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Welcome!

- The session will begin shortly; for those joining via Zoom, please take a moment to make sure your microphone is muted.
- There will be a Q&A session after this presentation
- Please reserve your questions until then OR put questions in the chat if participating via Zoom, and we will address them after the presentation
- The session will be recorded.
- Not registered? Please register now using the QR code.

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IRB Review: Common Issues

Tips and Tricks for a Successful IRB Submission and Review Process

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12 years of experience in human research protections

Joined WCM in 2011

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Anjani K. Singh, M.D.

2 years of IRB experience in human research protections

Joined WCM in January 2022

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5+ years of experience in human research protections

Joined WCM in 2021

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Margaret Mackenzie, MM

9+ years of experience in human research protections

Joined WCM in October 2014

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6+ years of experience in human research protections

Joined WCM in February 2022

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Alyssa Wheeler, RN, CIP

7+ years of experience in human research protections

Joined WCM in 2020

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Today's Topics

- The Basics: requirements for successful submissions to the IRB
- Things to avoid: common submission problems and how to address them
- Tips & tricks
- Resources: further education and assistance

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The Basics

Requirements for successful submissions to the IRB

Access to WRG-HS and WRG-CT

- Modules to have access:
  - WRG-Clinical Trials
  - WRG-Human Subjects
- Your Department's DA needs to submit a WRG access request form
- Make sure to select "*add*" for both "regulatory coordinator" for IRB/PRMC submission, *and/or* "clinical research associate" for enrollment/management of study subjects, as applicable.
- WRG Comprehensive Job Aid

The Out-the-Front-Door Checklist

Up-to-date Human Research Training – CITI
Investigator and other staff COI reporting and training completed & filed with the Office of Research Compliance
Complete and accurate study application with protocol and IRA when applicable
All required documents uploaded and attached to the submission

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Basic Requirements, cont'd

Approvals from other committees as applicable: Protocol Review & Monitoring Committee (PRMC), Radiation Safety Committee (RSC), Institutional Biosafety Committee (IBC), etc.

All documents are proofread for typographical and formatting errors with complete answers to questions

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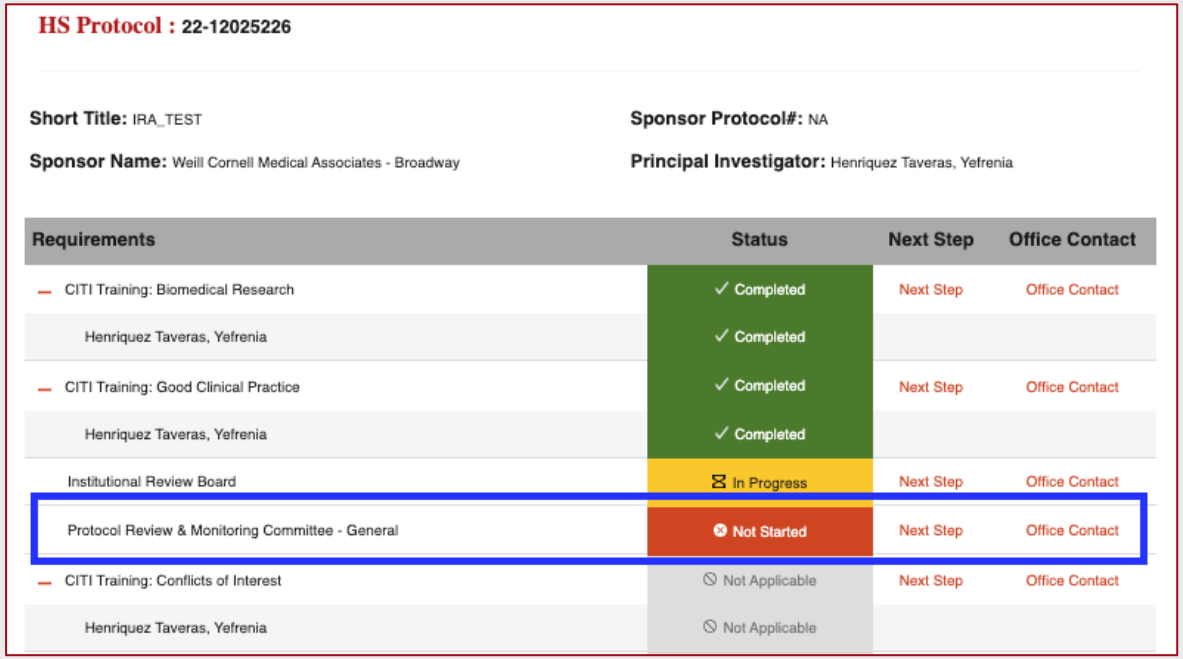
Things to avoid:

Common submission problems and how to address them

Top Ten Problems with IRB Submissions

1. Missing/pending scientific review approval
2. Certification issues
3. Inconsistency
4. Insufficient detail
5. Immaterial responses
6. Amendment issues
7. Incomplete data element details (use, disclosure, & storage)
8. HIPAA – Minimum necessary PHI justification
9. Consent/HIPAA waivers – justification
10. Incomplete or expired CITI training/COI survey

Top Ten Problems #1: Missing Scientific Review Approval



HS Protocol : 22-12025226

Short Title: IRA_TEST

Sponsor Protocol#: NA

Sponsor Name: Weill Cornell Medical Associates - Broadway

Principal Investigator: Henriquez Taveras, Yefrenia

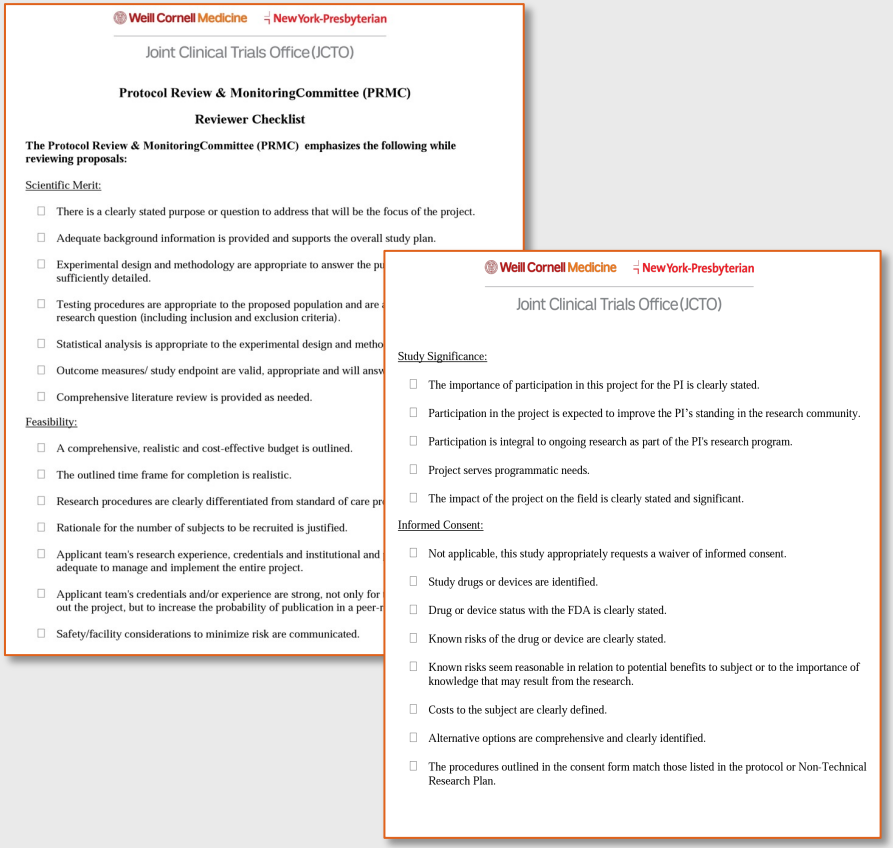
Requirements	Status	Next Step	Office Contact
CITI Training: Biomedical Research	✓ Completed	Next Step	Office Contact
Henriquez Taveras, Yefrenia	✓ Completed		
CITI Training: Good Clinical Practice	✓ Completed	Next Step	Office Contact
Henriquez Taveras, Yefrenia	✓ Completed		
Institutional Review Board	In Progress	Next Step	Office Contact
Protocol Review & Monitoring Committee - General	Not Started	Next Step	Office Contact
CITI Training: Conflicts of Interest	Not Applicable	Next Step	Office Contact
Henriquez Taveras, Yefrenia	Not Applicable		

See *"Overview: The Study Activation Status Page (SASP)"* on ITS site

Missing Scientific Review: Resolution

Obtain Scientific Review (i.e., PRMC or equivalent) approval *prior* to submitting to the IRB

See *"HowTo: Submit Your Protocol to the PRMC in ePRMS"* on ITS site



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Joint Clinical Trials Office (JCTO)

Protocol Review & MonitoringCommittee (PRMC)

Reviewer Checklist

The Protocol Review & MonitoringCommittee (PRMC) emphasizes the following while reviewing proposals:

Scientific Merit:

- ☐ There is a clearly stated purpose or question to address that will be the focus of the project.
- ☐ Adequate background information is provided and supports the overall study plan.
- ☐ Experimental design and methodology are appropriate to answer the pu… sufficiently detailed.
- ☐ Testing procedures are appropriate to the proposed population and are … research question (including inclusion and exclusion criteria).
- ☐ Statistical analysis is appropriate to the experimental design and metho…
- ☐ Outcome measures/ study endpoint are valid, appropriate and will answ…
- ☐ Comprehensive literature review is provided as needed.

Feasibility:

- ☐ A comprehensive, realistic and cost-effective budget is outlined.
- ☐ The outlined time frame for completion is realistic.
- ☐ Research procedures are clearly differentiated from standard of care pr…
- ☐ Rationale for the number of subjects to be recruited is justified.
- ☐ Applicant team's research experience, credentials and institutional and … adequate to manage and implement the entire project.
- ☐ Applicant team's credentials and/or experience are strong, not only for … out the project, but to increase the probability of publication in a peer-r…
- ☐ Safety/facility considerations to minimize risk are communicated.

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Joint Clinical Trials Office (JCTO)

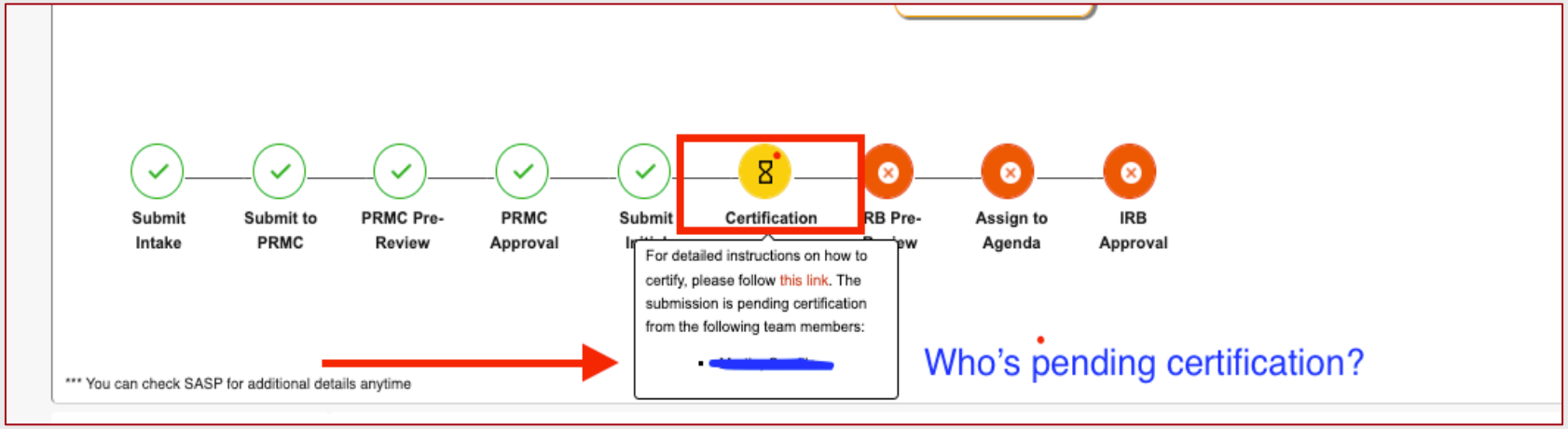
Study Significance:

- ☐ The importance of participation in this project for the PI is clearly stated.
- ☐ Participation in the project is expected to improve the PI's standing in the research community.
- ☐ Participation is integral to ongoing research as part of the PI's research program.
- ☐ Project serves programmatic needs.
- ☐ The impact of the project on the field is clearly stated and significant.

Informed Consent:

- ☐ Not applicable, this study appropriately requests a waiver of informed consent.
- ☐ Study drugs or devices are identified.
- ☐ Drug or device status with the FDA is clearly stated.
- ☐ Known risks of the drug or device are clearly stated.
- ☐ Known risks seem reasonable in relation to potential benefits to subject or to the importance of knowledge that may result from the research.
- ☐ Costs to the subject are clearly defined.
- ☐ Alternative options are comprehensive and clearly identified.
- ☐ The procedures outlined in the consent form match those listed in the protocol or Non-Technical Research Plan.

Top Ten Problems #2: Certification



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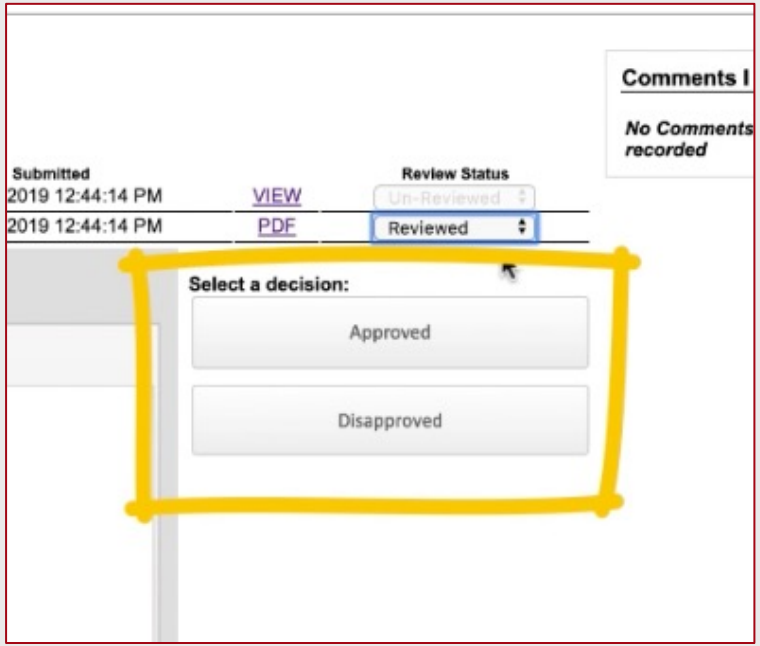
Certification, cont'd



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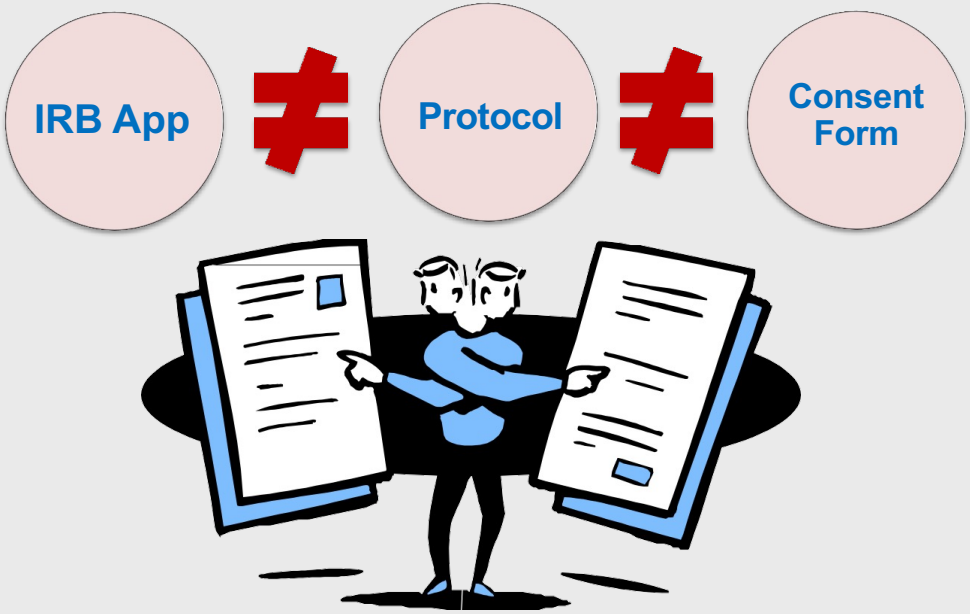
See *"HowTo: Certify on an IRB Application or Other Submission Type"* on ITS site

Top Ten Problems #3: Inconsistency



IRB Reviewer

Needs to Understand to Approve

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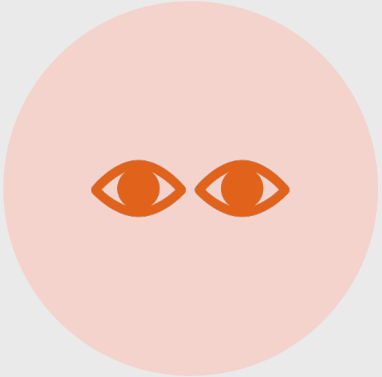
Tips to Ensure Consistent Materials

Review all documents for consistency before submitting



A second set of eyes if available (better than one)

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Top Ten Problems #4: Insufficient Detail

- Protocol and IRA lack specific details to identify **what** is being done, **by whom**, **how** it is being done, **where** information is stored, and **who** has access.

- The IRB relies on this information to make .111 determinations, and thus to grant approval.

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Top Ten Problems #5: Incomplete/Immaterial Responses

Q: What is an incomplete or immaterial response?

A: That's easy.

Incomplete/Immaterial Response: Example

Sample Prompt:

"Describe all reasonable expected risks, harms and/or discomforts that may apply to research. Discuss the severity and likelihood of occurrence. Consider the range of risks, including physical, psychological, social, legal, and economic."

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Incomplete/Immaterial Response: Example

Incomplete Response:

"There are no foreseeable risks or harms to subjects as this study is minimal risk."

Better Response:

"The primary risk from participating in this study include:

- *Distress from not being sure how to answer some questions, and*
- *Potential breach in confidentiality*

Subjects may choose not to answer any questions that make them feel uncomfortable. They may also withdraw from the study at any time without penalty.

The study team will protect subject confidentiality by utilizing RedCap to collect data and encrypting and storing data on password protected computers. Information that could be used to identify the subjects will be removed prior to data analysis."

Top Ten Problems #4: Amendment Issues

- **Amendment submitted**
- **Not reflected on study application**

- **Living Document – current state of study**
- **Requires revisions**

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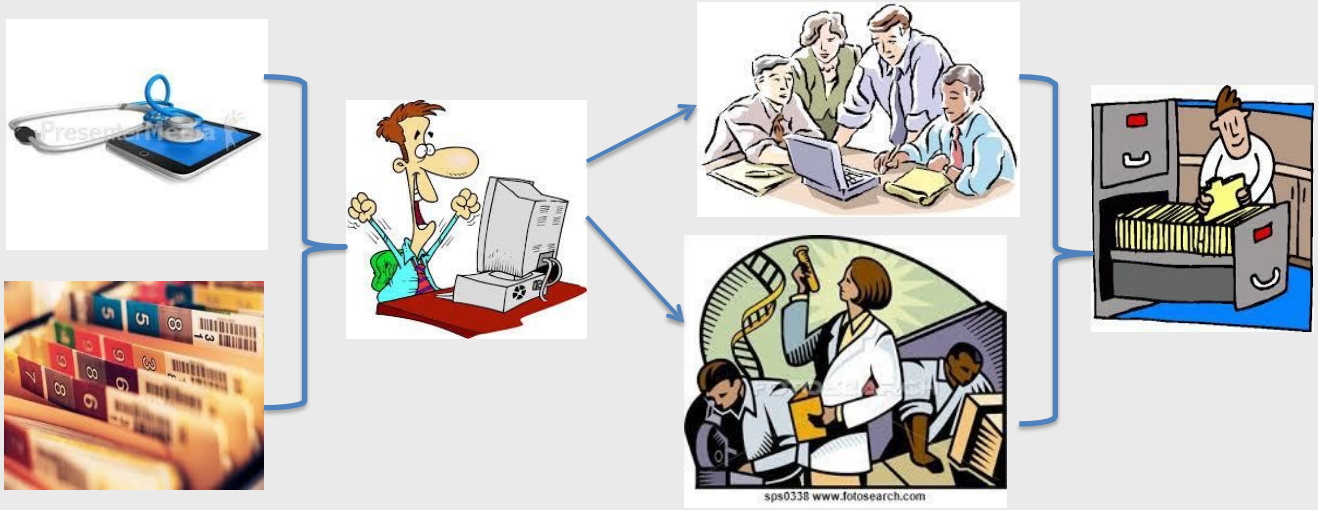
Amendment Tips

Before submitting amendment:

- Think about changes
- Think about re-consent (SACHRP guidance on reconsent)
- Consider whether the changes warrant a new application
- Review application
- Revise all applicable sections
- Revise all applicable documents (consent form, protocol, IRA, etc.), provide track-change versions of all amended documents, and upload clean versions to the appropriate section of the application

Top Ten Problems #7: Data Element Detail

Lack of data elements details, specifically PHI elements that are being used and/or disclosed, what sources are used to obtain data, where data is stored, and who has access



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Top Ten Problems #7: Data Element Details

Details are important!

- ✓ Where will data be obtained?
- ✓ Who will receive the data?
- ✓ If data is shared, who will receive, and how will data be sent?
- ✓ Who has access to the dataset?
- ✓ What will happen to the data when the study is completed?

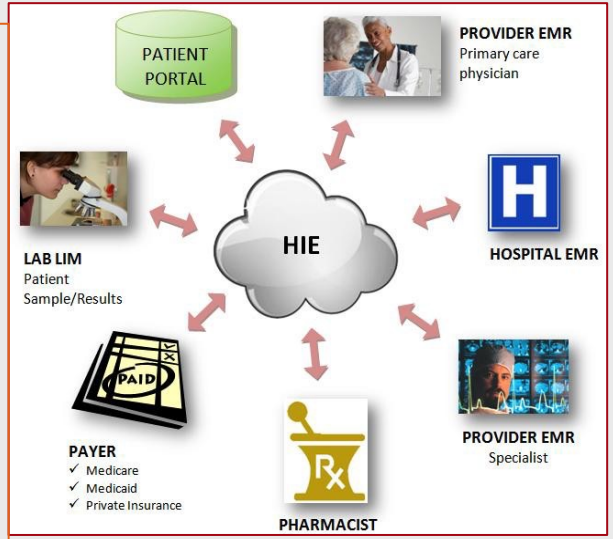
https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.111

Data Element Details: Resolution

What data sources are used?

Appropriate Response

*"Weill Cornell Medical Center's **EPIC** database will be queried for patients with the **diagnosis code of X disease** and taking the **medication ABC** in the same encounter. The **dose** of ABC, medication course, **demographic data** (date of birth, age, weight, height, race/ethnicity), blood pressure history (occurring within 12 months before, or concurrent with, initiation of **oral ABC** and occurring **1-12 months** after discontinuation of ABC) will be obtained from EPIC. Patients with the diagnosis of Z will be **excluded.**"*



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Top Ten Problems #8: Minimum Necessary PHI Justification

Typical generic response:

"The PHI requested is the minimum necessary because the study cannot be practicably conducted without the use of the PHI."

Inadequate response

X Needs to be specific and each PHI element adequately addressed

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Minimum Necessary: Resolution

Appropriate response:

*"**Medical Record Numbers** are required for pre- screening procedures and to identify the patients and collect the required data points from EPIC. **Names and addresses** are required to mail the pre- and post-study surveys, and **phone numbers** are required because subjects will be contacted by phone at the study mid-point as a compliance check and to ensure that subjects are not having any complications."*

Top Ten Problems #9a: Inadequate Justification for Full Consent Waiver

Q. May the requirement for obtaining informed consent or parental permission be altered or waived?

A. Yes, if <u>ALL</u> the following criteria are met:

(i) The research involves no more than minimal risk to the subjects;

(ii) The research could not **practicably** be carried out without the requested waiver or alteration;

(iii) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;

(iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and

(v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

Top Ten Problems #9a: Inadequate Justification for Consent Waivers

Must provide adequate justification for waiver!

- **The following is an inadequate justification:**
  - **Too difficult for study team to obtain**
  - **Getting consent would take too long**
  - **Patients might say no; therefore, would not get enough subjects**
  - **Restatement of waiver criteria**

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A Better Justification for a Full Consent Waiver

Adequate justification for waiver of consent would be:

- ✓ This is a chart review for services that have already been performed per standard of care and as such involves no more than minimal risk to the subjects
- ✓ This study involves records of subjects who have been lost to follow-up. Moreover, identifying and contacting the thousands of potential subjects, although not impossible, would not be feasible for a review of their medical records for information that would not change the care they would already have received.

Top Ten Problems #9b: Justification for Waiver of Signed Documentation

Waiver of **signed** consent form for some or all subjects, **if**:

(1) Only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; **or**

(2) The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; **or**

(3) If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

Top Ten Problems #9b: Tip Waiver of Signed Documentation

In cases in which the documentation requirement is waived, the IRB **may** require the investigator to provide subjects with a written statement regarding the research (e.g., an information sheet).

Top Ten Problems: #9c Inadequate Justification for HIPAA Waivers

Common types of HIPAA waivers requested by researchers:

- ❑ **Full waiver of HIPAA authorization**
  - **E.g., For retrospective chart review projects**
- ❑ **Partial waiver of HIPAA authorization**
  - **E.g., For conducting screening/recruitment activities only**

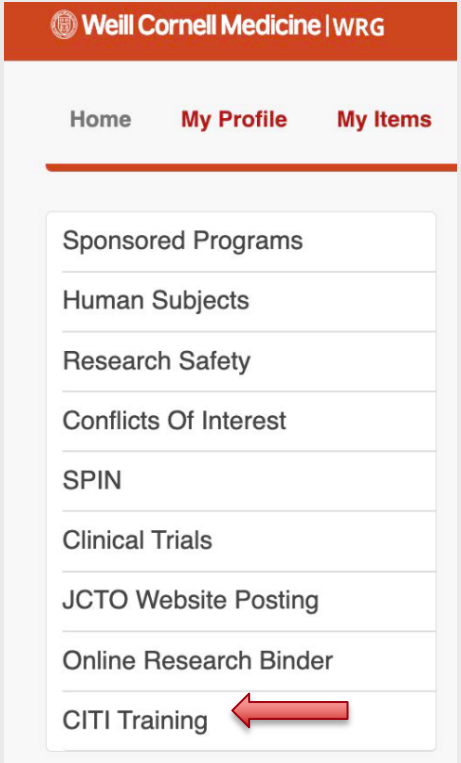
Top Ten Problems: #9c Solution

The IRB **MUST** determine:

1. Researcher is requesting the minimum PHI necessary to meet research objectives;
2. Research could not practicably be conducted without the waiver and access to PHI;
3. Research poses no more than minimal risk to participant's privacy;
4. Researcher has provided an adequate plan to:
   - **Protect HIPAA identifiers from improper use/disclosure**
   - **Destroy the HIPAA identifiers at the EARLIEST OPPORTUNITY unless retention is justified or required by law**

Top Ten Problems #10a: Personnel CITI Training

- Biomedical Research Investigators and Key Personnel course
- Good Clinical Practice course



See Training and Education requirements on the Research Team Training & Education page of IRB site

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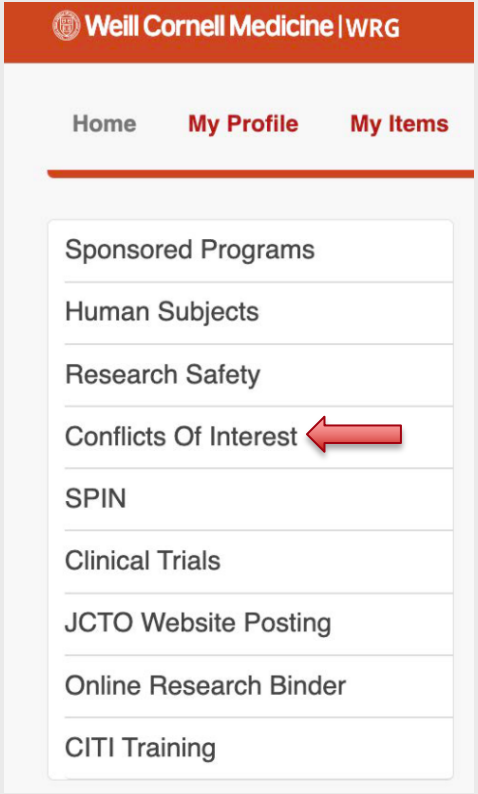
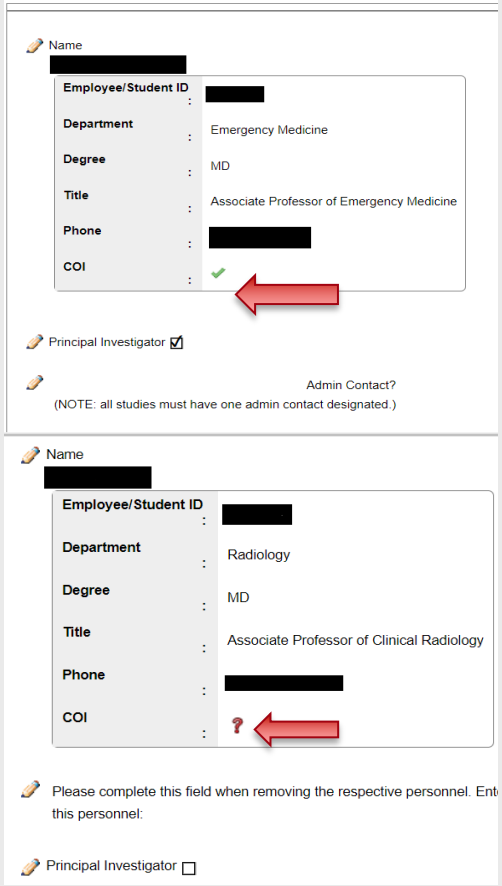
Top Ten Problems #10b: COI Survey

All personnel listed on application must have completed Conflicts Survey on file

Find the “Conflicts of Interest" tab on WRG or within your WRG application





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Expectations

- Expectations for researchers & their staff are high
  - IRB members expect high quality submissions
  - Funding agencies seek well designed protocols, applications, and a thorough IRB review
- Expectations for the IRB staff and members are equally as high!

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Top Ten Tips: Wrap-Up

Top Ten Tips: Wrap-Up

1. Obtain PRMC (or equivalent) approval prior to submission
2. Submit a thorough and complete IRB Application
3. Upload copies of approval documentation from other research committees as necessary (e.g., local approval)
   - Missing documents = **SUBMISSION Returned**
4. Contact IRB staff prior to submission to discuss any questionable submission.
5. Read and answer all the questions – ***don't leave blanks.***

Top Ten Tips: Wrap-Up

6. Communicate with the PI prior to submission don't leave it open to interpretation.
7. Make sure that the appropriate justification/rationale is provided whenever requesting waivers (consent and/or HIPAA).
8. Confirm that the PI and all study staff have current CITI certification prior to submitting.
9. Confirm that all investigators have completed the appropriate research financial Conflict of Interest Survey and training prior to submission.
10. Track the WRG submission to be sure that the submission was received by the IRB

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Resources:

How and where to seek assistance when necessary

Helpful Resources

- Research Team Resources
- Forms, Templates, Guidance
- ITS Study Activation Guides
- JCTO Researcher's Toolbox
- *PRMC-related questions*: generalprmc@med.cornell.edu *(non-cancer studies)*; cancerprmc@med.cornell.edu
- *Single IRB/reliance-related questions*: singleirb@med.cornell.edu
- *Oncore, WRG-CT-related questions:* jctoctms@med.cornell.edu
- *WRG-related issues/questions:* wrg-support@med.cornell.edu

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Questions?

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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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