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IRB 101: An Introduction to the WCM IRB

Presented by

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

Today's Topics

- Office of Human Research Compliance Organizational Chart
- Is IRB Review Required?
- Preparing and Submitting to the IRB
- Things to Know About WRG-HS
- What Kind of Review?
- Common Causes of Delays
- Post Approval Process

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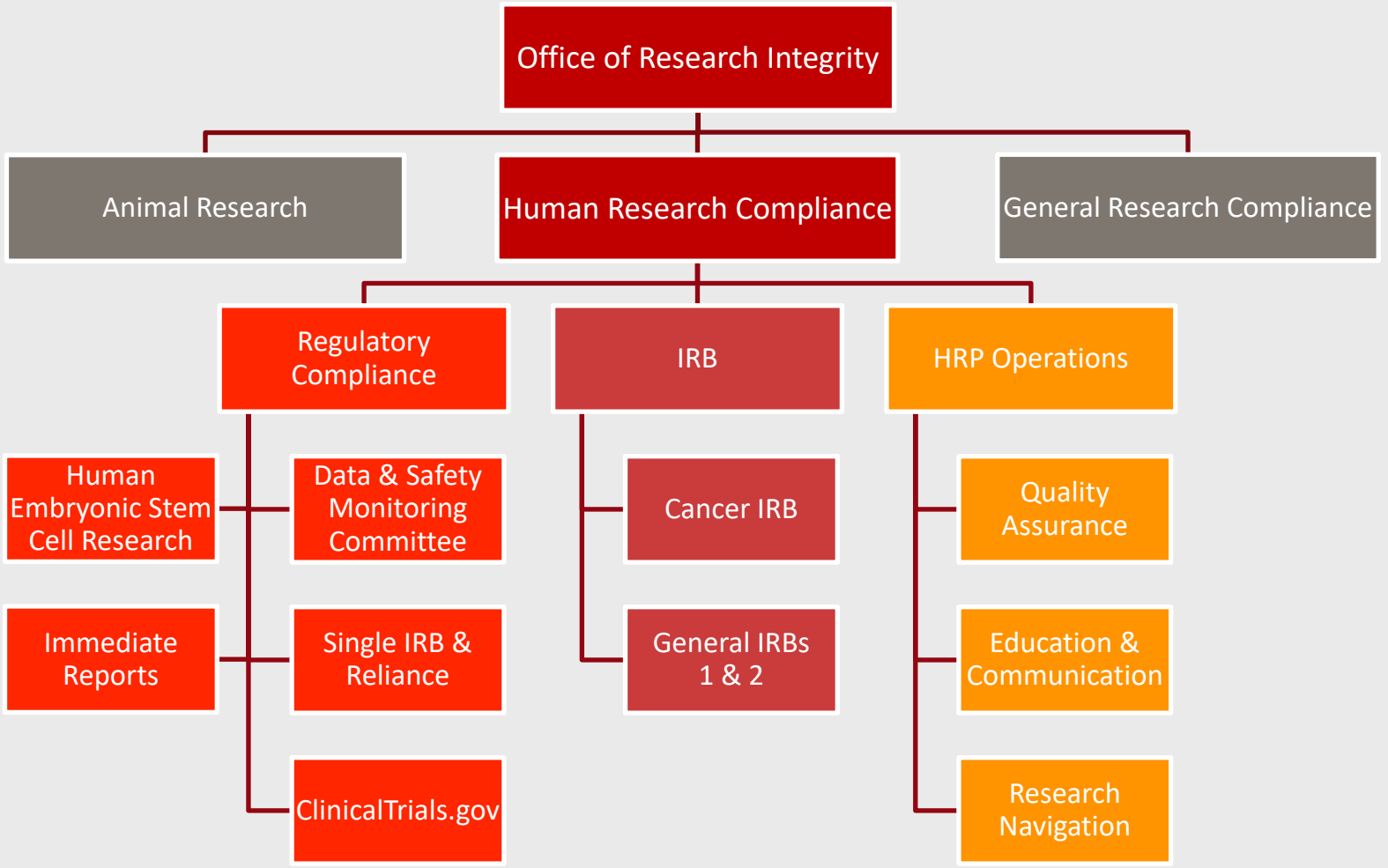
Office of Human Research Compliance Organizational Chart



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

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What is **Research**?

Is IRB Review Required?

45 CFR 46.102(e):

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

FDA definition 312.3(b) and 812.3(h)

- **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 a **Human Subject?**

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:

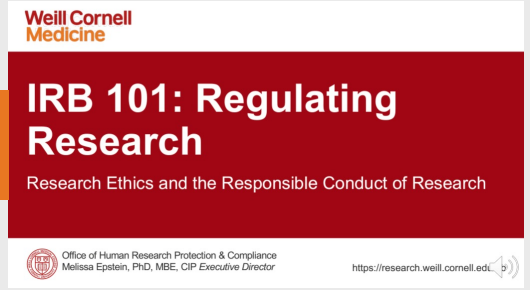
- Either as a recipient of the new test article or as a control.
  - A subject may be a healthy human or a patient with a disease. [21 CFR 312.3(b)]
- Either as an individual on whom or on whose specimen a test article is used or as a control.
  - A subject may be in normal health or may have a medical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

What Regulations Apply?

Is IRB Review Required?

Organization	Regulation
OHRP	**Common Rule** (45 CFR §46)
FDA	Device, Drug and IRB regulations (21 CFR §812; §312, §50, and §56)
DoD	Instruction 3216.02
Office of Civil Rights	**HIPAA** (45 CFR §160 and §164)
ICH	International Conference on Harmonisation (ICH) Good Clinical Practice
EUGDPR	European Union General Data Protection Regulation
NIH	Imposes requirements on funded research
State, **Local**, and **Institutional** Regulations	

For a discussion on which regulations apply when, please watch our METS from September 2022



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Approval Criteria (45 CFR 46.111 / 21 CFR 56.111)

In order to approve research involving human subjects, the IRB must determine the following requirements are satisfied:

- ❑ Risks to subjects are minimized by:
  1) Using procedures consistent with sound research design, using procedures already done on the subjects for other purposes, and;
  2) Without exposing subjects to unnecessary risk.
- ❑ Risk to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be reasonably expected as a result
- ❑ Selection of subjects is equitable
- ❑ Additional safeguards have been included in the study to protect the rights and welfare of subjects who are vulnerable to coercion or undue influence
- ❑ Informed consent will be appropriately documented or appropriately waived in accordance with §46.117(c)
- ❑ The research plan has adequate provision for monitoring the data collected to ensure subject safety
- ❑ There are adequate provisions to protect the privacy of subjects
- ❑ There are adequate provisions to maintain the confidentiality of data
- ❑ The informed consent process is adequate
- ❑ The documentation of informed consent is adequate

Elements of a Successful Submission

- ✓ Well planned protocol
- ✓ Completed COI disclosure
- ✓ Completed CITI training
- ✓ Ancillary Committee(s) approval
- ✓ Appropriate informed consent process
- ✓ Complete and accurate IRB application
- ✓ Approval
- ✓ Post-approval compliance

Planning a Protocol

Preparing and Submitting to the IRB

- ✓ Well planned protocol
- ✓ Completed COI disclosure
- ✓ Completed CITI training
- ✓ Ancillary Committee(s) approval
- ✓ Appropriate informed consent process
- ✓ Complete and accurate IRB application
- ✓ Approval
- ✓ Post-approval compliance

- **Every new submission requires a protocol**
  - **'protocol' ≠ 'application'**
- **JCTO provides protocol templates for:**
  - Observational Correlative Studies
  - Therapeutic Studies
  - Tissue Use/Chart Reviews
- **Be aware of IRB policies**
  https://research.weill.cornell.edu/compliance/human-subjects-research/institutional-review-board/irb-policies-and-procedures

Conflict of Interest

Preparing and Submitting to the IRB

- ✓ Well planned protocol
- ✓ Completed COI disclosure
- ✓ Completed CITI training
- ✓ Ancillary Committee(s) approval
- ✓ Appropriate informed consent process
- ✓ Complete and accurate IRB application
- ✓ Approval
- ✓ Post-approval compliance

- **All researchers/investigators engaged in human subjects' research must have a current financial COI disclosure on file at the time of protocol submission**
- **COIs are submitted to the WCM COI Office through the Conflicts Survey in WRG**
- **COI Disclosures must be renewed annually**

To complete a Conflicts Survey:

1. Log into WRG (https://wrg.weill.cornell.edu) with your CWID/password
2. Once in WRG, click on Conflicts of Interest
3. Click on Create/Update Disclosure

Instructions also available here

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Educational Requirements

Preparing and Submitting to the IRB

- ✓ Well planned protocol
- ✓ Completed COI disclosure
- ✓ Completed CITI training
- ✓ Ancillary Committee(s) approval
- ✓ Appropriate informed consent process
- ✓ Complete and accurate IRB application
- ✓ Approval
- ✓ Post-approval compliance

- **Biomedical Research Investigators and Key Personnel**
  - Refresher course needed after 3 years
- **CITI Course in Good Clinical Practice (GCP)**
  - Refresher course needed after 3 years

Ancillary Approvals

Preparing and Submitting to the IRB

- ✓ Well planned protocol
- ✓ Completed COI disclosure
- ✓ Completed CITI training
- ✓ Ancillary Committee(s) approval
- ✓ Appropriate informed consent process
- ✓ Complete and accurate IRB application
- ✓ Approval
- ✓ Post-approval compliance

- **Protocol Review & Monitoring Committee (PRMC)**
  - Cancer PRMC: for cancer-related studies *cancerPRMC@med.cornell.edu*
  - General PRMC: for all other studies generalPRMC@med.cornell.edu
- **PRMC-equivalent committees**

Informed Consent

Preparing and Submitting to the IRB

- ✓ Well planned protocol
- ✓ Completed COI disclosure
- ✓ Completed CITI training
- ✓ Ancillary Committee(s) approval
- ✓ Appropriate informed consent process
- ✓ Complete and accurate IRB application
- ✓ Approval
- ✓ Post-approval compliance

- **Think of this as a *process***
- **Remember the purpose of the process**
  - To inform: use language that is easy to understand
  - Signed documentation
- **Other options, as appropriate, include:**
  - Waiver of Signed Documentation (e.g., oral consent)
  - Waiver of Informed Consent (e.g., for chart reviews)

Successful Informed Consent = Information + Comprehension + Voluntariness

Oral Consent and Waivers

Preparing and Submitting to the IRB

- ✓ Well planned protocol
- ✓ Completed COI disclosure
- ✓ Completed CITI training
- ✓ Ancillary Committee(s) approval
- ✓ Appropriate informed consent process
- ✓ Complete and accurate IRB application
- ✓ Approval
- ✓ Post-approval compliance

- **A waiver of signed documentation or a full waiver of consent is permitted under the regulations in certain circumstances for minimal risk research**
- **The research record should still contain documentation of the consent process, including the date and time**
- **Consent waivers and HIPAA waivers are two different things!**
  - You might satisfy the requirements of one but not the other
- **IRB approval of the oral consent or waiver is required**

Accurate IRB Application

Preparing and Submitting to the IRB

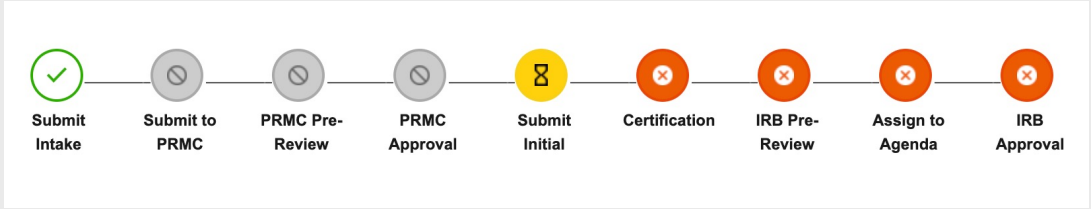
- ✓ Well planned protocol
- ✓ Completed COI disclosure
- ✓ Completed CITI training
- ✓ Ancillary Committee(s) approval
- ✓ Appropriate informed consent process
- ✓ Complete and accurate IRB application
- ✓ Approval
- ✓ Post-approval compliance

- **The application must reflect the research and be consistent with information presented in the other submission components (e.g., protocol, consent documents, etc.)**
- **IRB Review Application (IRA)**
  - **Biomedical IRA**: If using the JCTO Therapeutic Protocol template and/or your study uses a device/drug or implements a clinical trial
  - **Biorepository IRA**: If establishing a biorepository ONLY
  - **Medical Education IRA**: If your study is minimal risk and qualifies under exempt category 1
  - **SBER and Records IRA**: If using the JCTO Observational or Tissue Use/Chart Review template, and/or study is SBER

WRG-HS Electronic Submission System

Things to Know About WRG-HS

- **All protocols for review by the IRB must be submitted through the <u>Weill Research Gateway</u> Human Subjects portal (WRG-HS):**
  - Submission portal for protocols, continuing reviews, amendments, etc.
  - Check status of protocols
  - Edit, amend, and renewal of protocols
  - Reportable events (deviations, lapse requests)
- **<u>WRG Comprehensive Job Aid</u>**



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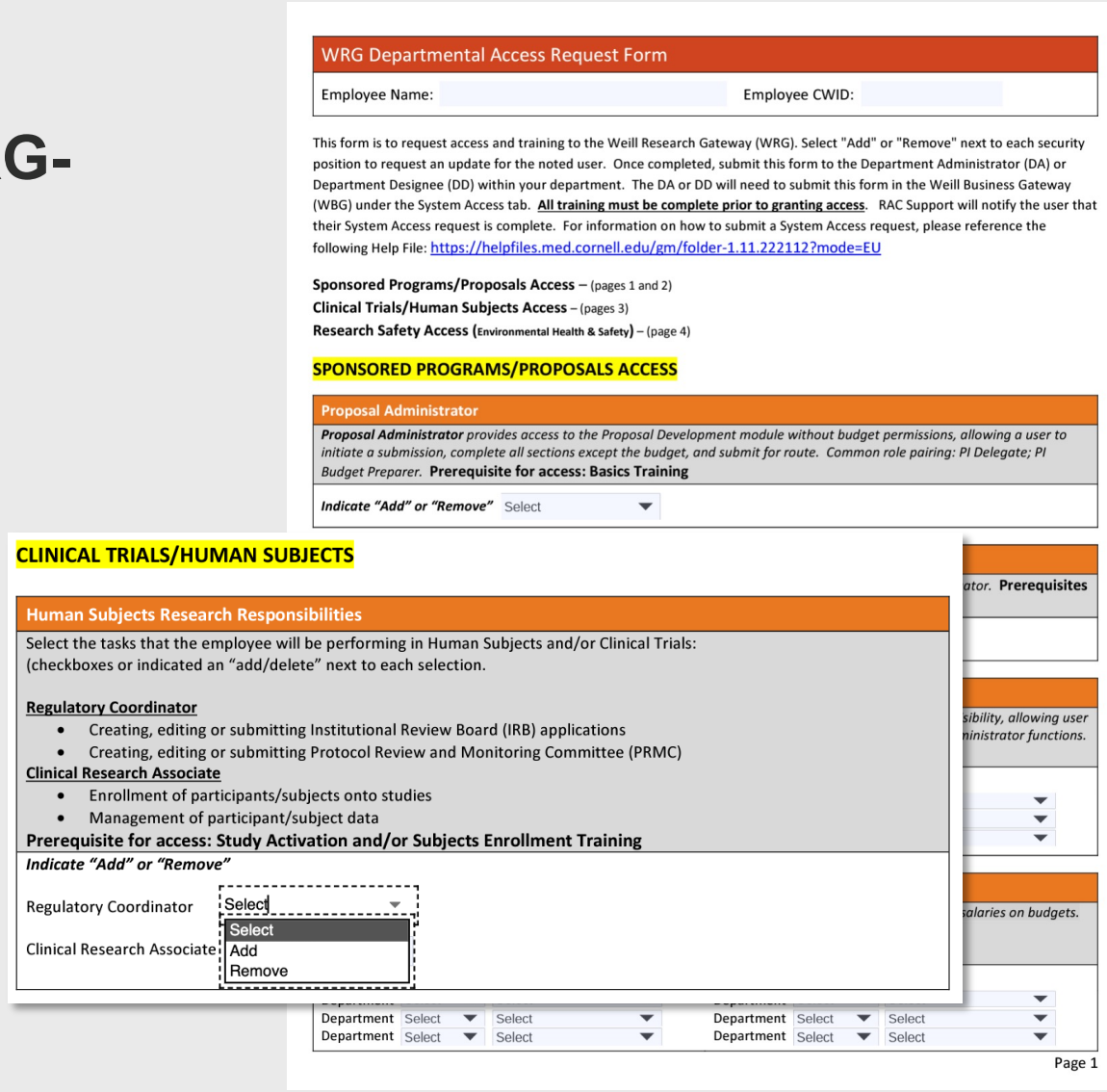
Weill Research Gateway (WRG)

Things to Know About WRG-HS

- **First things first: Access to WRG-HS (and CT, if applicable)**
- **Modules to have access to:**
  - Human Subjects (HS)
  - Clinical Trials (CT)
- Select **add** for both **regulatory coordinator** and **clinical research associate**



WRG Departmental Access Request Form

Employee Name: Employee CWID:

This form is to request access and training to the Weill Research Gateway (WRG). Select "Add" or "Remove" next to each security position to request an update for the noted user. Once completed, submit this form to the Department Administrator (DA) or Department Designee (DD) within your department. The DA or DD will need to submit this form in the Weill Business Gateway (WBG) under the System Access tab. **All training must be complete prior to granting access**. RAC Support will notify the user that their System Access request is complete. For information on how to submit a System Access request, please reference the following Help File: https://helpfiles.med.cornell.edu/gm/folder-1.11.222112?mode=EU

Sponsored Programs/Proposals Access – (pages 1 and 2)
Clinical Trials/Human Subjects Access – (pages 3)
Research Safety Access (Environmental Health & Safety) – (page 4)

SPONSORED PROGRAMS/PROPOSALS ACCESS

Proposal Administrator

Proposal Administrator *provides access to the Proposal Development module without budget permissions, allowing a user to initiate a submission, complete all sections except the budget, and submit for route. Common role pairing: PI Delegate; PI Budget Preparer.* **Prerequisite for access: Basics Training**

Indicate "Add" or "Remove" Select

CLINICAL TRIALS/HUMAN SUBJECTS

Human Subjects Research Responsibilities

Select the tasks that the employee will be performing in Human Subjects and/or Clinical Trials:
(checkboxes or indicated an "add/delete" next to each selection.

Regulatory Coordinator
- Creating, editing or submitting Institutional Review Board (IRB) applications
- Creating, editing or submitting Protocol Review and Monitoring Committee (PRMC)

Clinical Research Associate
- Enrollment of participants/subjects onto studies
- Management of participant/subject data

Prerequisite for access: Study Activation and/or Subjects Enrollment Training

Indicate "Add" or "Remove"

Regulatory Coordinator: Select

Clinical Research Associate: Select / Add / Remove

Department Select Select Department Select Select

Department Select Select Department Select Select

Page 1

WRG-HS Submission

Things to Know About WRG-HS

Plan/Draft Protocol

Plan/Draft Consent(s)

Confirm CITI/COI Certification

Complete & Submit IRB Application

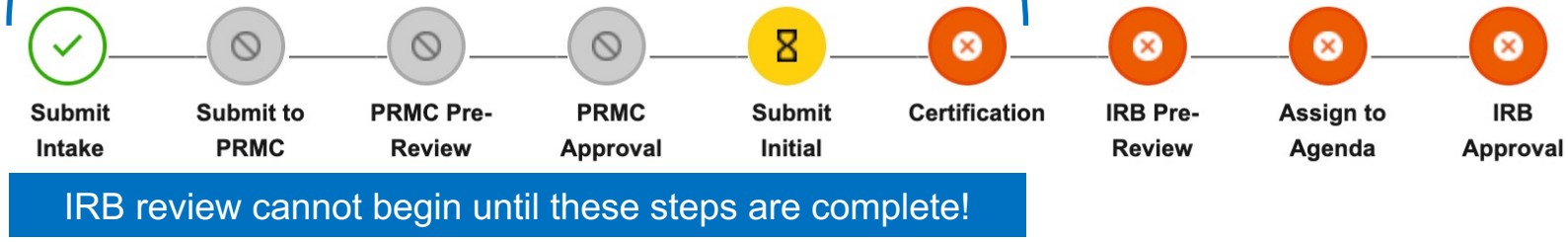
Received by IRB for pre-review

Returned for stipulations (revisions)

Formal IRB Review

Approval!

WRG Widget



IRB review cannot begin until these steps are complete!

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Categories of Review and Submission Timing

What Kind of Review?

Meeting dates are on our webpage

Degree of Risk	Category of Review	WCM IRB Form	Submission Deadline	Typical Turnaround*
minimal	Exempt	WRG-HS	Rolling	~2 weeks
minimal	Expedited	WRG-HS	Rolling	~2 weeks
> minimal	Full	WRG-HS	Rolling	~2 weeks

*Turnaround means first response by IRB. This may be approval, or more often, a request for changes or additional information in order to start a formal review

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Exempt Research

What Kind of Review?

Review Procedure:

- **Exempt research requires submission to and verification by the WCM IRB**
- **Researcher must submit to the WCM IRB:**
  - WRG-HS Application and detailed protocol, including required documents
- **Exempt studies require an informational sheet (if applicable) to provide relevant information about the study to potential participants**
- **WCM IRB will issue a formal determination of exemption**

Expedited Review

What Kind of Review?

- **Research involves no more than minimal risk and procedures listed in one or more of the federally defined categories**
  - https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html
- **Protocol is reviewed by one or more IRB member**
- **If protocol is determined to be more than minimal risk, review will send it to full committee review**
- **A single reviewer may not disapprove the research**
  - BUT they may determine that is should have full committee review.

Full Board Review

What Kind of Review?

The following human subjects research requires review by a convened IRB:

- **Research that does not qualify for expedited review or exemption from federal regulations**
- **Research that is referred to full board during expedited review by an IRB member**
  - For disapproval
- **Research involving certain vulnerable populations**

How Does Full Board Review Work?

What Kind of Review?

1. **Submissions are assigned to a board on a rolling basis once they are determined to be complete**
2. **Protocol assigned to two IRB members for detailed review**
   - Reviewers may consult with the PI to resolve issues before the meeting
3. **Reviewers present the protocol to the IRB for discussion**
   - IRB members with COI must recuse themselves
4. **Further discussion followed by a vote to approve, request modifications, or disapprove the protocol**
5. **PI is notified of outcome and any required changes for approval**

Full Board Determinations

What Kind of Review?

- **Approved**: Meets regulatory requirements for approval; no changes necessary
- **Modifications required**:
  - Directive changes necessary
  - Substantive changes necessary
- **Disapproved**: The board cannot reasonably imagine revising the study in such a way that the benefits outweigh the risks

Notification of Approval!

What Kind of Review?

Note:

- **Approval period***
- **Any provisos**
- **“Stamped” (digitally) documents available in WRG-HS:**
  - Consent forms
  - Recruitment material
  - Any other patient-facing materials

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*No expiration date in the stamp for PAM-AR eligible studies

Approval/Expiration Dates

What Kind of Review?

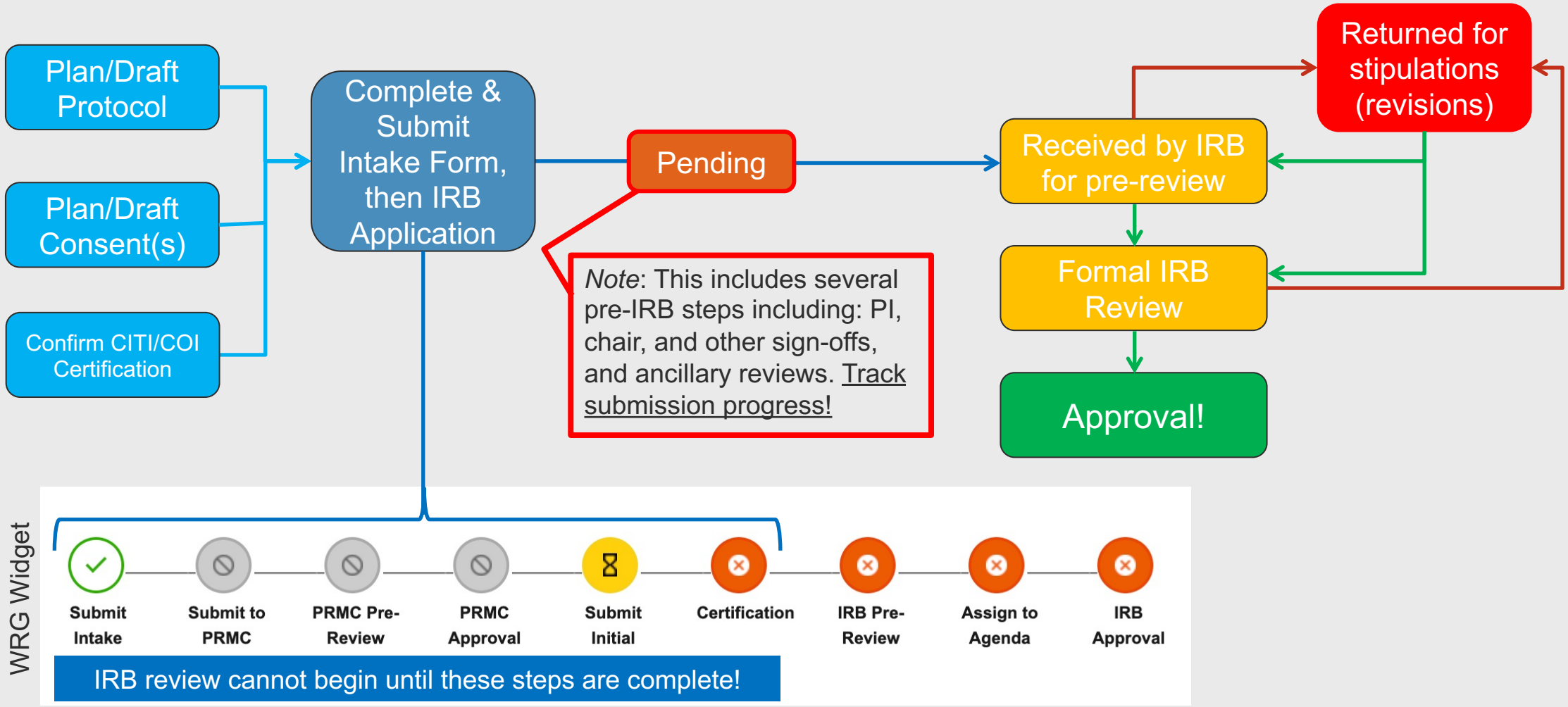
Protocol & Informed Consent

- **First page of ICF is "stamped", showing:**
  - Approval date (from)
  - Expiration date (to) *
- **Re-approval after any changes are made (via amendment)**
- **Do not let your approval lapse!**
  - Submit your renewal ***at least*** 60 days before your expiration date
- **Most recently approved document must be used at all times**
  - Available in WRG-HS

Where Is My Study?

WRG-HS Submission

Things to Know About WRG-HS



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Common Causes For Delays

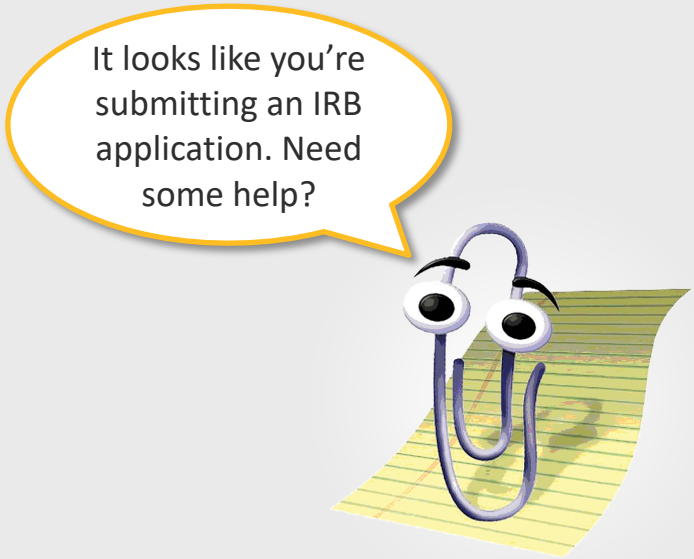
Common Causes of Delays

- **Submission not fully submitted**
  - e.g., still in draft, signature routing not completed correctly, etc.
- **Missing PRMC approval**
- **CITI not current for key personnel**
- **COI not current for key personnel, if applicable**
- **Incomplete/inaccurate/ inconsistent submission**
- **Slow responses to stipulations**
- **Common WRG errors:**
  - Application errors (read the questions carefully)

Missing/incorrect/incomplete answers in your WRG application, and/or the absence of required documents, will delay your review!

Tip #1: Complete the WRG-HS Training

- **Book a training**
- **Consult the WRG-HS Knowledge Base documents**
- **Make sure your CITI account is linked to your WRG-HS email that your training is up to date**
- **Make sure your COI survey is submitted**



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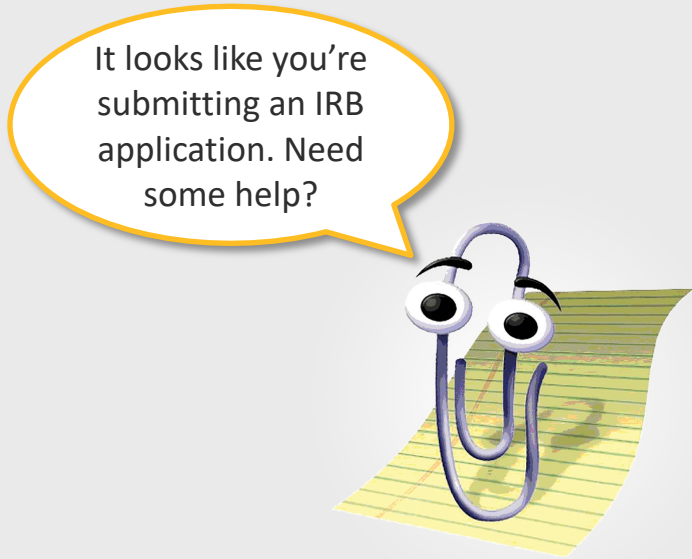
Tip #2: Avoid Incomplete or Sloppy Paperwork

- **Remove all help text and irrelevant sections from consent form templates**
- **Include ALL documents:**
  - Data collection tool
  - Recruitment flyers
  - FDA documentation
  - etc.



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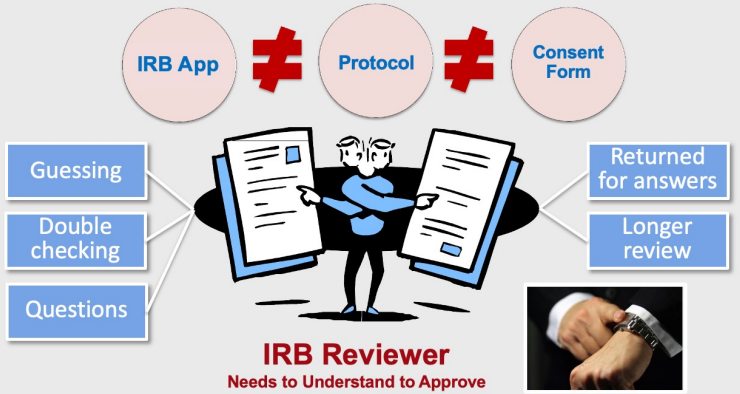
Tip #3: Avoid Discrepancies!



The IRB pays close attention to detail and cannot process submissions when discrepancies exist!

Example 1

IRB application states the PI is requesting a QI determination but the protocol describes the project as a research study

- The IRB follows a very specific federal definition of what qualifies as research. It's important for the IRB to understand the intent of the PI but also to ensure consistency across documents (since the research vs. QI determination impacts regulatory requirements for the PI and the institution.)

Example 2

Protocol states no identifiers will be collected; data collection tool indicates that dates of service will be collected

- Dates are indirect identifiers under HIPAA
- The IRB is also a HIPAA privacy board so will ask you for a detailed data collection tool in order to make HIPAA determinations

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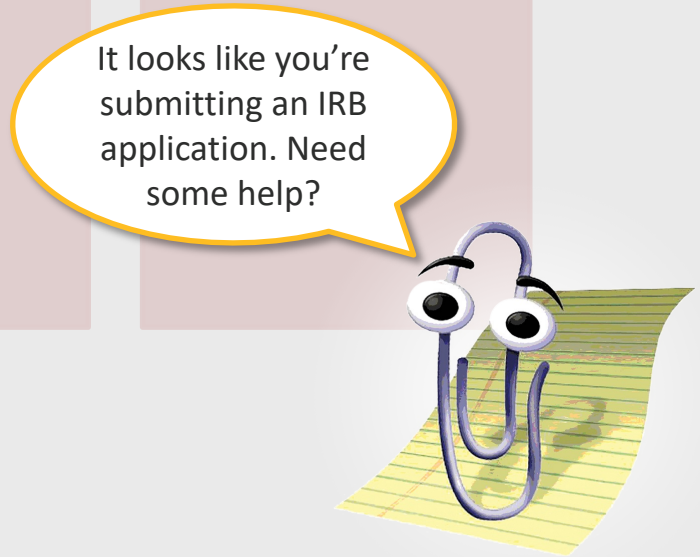
Tip #4: Describe Recruitment in Detail

Who?	Where?	Why?	When?	How?
• Any secondary subjects involved? • Proxy or LAR consent? • Parental permission?	• Appropriate institutional permission in place? • Does location of recruitment cause risk to subject or chance for undue influence or coercion? • Any international or state laws to consider?	• Rationale for including or excluding certain populations?	• Consider potential for undue influence or coercion	• Which individuals will conduct consent? • How will you notify potential participants about a study?



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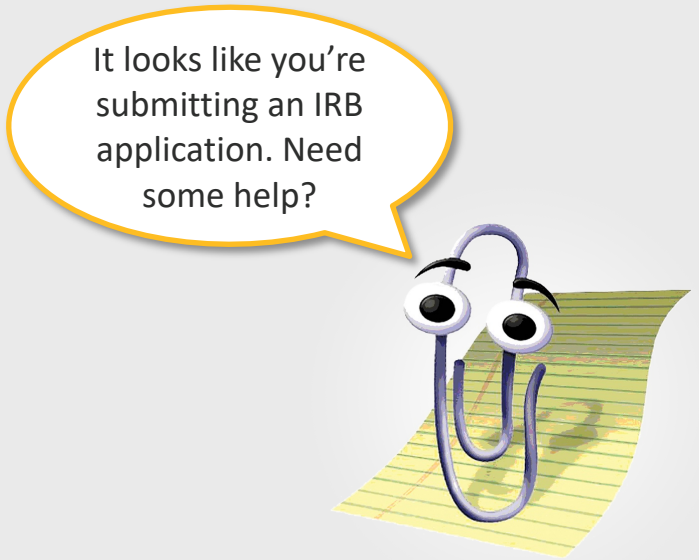
Tip #5: Describe the Flow of Information

- **If the institution receives or shares identifiable information for human subjects research purposes, IRB review is required**
- **If the institution sends out PHI for human subjects research purposes, the IRB must verify that a valid HIPAA Authorization is in place to allow the disclosure**
  - Or, the IRB may approve a waiver of HIPAA Authorization
  - For non-HRS purposes, contact the Privacy Office
- **DUAs and/or MTAs may be required prior to sending or receiving data and/or specimens**
- **Please describe very clearly what, exactly, is being sent where**



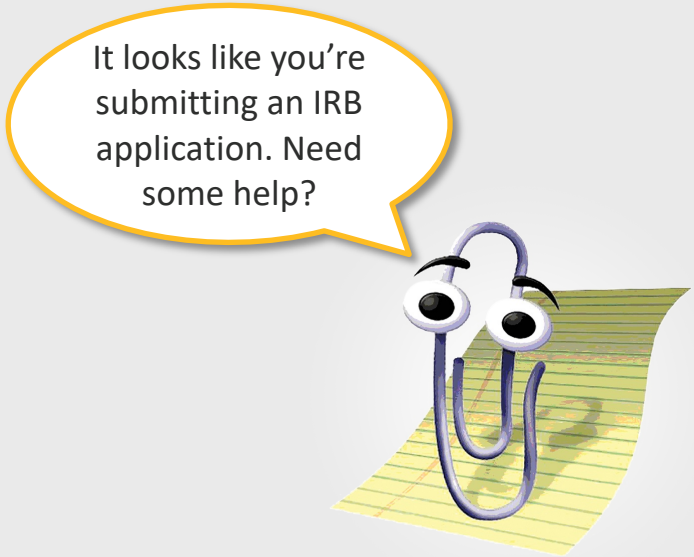
Protected Health Information Identifiers

Protected Health Information (PHI) Identifiers

The 18 Identifiers defined by HIPAA are:

- ☑ Name
- ☑ Postal address
- ☑ All elements of dates except year
- ☑ Telephone number
- ☑ Fax number
- ☑ Email address
- ☑ URL address
- ☑ IP address
- ☑ Social security number
- ☑ Account numbers
- ☑ License numbers
- ☑ Medical record number
- ☑ Health plan beneficiary #
- ☑ Device identifiers and their serial numbers
- ☑ Vehicle identifiers and serial number
- ☑ Biometric identifiers (finger and voice prints)
- ☑ Full face photos and other comparable images
- ☑ Any other unique identifying number, code, or characteristic

Reminder: Dates and zip codes or other geographic indicators are *indirect* HIPAA identifiers. Data that contains dates, zip codes, etc., is *not* considered de-identified under HIPAA



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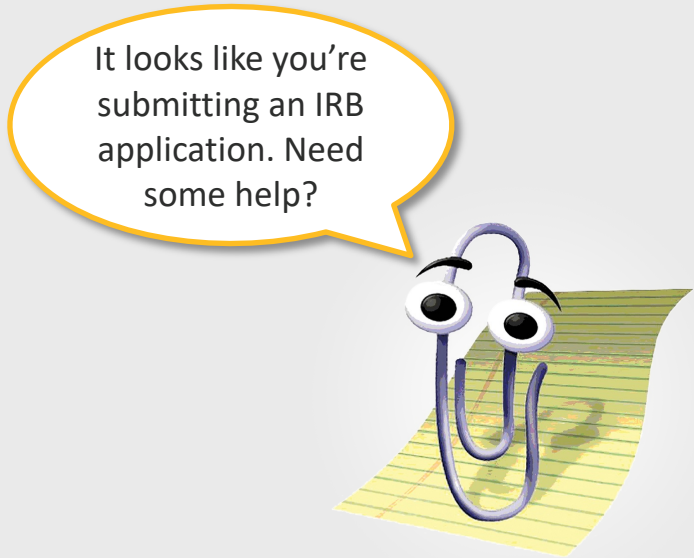
Tip #6: List all External Sites

- **List all sites involved in the research including coordinating centers and protocol sites**
- **External collaborators working on human subjects research need IRB approval**
  - IRB approval should be obtained through the collaborator's home institution or through the WCM IRB
  - For federally-funded, non-exempt research, a reliance agreement must be in place. Please email reliance@med.cornell.edu to set up reliance agreements or for questions related to single IRBs/collaborators



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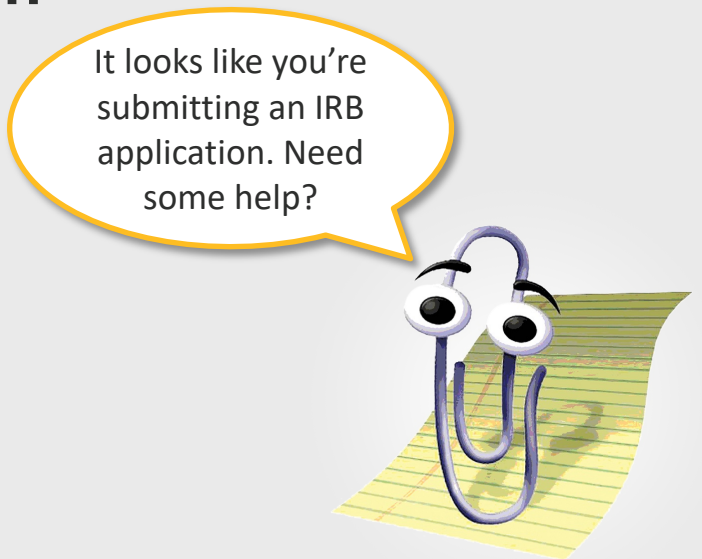
Tip #7: Clearly Distinguish between Research and Standard of Care

- **Generally speaking, the protocol and consent should describe the risks and benefits associated only with the *research* and not any related SOC procedures**
- **The IRB weighs the risks and benefits of research procedures only, and approval will be delayed if it is not clear to the IRB which procedures are part of standard of care and which are for research purposes only.**
- **Please describe research procedures and SOC clearly and chronologically**



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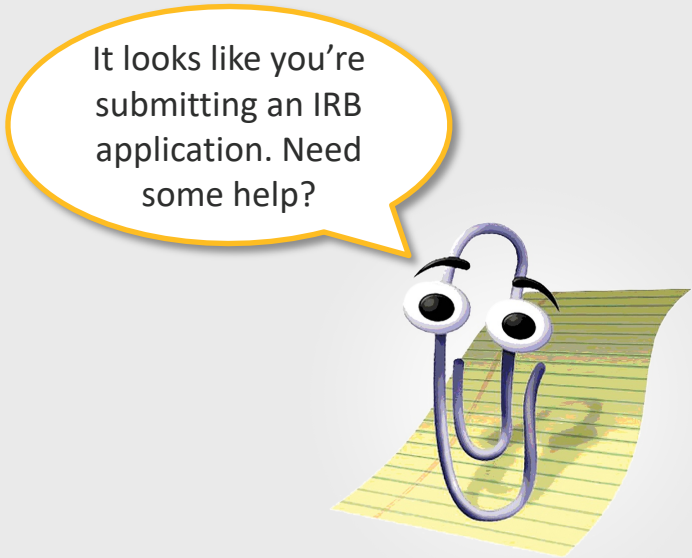
Tip #8: Include a Data Analysis Plan

- **Is the sample size adequate to answer the research question and to justify putting subjects at risk?**
- **Is the data analysis appropriate for the question being asked?**



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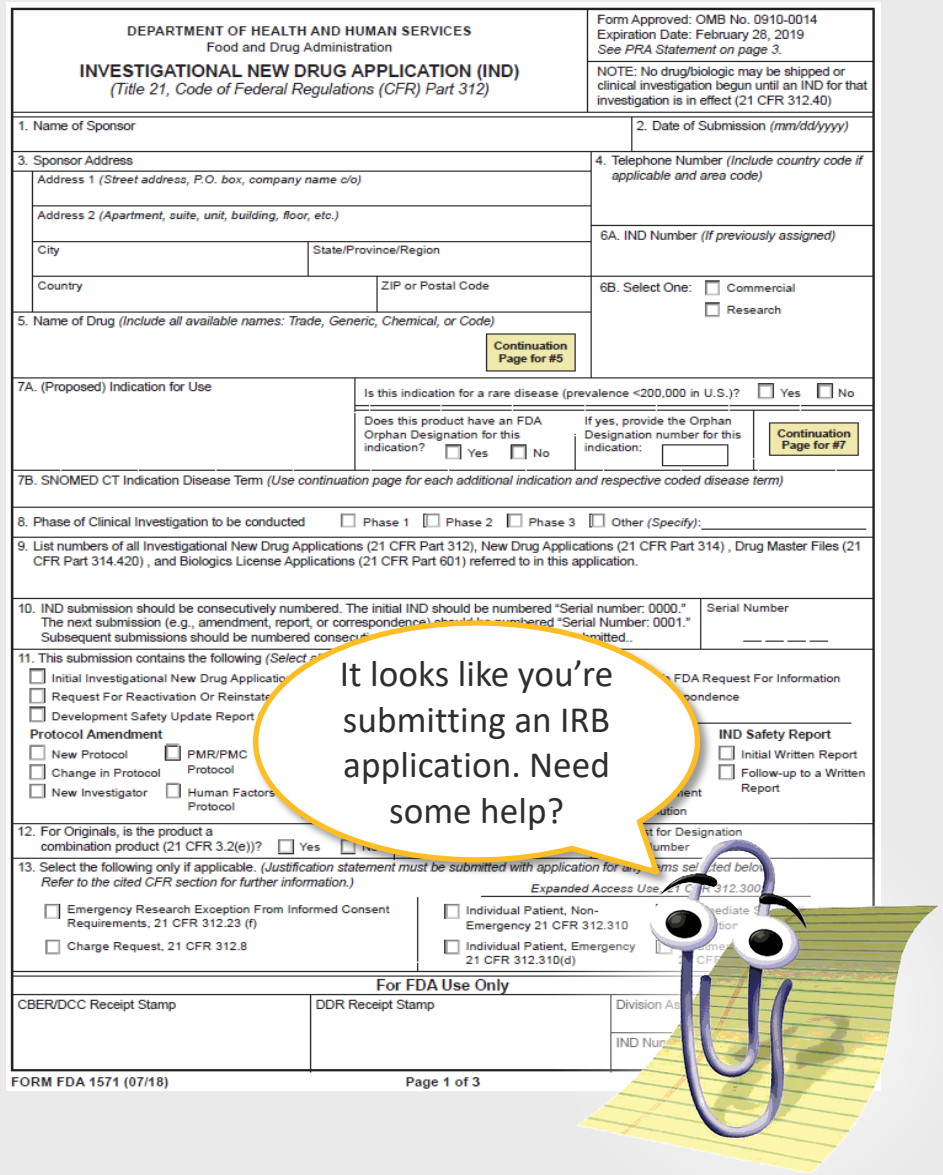
Tip #9: Make Sure Your FDA Paperwork is Up To Date

- **If you are the sponsor investigator, as defined by the FDA, please be sure your IDE or IND paperwork is up to date (including amendments for any new protocols submitted to the IRB)**
- **For assistance with FDA paperwork or questions about FDA regulated research, please submit an IRB Training and Consultation Request here**



Tip #10: Ensure your ICF Meets IRB Expectations

1. WHAT IS IT ABOUT?
A statement about, and description of, the study

2. WHAT ARE THE RISKS?
A description of risks or discomforts to the subject

3. WHAT ARE THE BENEFITS?
A description of any benefits to the subjects

4. ARE THERE ALTERNATIVES?
A disclosure of appropriate alternative procedures or courses of treatment

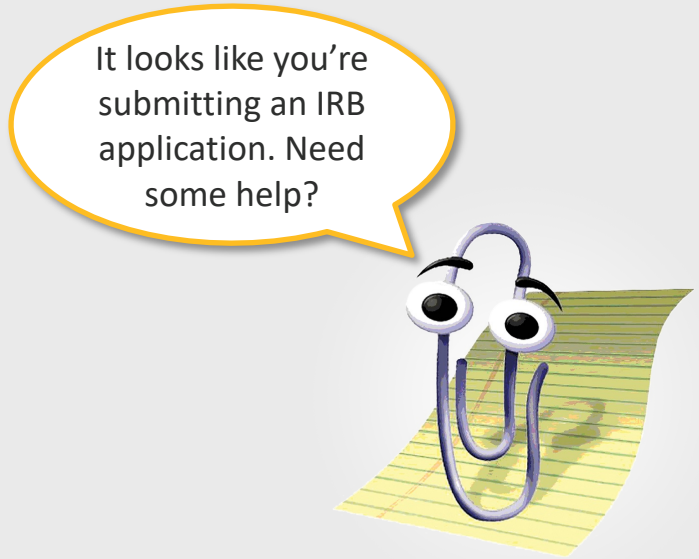
5. WHO WILL KNOW?
A statement describing how confidentiality will be maintained

6. IS THERE COMPENSATION?
For greater-than-minimal risk studies, compensation and/or medical treatment

7. WHO IS THE CONTACT?
Contact information for questions or more information

8. IS IT MANDATORY?
A statement that participation is voluntary

9. WHAT HAPPENS AFTER?
A statement about what will be done with collected information



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For more on the ICF…

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Informed Consent in Research

Regulatory Requirements and Ethical Considerations

Kaori Kubo Germano, Ph.D.
Human Research Compliance

Thursday, Augus

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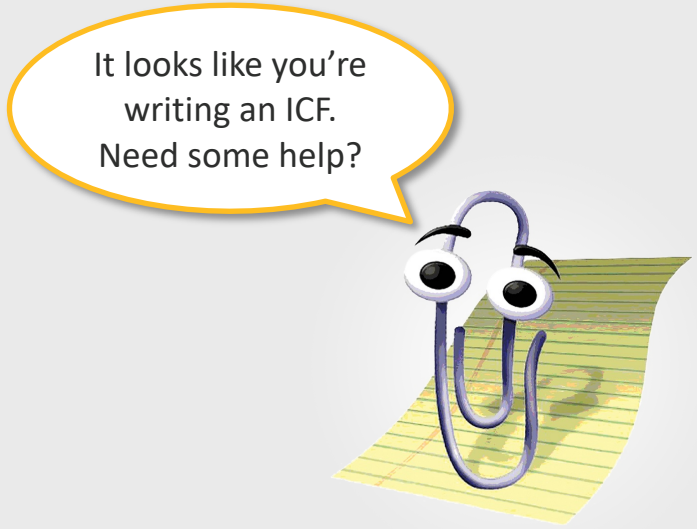
Key Information Section

A 2018 Common Rule Requirement
for the Informed Consent Form

Office of Research Integrity
Human Research Compliance

http://research.weill.cornell.e



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Checking Readability

The Flesch-Kincaid Grade Level Readability Test

Office of Human Research Protection & Compliance
Melissa Epstein, PhD, MBE, CIP *Executive Director*

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

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For more Tips and Tricks…

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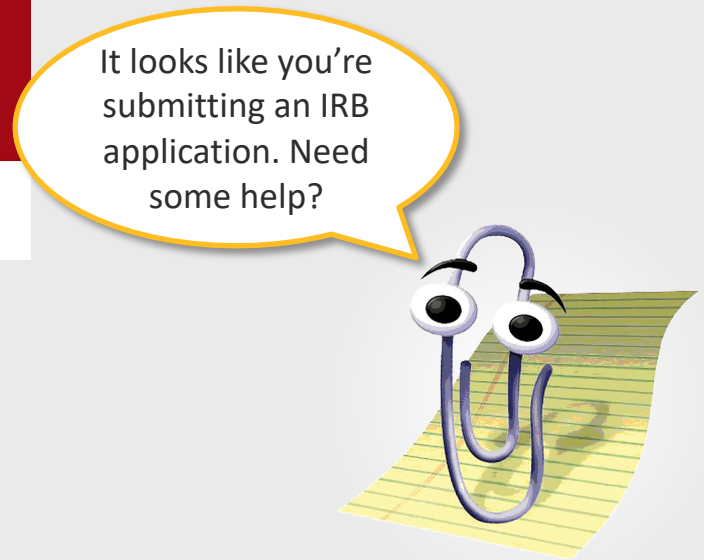
Tips and Tricks:
Successful IRB Submission and Review Process

Yefrenia Henriquez Taveras, MPH, MHA, CHES
Clinical Research Program Manager & Sr. IRB Navigator
Human Research Compliance Office

Wednesday, March 1, 2023
https://research.med.cornell.edu/irb



Ongoing (Post-Approval) Requirements

Post Approval Process

- ✓ Well planned protocol
- ✓ Completed COI disclosure
- ✓ Completed CITI training
- ✓ Ancillary Committee(s) approval
- ✓ Appropriate informed consent process
- ✓ Complete and accurate IRB application
- ✓ Approval
- ✓ Post-approval compliance

- **Advertisements and amendments must be reviewed *prior to* implementation**
- **Continuing review required for re-approval**
- **Protocol exception requests for planned, one-time deviation from protocol**
- **Reportable events must be reported within 5 business days**
- **Everything is submitted in WRG**

Protocol Recertification: Continuing Review & PAM-AR

Post Approval Process

- ✓ Well planned protocol
- ✓ Completed COI disclosure
- ✓ Completed CITI training
- ✓ Ancillary Committee(s) approval
- ✓ Appropriate informed consent process
- ✓ Complete and accurate IRB application
- ✓ Approval
- ✓ Post-approval compliance

- **On-going research must be re-reviewed at intervals appropriate to the degree of risk, at least once per year**
- **PI is notified in advance of the due date**
  - Notifications emailed **90**, **60**, & **30** days before, and **on,** the expiration date
- **All research must halt once IRB approval expires**
  - Remember: maintenance of identifiable data is considered research activity!

*If you have a reliance agreement in place and we are NOT the IRB of record, research does not have to be halted as long as a CR/PAM-AR has been submitted to the WCM IRB within 2 weeks of the IRB of record's CR/PAM-AR approval

Reportable Events Policy

Post Approval Process

- ✓ Well planned protocol
- ✓ Completed COI disclosure
- ✓ Completed CITI training
- ✓ Ancillary Committee(s) approval
- ✓ Appropriate informed consent process
- ✓ Complete and accurate IRB application
- ✓ Approval
- ✓ Post-approval compliance

Events must be reported to the IRB within 7 calendar days:

- **Unanticipated Problems**
- **Protocol deviations**
- **Breach of confidentiality (*within 24 hours*)**
- **Action taken to eliminate an apparent immediate hazard to subjects**
- **Other events listed in the policy, found here**

What We've Covered

- Office of Human Research Compliance Organizational Chart
- Is IRB Review Required?
- Preparing and Submitting to the IRB
- Things to Know About WRG-HS
- What Kind of Review?
- Common Causes of Delays
- Post Approval Process

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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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Resources

Office of Human Research Compliance website

https://research.weill.edu/irb

Includes:
- Policies and Procedures
- Submission Guidelines
- Educational Materials
- Staff Directory

Visit our Human Research Compliance Monthly Education and Training Series (METS) page to watch recordings of our past METS presentations!

Need help? We are here for you!

or

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

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WCM IRB Contact Information

irb@med.cornell.edu

Office of Human Research Protections and Compliance website

https://research.weill.edu/irb

includes

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Submission Guidelines

Educational Materials

Staff listing

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