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Tips and Tricks: *Successful IRB Submission and Review Process*

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Human Research Compliance Office

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https://research.med.cornell.edu/irb

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Today's Topics

- Explain the basic requirements for successful submissions to the IRB.
- Identify submission problems and how to address them
- Describe how and where to seek assistance when necessary.

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BUT…..First Things First: 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
- Within the 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

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Basic Requirements

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 and protocol

All required documents uploaded and attached to the submission

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Basic Requirements - continued

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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Top Ten Problems with IRB Submissions

1. Routing and personnel certification of submission
2. Missing/pending PRMC approval
3. Inconsistency between IRB application, protocol, and consent form.
4. Issues when updating application with amendment
5. HIPAA – Minimum necessary PHI justification
6. Incomplete/Incorrect responses
7. Protocol and IRA lack details (who, what, where, when, & how)
8. Incomplete data element details (use, disclosure, & storage)
9. Consent/HIPAA waivers – justification
10. Incomplete or expired CITI training/COI survey

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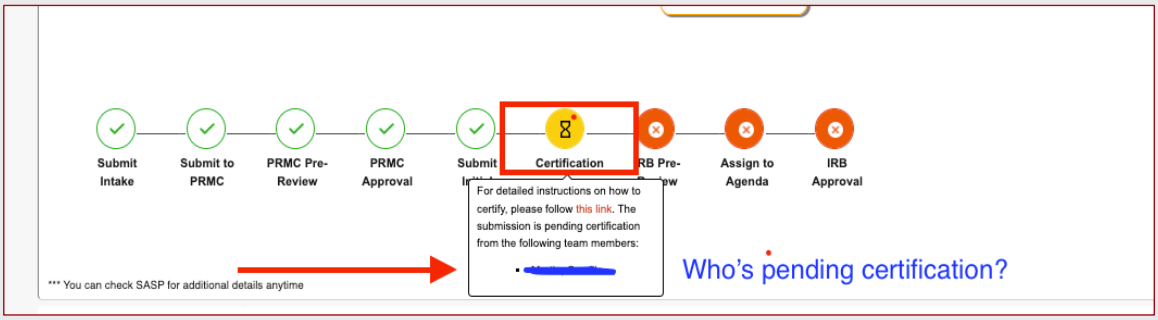
Top Ten Problems: #1 Routing/Certification



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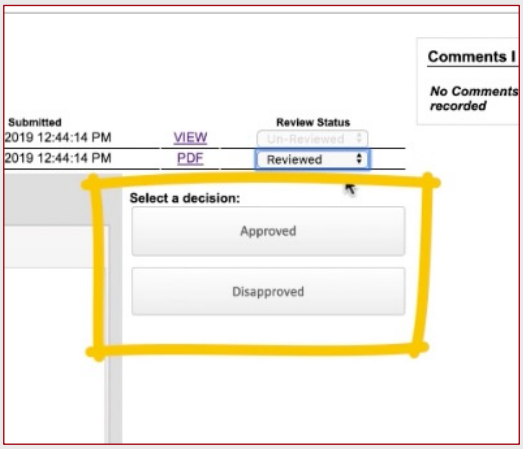
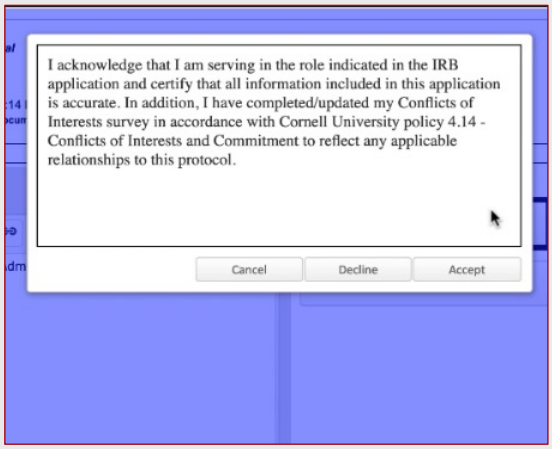
Top Ten Problems: #1 Solution





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

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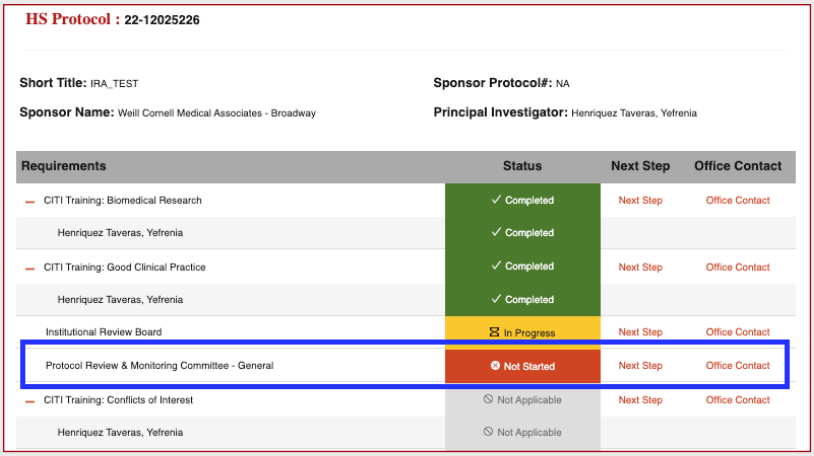
Top Ten Problems: #2 PRMC approval



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		

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

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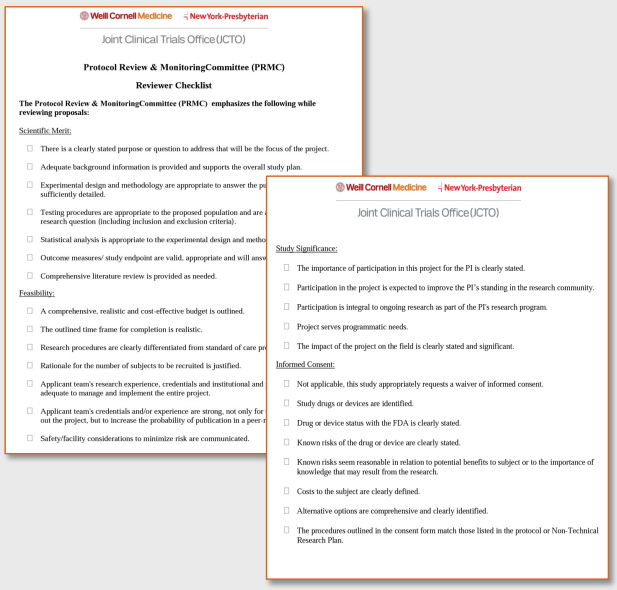
Top Ten Problems: #2 Solution

Obtain Protocol Review and Monitoring Committee (PRMC) 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 pr… 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.

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Top Ten Problems: #3 Inconsistency

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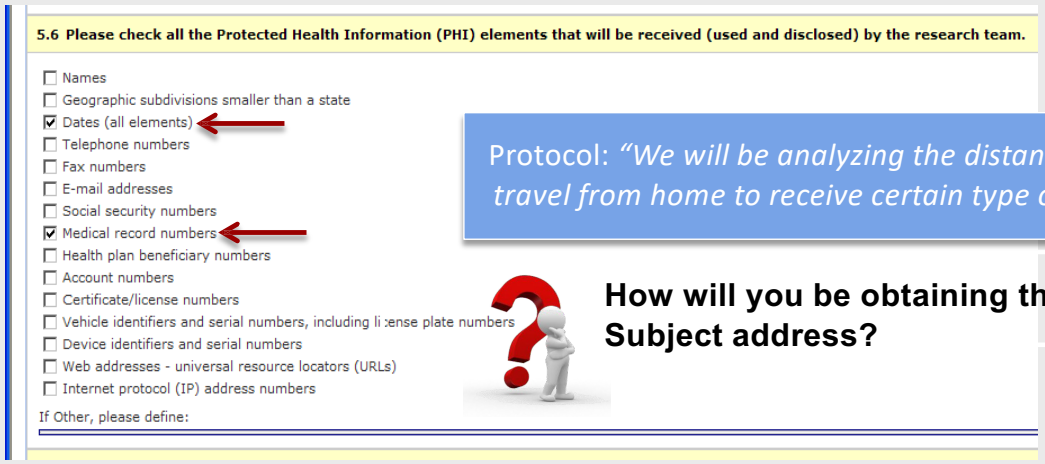
Top Ten Problems: #3 Inconsistency



Protocol: *"We will be analyzing the distance patients travel from home to receive certain type of surgery"*

How will you be obtaining the distance? Subject address?

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Top Ten Problems: #3 Solution

Review all documents for consistency before submitting

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

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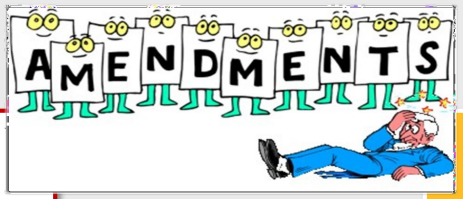
Top Ten Problems: #4 Updating App



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

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

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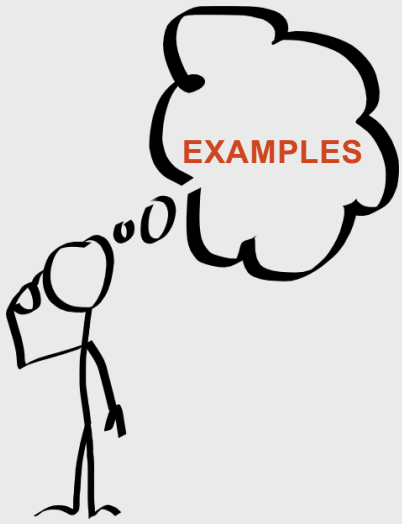
Top Ten Problems: #4 Updating App

- # of enrolled/screened
- Recruitment process
- Additional risks
- Additional population
- Additional data point – PHI element
- Adding study personnel
- Adding a study site



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Top Ten Problems: #4 Solution

Before submitting amendment:

- Think about changes
- 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

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Top Ten Problems: #5 Minimum Necessary

Justification of Minimum Necessary PHI

"The Privacy Rule requires that when a waiver is granted that only the minimum necessary health information be used/disclosed. Therefore, a clear justification that the PHI being requested is the minimum necessary information reasonably necessary to accomplish objectives of the proposed research."

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Top Ten Problems: #5 Minimum Necessary

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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Top Ten Problems: #5 Solution

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."

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Top Ten Problems: #6 Incomplete/Incorrect

Could result in:

- X Extra work for both IRB and Study Teams
- X Unnecessary inconsistencies in submission
- X Delay in IRB review/approval
- X IRB approval cannot be granted

And prevented by:

- ✓ Reading each section of the application carefully
- ✓ Proofreading your responses prior to submitting
- ✓ Having another study team member proofread

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Top Ten Problems: #6 Incomplete/Incorrect

The application question asks:

"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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Top Ten Problems: #6 Solution

Typical Response :

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

Appropriate Response:

"Taking part in this research may expose subjects to risks. The study team will explain the risks of this research to the subjects before they decide about participation. The main risk from this study come from the following:

- Distress from not being sure how to answer some questions.

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.

Another risk of taking part in this study is the possibility of a loss of confidentiality or privacy. The study team plans to protect subject privacy using strict procedures in keeping with institutional and federal requirements. Moreover, any information that could be used to identify the subjects will be removed prior to data analysis."

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Top Ten Problems: #7 Lacking Details

- 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.
- Protocol and IRA help us know the study ensure subjects safety

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Top Ten Problems: #7 Lacking Details

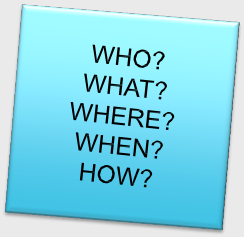
5.5 Data Management

5.5.1 Data Collection and Storage

Data will be requested from the Medicine Research Database, IRB 220-001, PI Dr. Grey and from B Database Permission to use these data was obtained from Dr Grey and Dr. McDreamy respectively.

Data will be stored in password protected computers

need to know



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Top Ten Problems: #7 Solution

5.5 Data Management

5.5.1 Data Collection and Storage

Data will be requested from the Medicine Research Database, IRB 220-001 , PI Dr. Grey and from B Dtabase . Permission to use these data was obtained from Dr Grey and Dr McDreamy , retrospectively.

Data will be extracted by a data broker in the Division of Medicine Biostatistician group based on the inclusion/exclusion criteria described above.

Data will be de-identified and electronically transmitted through secure Geisinger network. Data will be stored in password protected computers on secure network. The PI and members of the study team will be the only persons with access to this data.

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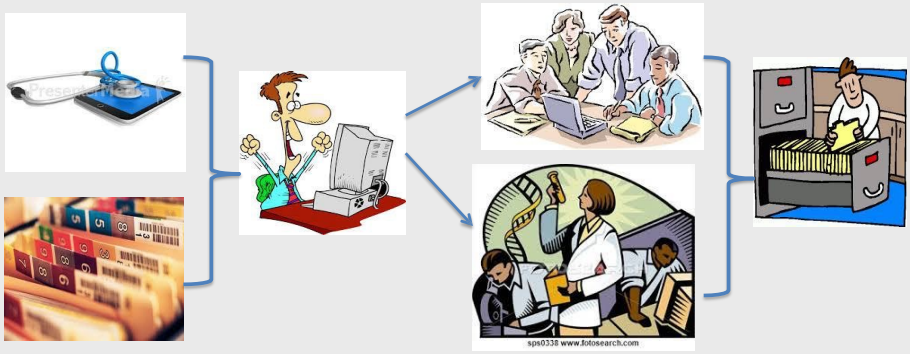
Top Ten Problems: #8 Data Elements

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: #8 Data Elements

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?

Show Details

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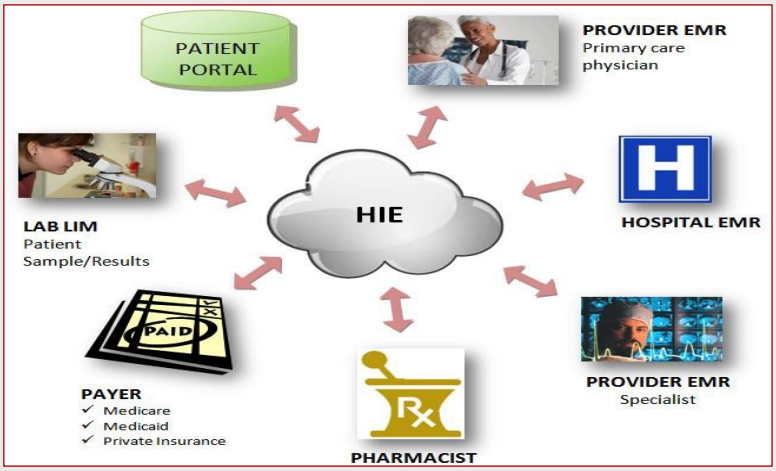
Top Ten Problems: #8 Solution

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: #9a Inadequate Justification for Consent Waivers

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

A. Yes, if ALL 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.

Note: 'Practicably' means possible, NOT convenient

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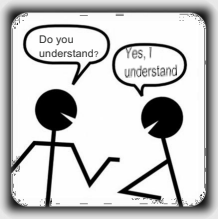
Top Ten Problems: #9a Inadequate Justification for Consent Waivers



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.

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

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).

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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**

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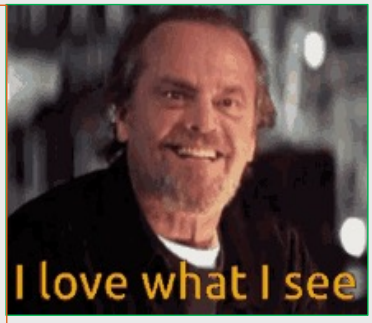
Top Ten Problems: #9a Solution

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.
- ✓ None of the results of the research would affect the clinical decisions about the individual's care because the results are analyzed after the fact. Subjects will not be deprived of clinical care to which they would normally be entitled to.



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Top Ten Problems: #9b 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**

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Top Ten Problems: #9b 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;

Note: 'Practicably' means possible, NOT convenient

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**

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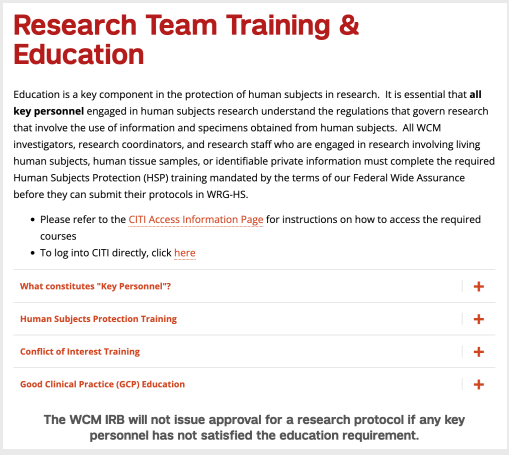
Top Ten Problems: #10a Personnel CITI Training

- 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



Research Team Training & Education

Education is a key component in the protection of human subjects in research. It is essential that **all key personnel** engaged in human subjects research understand the regulations that govern research that involve the use of information and specimens obtained from human subjects. All WCM investigators, research coordinators, and research staff who are engaged in research involving living human subjects, human tissue samples, or identifiable private information must complete the required Human Subjects Protection (HSP) training mandated by the terms of our Federal Wide Assurance before they can submit their protocols in WRG-HS.

- Please refer to the CITI Access Information Page for instructions on how to access the required courses
- To log into CITI directly, click here

What constitutes "Key Personnel"? +

Human Subjects Protection Training +

Conflict of Interest Training +

Good Clinical Practice (GCP) Education +

The WCM IRB will not issue approval for a research protocol if any key personnel has not satisfied the education requirement.

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Top Ten Problems: #10b COI Survey

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

Find the "COI Annual Disclosure Survey" button on the Conflicts of Interest website

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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 IRB staff and members (thorough and timely) are equally high!

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How can the IRB staff help you?

- Update IRB website to include up-to-date policies, procedures, and guidance documents
- Be available for consultation services when needed, especially for new research staff
- Review the submission early enough to send requests for modifications or clarifications during the pre-review
- Send the submission to the fully convened IRB with pre-review questions answered so that the outcome review and discussion (full committee) requires only minimal modifications
- Send timely and complete approval letters

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Top Ten Tips: Wrap-Up

1. Obtain PRMC approval prior to submission
2. Thorough and complete IRB Application
3. Upload copies 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.***
6. Make sure that the appropriate justification/rationale is provided whenever requesting waivers (consent and/or HIPAA).
7. Communicate with the PI prior to submission – don't leave it open to interpretation.
8. Confirm that the PI and all study staff have current Human Research Training with CITI prior to submission.
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

or

Email:
WCM IRB Office: irb@med.cornell.edu
HRPO team: hrpo@med.cornell.edu

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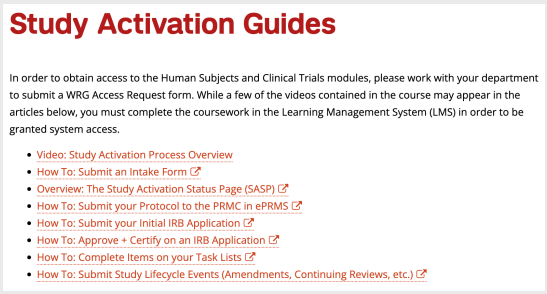
Resources

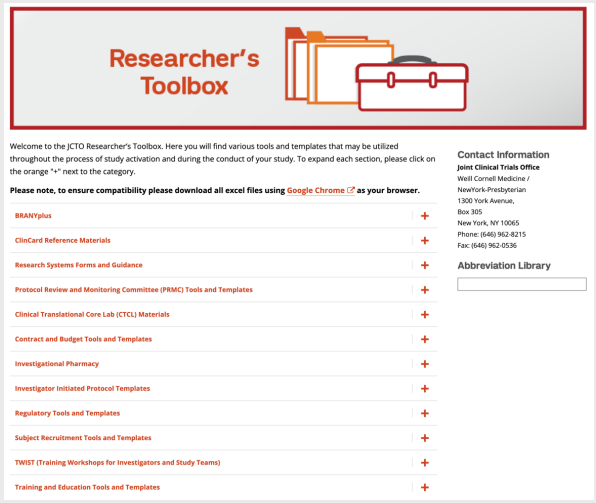
- **ITS Study Activation Guides**
- **JCTO Researcher's Toolbox**



Study Activation Guides

In order to obtain access to the Human Subjects and Clinical Trials modules, please work with your department to submit a WRG Access Request form. While a few of the videos contained in the course may appear in the articles below, you must complete the coursework in the Learning Management System (LMS) in order to be granted system access.

- Video: Study Activation Process Overview
- How To: Submit an Intake Form
- Overview: The Study Activation Status Page (SASP)
- How To: Submit your Protocol to the PRMC in ePRMS
- How To: Submit your Initial IRB Application
- How To: Approve + Certify on an IRB Application
- How To: Complete Items on your Task Lists
- How To: Submit Study Lifecycle Events (Amendments, Continuing Reviews, etc.)



Researcher's Toolbox

Welcome to the JCTO Researcher's Toolbox. Here you will find various tools and templates that may be utilized throughout the process of study activation and during the conduct of your study. To expand each section, please click on the orange "+" next to the category.

Please note, to ensure compatibility please download all excel files using Google Chrome as your browser.

- BRANYplus
- ClinCard Reference Materials
- Research Systems Forms and Guidance
- Protocol Review and Monitoring Committee (PRMC) Tools and Templates
- Clinical Translational Core Lab (CTCL) Materials
- Contract and Budget Tools and Templates
- Investigational Pharmacy
- Investigator Initiated Protocol Templates
- Regulatory Tools and Templates
- Subject Recruitment Tools and Templates
- TWIST (Training Workshops for Investigators and Study Teams)
- Training and Education Tools and Templates

Contact Information
Joint Clinical Trials Office
Weill Cornell Medicine /
NewYork-Presbyterian
1300 York Avenue,
Box 305
New York, NY 10065
Phone: (646) 962-8215
Fax: (646) 962-0536

Abbreviation Library

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Helpful contacts

- *BRANYplus-related questions:* branyplus@med.cornell.edu
- *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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