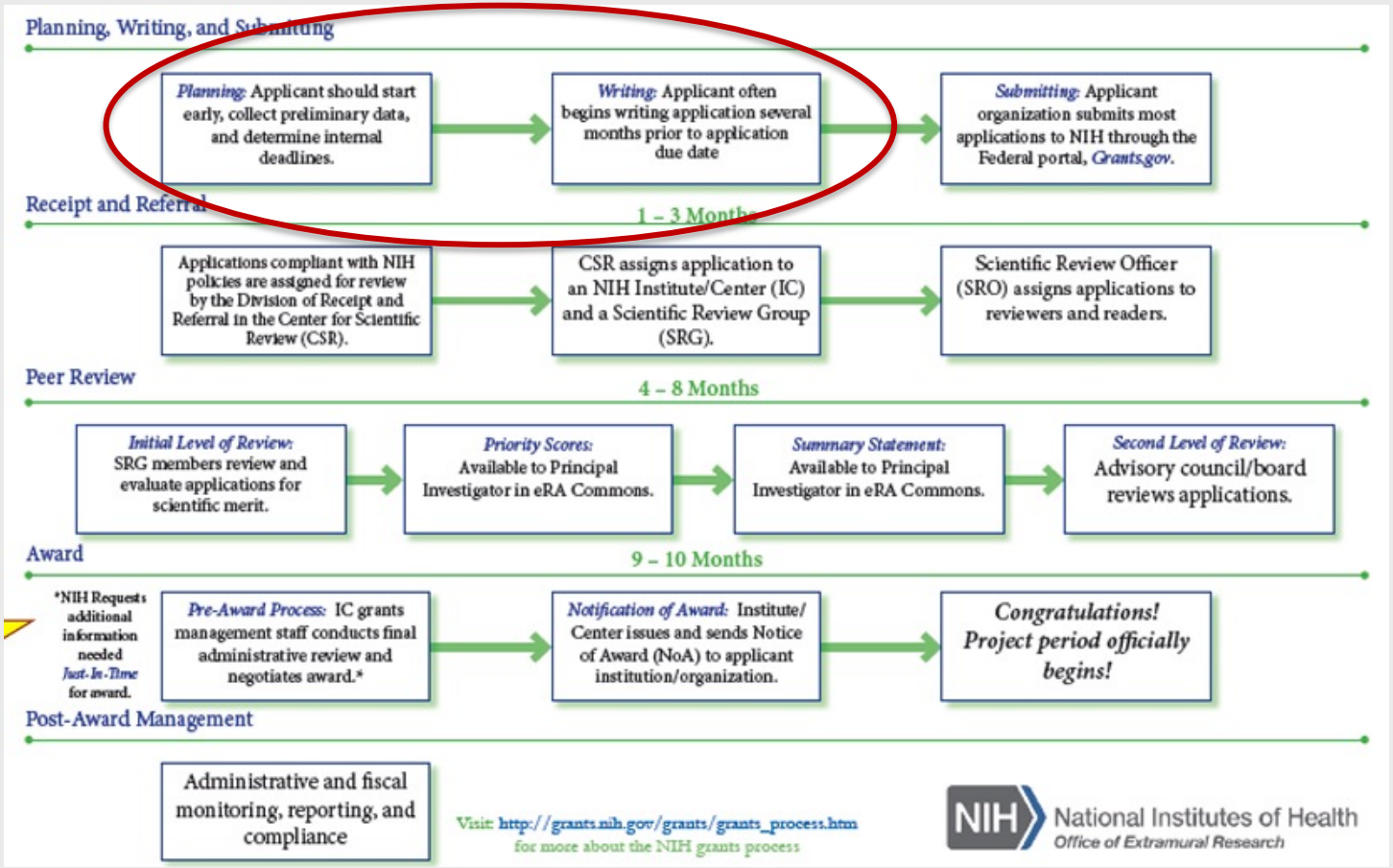

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Grant Application vs Protocol Application

Grant

Formal application submitted to sponsor to obtain funding for study. It provides a high-level overview of the HS research proposed.

HS study record includes:

- Section 1 – Basic Information
- Section 2 – Study Population Characteristics
- Section 3 – Protection & Monitoring Plans
- Section 4 – Protocol Synopsis

Sections completed depend on type of HS research proposed.

Protocol

A protocol is the precise and detailed design for conducting a research study; specifically, it is the study plan submitted to an IRB for review.

Key details include:

- Objectives and Rationale
- Methods and Procedures
- Subject Population Selection and Inclusion/Exclusion Criteria
- Risks and Benefits
- Provisions for Treatment of Adverse Events

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Human Subjects Research (HSR) Considerations

Grant Considerations

Is your proposal Research?

Does the proposed activity meet the IRB's definition of HSR?

Will your proposal involve multiple external sites engaged in Human Subjects Research?

Is your proposal **Research**?

45 CFR 46.102(l):

- **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.

Will your proposal involve 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)]

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OHRP Decision Tool: Am I Doing Human Subjects Research?
https://grants.nih.gov/policy/humansubjects/hs-decision.htm

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.

Does your proposal involve **multiple external sites** warranting use of an s**IRB**?

NIH sIRB Policy:

- NIH sponsored multi-site studies, where the same protocol is used at multiple sites
- Domestic research only
- Non-exempt research only

Revised Common Rule:

- NIH sponsored multi-site studies, where the same protocol is
- Cooperative non-exempt studies
- Domestic research only
- Sites need not perform the same research activities

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Single IRB (sIRB)

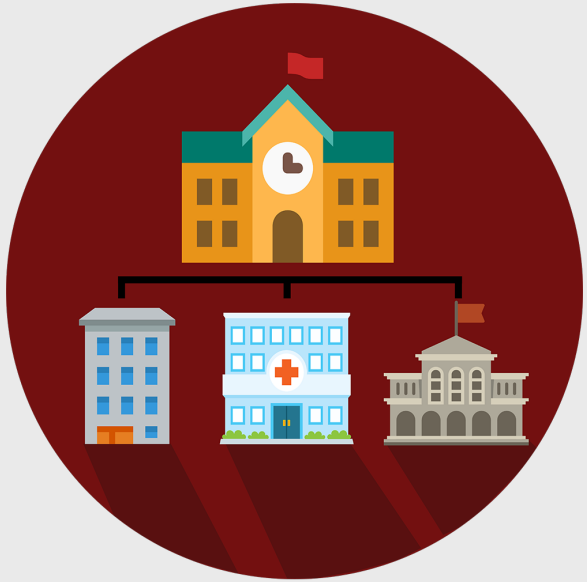
The Bigger Picture

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



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Establishing an sIRB via **Reliance Agreement**?

A reliance agreement is a legal document establishing the ability for one IRB (the "Relying IRB") to cede review to another IRB (the "IRB of Record")

The two scenarios are:

- WCM (Relying IRB) may cede review to an external IRB (IRB of Record)

WCM is **not** the IRB of record

- External IRB (Relying IRB) may cede review to WCM (IRB of Record)

WCM **is** the IRB of record

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Budgeting considerations for sIRB

The additional costs associated with sIRB review may be charged to grants or contracts as direct costs provided that such costs are well-justified and consistently treated as either direct or indirect costs according to applicable cost principles in the NIH Grants Policy Statement and the FAR 31.202 (Direct Costs) and FAR 31.203 (Indirect Costs)

Primary activities: Activities associated with conducting the ethical review of the proposed research protocol that will be carried out at all sites.

- Charged as indirect costs because Institution has Federally approved F&A rate and is a participating site.

Secondary activities related to the other participating sites: Activities associated with review of site-specific information, such as investigator qualifications, institutional capabilities and state/local regulatory requirements.

- May be charged as Institution's direct costs.

Who will serve as Single IRB (IRB of Record)

*Do not enter into Reliance commitments without first discussing with WCM IRB Reliance Team.

WCM IRB and External IRBs will collect and review basic information about the planned collaboration via a formal request form.

WCM IRB <u>may agree to serve as the Reviewing IRB on limited case by case basis, depending on</u>:

- **Funding source (*federally funded*)**
- **Risk level (*minimal risk*)**
- **Number of sites (*no more than 3 domestic sites involved*)**

How and When Do I Establish sIRB Reliance?

Note: The same reliance request form is used to request either an academic IRB or a commercial IRB to serve as IRB of Record.

Submit a WCM Reliance Request Form in Qualtrics:

- WCM and Lead PI names
- Propose Reviewing IRB
- Funding source: e.g., Federal, Institutional, Industry
- Protocol activities at WCM and External Site(s)

Submit a request:

- At grant proposal stage when considering multi-site non-exempt research
- At Just In Time (JIT) when moving forward with IRB submission considerations

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What if I still have questions?

The IRB is here to Help!

- Set-up a **1-on-1 consult** with our Consultation Service or request the IRB come present to study teams or Departments
- Reach out to the **IRB inbox** @ irb@med.cornell.edu

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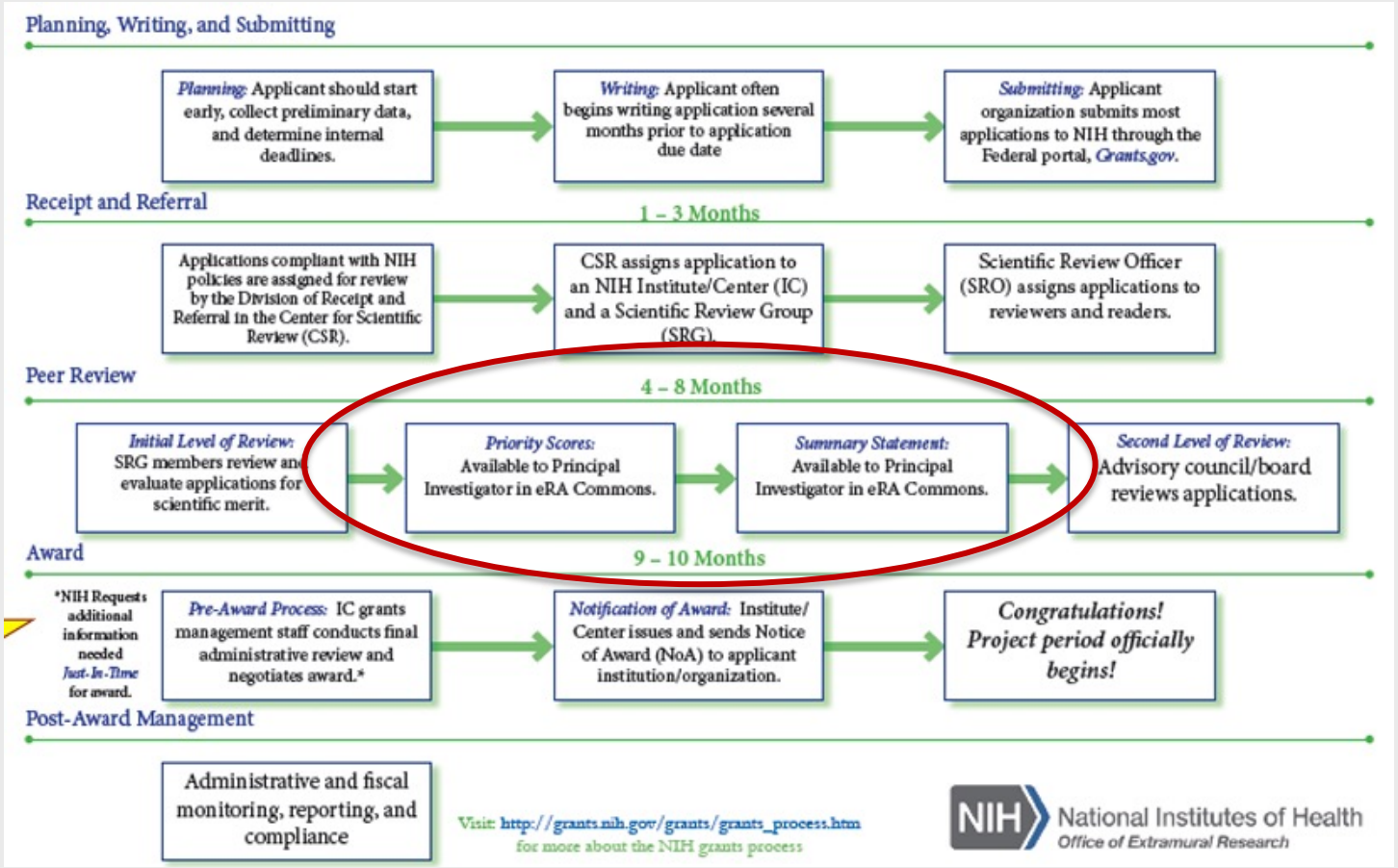
Pre-Post Score Planning

Secondary Title



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How do I check my application score?

Only the PI can view the summary statement, score and percentile information for a submitted application. The information is available in the eRA Commons within 30 days of the review of the application.

PIs and Department support staff should monitor the summary statement and score release to determine if funding is likely.

When do I submit to the IRB?

If your application scores within or near the NIH Institute or Center published paylines or near the previous fiscal year published paylines, you should begin the protocol/submission amendment process. This will help ensure IRB approval is in place by the time a formal JIT request is received from the funding agency.

While funding is not guaranteed at this stage, it is best to begin the process now. Waiting to submit to the IRB until a formal JIT request is received can result in delays in the issuance of the Notice of Award, if the proposal is funded.

What is a “Just-in-Time”?

Refers to the application timeframe requiring applicants to send updated information to the NIH only if an award is likely. This process decreases the administrative burden for 75%-80% of the applicants that will not receive funding and provides NIH with the most current information “just-in-time” for award.

When to Respond to the Just In Time?

Applicants will see a JIT link appear on the eRA Commons’ Status screen soon after the review scores are posted but should only submit JIT information when it is specifically requested by the grantor agency.

Any applications with an overall impact score of 40 or less will receive automatic system generated email requesting JIT materials. Applicants may choose to respond to the automated JIT requests or wait until a formal request is received from agency staff.

JIT Involving HSR – what is required:

- Federalwide Assurance (FWA) number (available here and populated by OSRA)
- Date of IRB approval
- Letter to Document Training in the Protection of Human Subjects, or copies of the training certificates.
- Genomic Data Sharing Institutional Certification, for the applicable projects. This may not be requested during the 1st stages of JIT but will be required before the award can be released.

IRB Approval:

For applications proposing Human Subjects research (including exempt human subjects research), the IRB certification is typically due at the JIT stage.

- Formal submission to and approval from to the WCM IRB via WRG-HS is required
- IRB applications should include a copy of any JIT request email/memo notification
- Rush Review requests for JIT's are available and require notification to the WCM IRB via the WCM IRB Consult Request Portal
- If IRB review is in process, the date expected for the protocol review.

Training in the Protection of Human Subjects:

Evidence of completed human subjects training must be submitted for all senior/key personnel identified in the application and involved in a human subjects project (including subcontractors, if applicable).

CITI is the approved training program for WCM.

- At WCM, human subjects trainings need to be completed every three years. The investigator and their department is responsible for tracking these trainings.

JIT Involving HSR – what is required (cont):

Genomic Data Sharing Institutional Certification:

Investigators working with large-scale human genomic data are required to provide a **GDS Institutional Certification** before an award can be issued. NIH expects investigators and institutions to:

- Develop and provide a plan for sharing genomic data as a part of the Data Management and Sharing Plan
- Provide an Institutional Certification form at Just-in-Time
- Submit genomic data in a timely manner to an appropriate repository
- Responsibly use controlled-access data
- Appropriately cite controlled-access data in publications and presentations

Internal workflow for GDS certification:

IRB approval has been obtained: Department/PI prepare the GDS Institutional Certification and submit it to the IRB for review & approval. Once approved, Department sends the document signed by the PI to the OSRA Specialist for AOR signature and submission, informing that the document has already been vetted by IRB.

IRB approval is pending: Department/PI prepare the Provisional GDS Certification and submit it to the OSRA Specialist for AOR signature and submission. A final certification will be required once IRB review is concluded.

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Considerations

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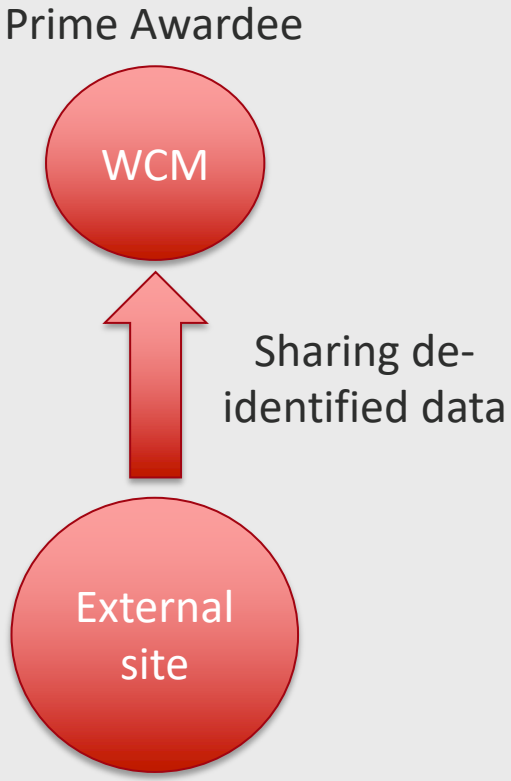
What if I am the primary awardee of the grant, but I am only receiving de-identified data/samples?



- Submission to WCM IRB required
- The Associated protocol includes details on sharing including each site's role in the study

Does the title of my grant need to match the title of my IRB protocol?

- Ideally, YES!
  - Funding agencies must be able to connect an IRB approval to a particular grant.

Is my grant subject to the NIH data management and sharing policy?

**https://library.weill.cornell.edu/research-support/creating-nih-data-management-and-sharing-plan*

- The DMS Policy applies to all research that generates scientific data, hence all research projects are covered under the policy.

- The plan submitted at the time of the application or revised during just-in-time phase must be observed during the entire lifetime of the award.

- When revisions are necessary (e.g., new scientific direction, a different data repository, or a timeline revision), the DMS Plan must be updated and submitted to the NIH for review and approval through OSRA at least 30 days in advance of the requested change

What if an IRB project is supported by more than one federal grant?

- **It is possible to have several sources of funding, both federal and non-federal, but the activities as described in the IRB protocol must be consistent with the research activities as described across all of the grants.**

- **Protocols need to be amended to include the new award and any new personnel involved in HS research under that award and protocol.**

What if I am serving as the lead PI or coordinating center of a multi-center federally funded research project, but I am not serving as the enrolling Investigator?

- **Any time an Investigator participates in human research, IRB approval must be in place as the lead PI or the coordinating center PI will typically have the potential for access to identifiable human information.**

  NOTE: As previously discussed, Non-exempt human research with multiple sites is subject to Single IRB requirements.

What if I am an investigator transferring in a grant that involves human subjects research?

- To ensure a smooth transfers process and continue the project at WCM as soon as possible, it is important to plan for required transfer documentation in advance.

- When a transfer application is being developed (also referred to as Type 7 application type), IRB approval letter is part of the required documents. If the review has not been concluded, the NIH GMS will be informed that the IRB is pending approval, however this may delay release of the award to WCM. OSRA recommends submitting the protocol for review as soon as possible to prevent delays.

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Takeaways

Secondary Title

Takeaways:

- Engage IRB early in the grant planning/writing phase
- Initiate protocol application/amendment as soon as score is released, and it is falls within a fundable range. Do not wait for formal JIT request from GMS.
- For transfers, initiate protocol application as soon as the award is relinquished by the original institution, or as early as possible.

IRB Resources

- **IRB Reliance Request Form**
  https://weillcornell.az1.qualtrics.com/jfe/form/SV_9sQ5rUvSSFd7abH
- **WCM IRB Website**
  hrp.weill.cornell.edu
- **IRB Consultation Service**
  https://weillcornell.az1.qualtrics.com/jfe/form/SV_8B8nCOcC8q7pUN0
- **WCM IRB Reliance Team**
  Singleirb@med.cornell.edu
- **WCM IRB Office**
  irb@med.cornell.edu

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OSRA Resources

- **OSRA Grants Website:**
  https://research.weill.cornell.edu/grant-services
- **OSRA Grants Consultation Service**
  https://weillcornell.az1.qualtrics.com/jfe/form/SV_03somk7FBSqdbJc
- **OSRA SOPS:**
  https://research.weill.cornell.edu/osra-standard-operating-procedures

Open Office Hours

Please submit a consultation request form to schedule a 30 minute zoom appointment with a representative of the grants team on Fridays from 11am – 1pm.

Have any Questions?

Call us at (646) 962-8290 or

email grantsandcontracts@med.cornell.edu

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Contact Us

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

Contact Us

IRB Member Portal

Forms, Templates & Guidelines

Request a Consultation

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