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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.
- Please take your phones out!
- Not registered? Please register now using the QR code.

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Pulling Back the Curtain:

A look into IRB Pre-Review and IRB Review

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

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8+ years of experience in human subjects research regulatory compliance.

My Masters is in Bioethics and Science Policy with a focus on the process of Informed Consent within the research context.

Joined WCM in March of 2022

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Karen Hawkins

7+ years in human subjects research regulatory compliance.

13+ years in human subjects research work.

Joined WCM in 2022.

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Lindsay Ropchock, JD, CIP

5+ years in human subjects research regulatory compliance.

Former course director on medical ethics.

10+ years experience as an attorney.

Joined WCM in December of 2021

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Today's Topics

IRB Pre-Review

IRB Member Review

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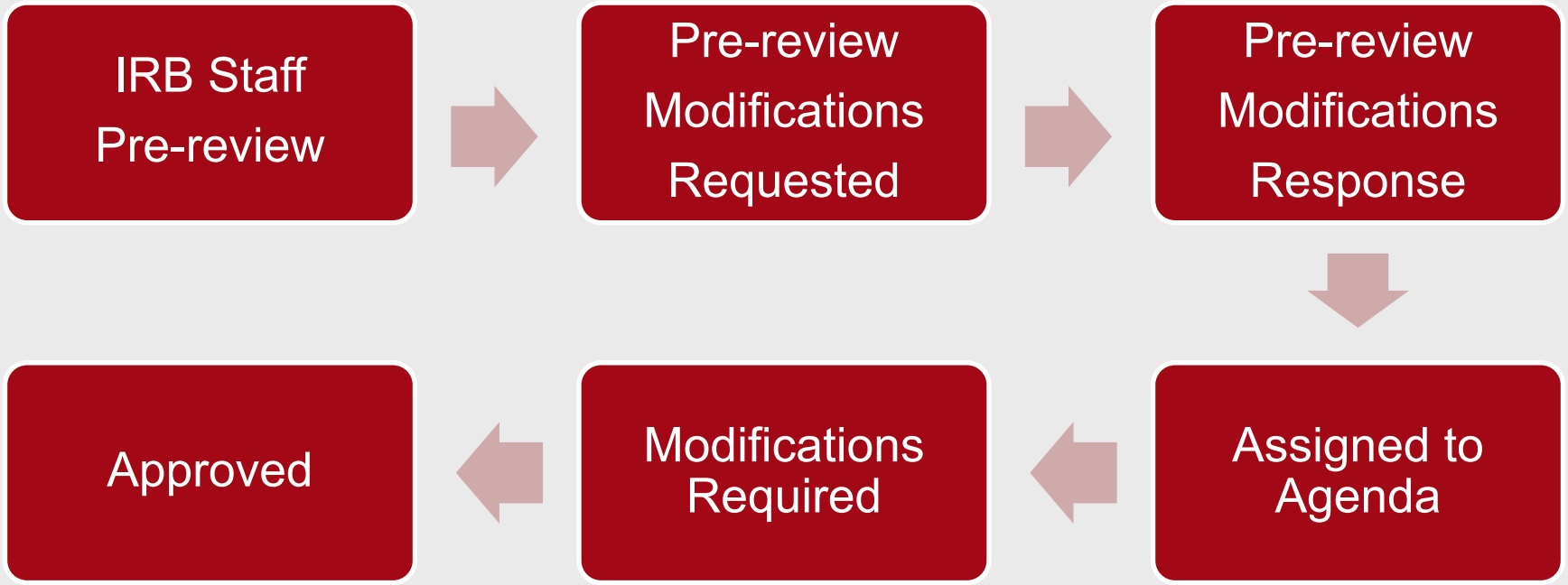
I submitted to the IRB….now what?

- Submissions enter into a queue.
- Managers assign the submissions to an analyst.
- Pre-review begins!

Study Statuses in WRG Progression: From Submitted to Approved



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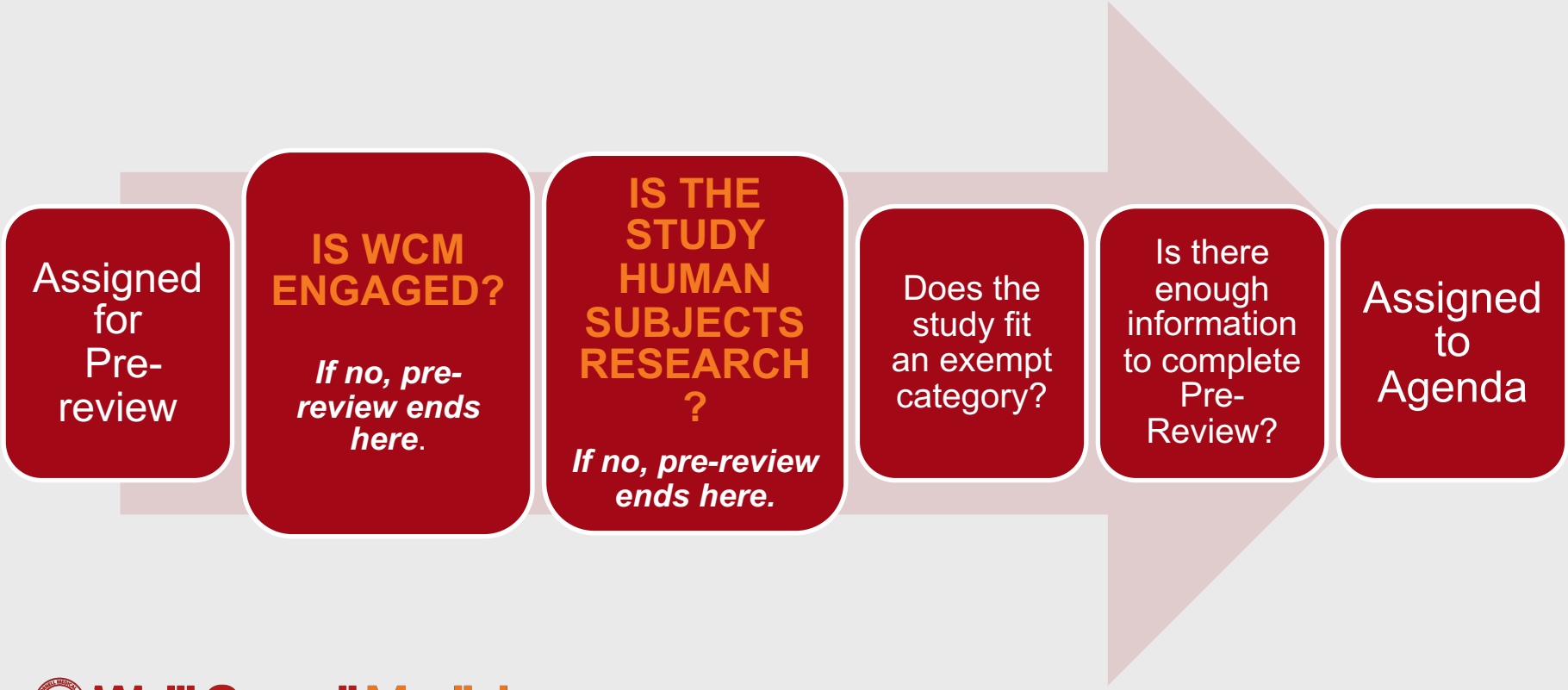
IRB Pre-Review

Pre-review Process



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Pre-Review Considerations

- IRB Analysts look for:

Engagement

Research

Human Subjects

- *If your study is NOT engaged or human subjects research, IRB review and oversight is **not required** and you will receive correspondence from the IRB.*

NOTE: You may need to contact other offices for other requirements, such as a Data Use Agreement (DUA) and HIPAA Authorization/Wavier.

Engagement

Does WCM's role in the proposed research involve any of the following?

IRB Analysts look for:

1. **Whether WCM is receiving funding.**
2. **Whether WCM employees or agents obtain any of the following for the purpose of the research:**
   - **Data about participants through intervention or interaction;**
   - **Identifiable private information about the participants; or**
   - **The informed consent of human participants for the research.**

Research

Research: “A systematic investigation designed to develop or contribute to generalizable knowledge.” 45 CFR 46.102.

IRB Analysts look for:

1. **Plan to study a specific topic or test a hypothesis or theory.**
2. **Plan for data collection and analysis.**
3. **Purpose of this stage of the study.**
4. **What do you intend to do with the results?**

Human Subjects

Human Subject: “A living individual about whom an investigator:

- Obtains information or biospecimens through interaction or intervention with the individual and uses, studies, or analyzes that information or biospecimens, **OR**
- Obtains, uses, studies, analyzes, or generates identifiable private information and identifiable biospecimens.” 45 CFR 46.102.

IRB Analysts look for:

1. **What data is being collected and from whom?**
2. **Is the data identifiable? Can the individual source be identified?**

Pre-review Process

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Exempt Studies

- **IRB Analyst considers:**
  - Study meets criterion of one or more exempt categories per Federal Regulations 45CFR46.104.
  - Whether any part of the study does not fall into one of these categories.
- *If your study is determined to be an exempt study, it will be added to an exempt agenda.*
  - You may need to work with other offices regarding concerns about DUAs, etc.
  - Future continuing review is not needed.
  - Amendments that may impact whether a study qualifies for exemption must be submitted.

Let’s try our hand at it!

- Link to Quiz

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Quiz Question:

A study involving video-recorded interviews where the researcher is examining how being diagnosed with HIV affects parenting. No names or other identifying information will be collected. All recordings and planned transcriptions will be saved in REDCap for analysis. Recruitment will take place at an HIV clinic.

Link to responses

Quiz Answers:

Exempt Category (2): Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.

ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

Pre-review Process

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Analyst Pre-Review Considerations

Analyst Pre-Review Considerations

Are all the necessary documents present?

- IRB Review Application (IRA) or IRB Application
- Consent
- Protocol
- Supplemental Forms: Specimen, Device, Drug
- Investigator's Brochure (IB) or Prescribing information
- FDA documentation: IND approval, IDE approval, 510k, etc.
- Recruitment Materials: Flyers, emails, etc.
- Data collection tools: Surveys, focus group topic guides, etc.
- Data Safety Monitoring Board (DSMB) Charter/Report

Analyst Pre-Review Considerations

Are all uploaded documents completely filled out?

- **IRB Review Application (IRA)**
  - ✓ Instructional language removed
  - ✓ Sections labeled “N/A” as needed
  - ✓ Detailed, complete descriptions of regulatorily relevant information
- **IRB Application**
  - ✓ All checkboxes and free text areas
- **Consent**
  - ✓ WCM template
  - ✓ All required elements and any appropriate additional elements from 45CFR46.116
  - ✓ Additional information from appendix as appropriate
- **Supplemental Forms**
  - ✓ All applicable checkboxes and free text areas

Analyst Pre-Review Considerations

Is the content consistent across all submitted documents and application?

- If the IRA says 50 subjects will be enrolled, the application (when applicable), consent, and protocol should say the same.
- The risks listed in the IRA should also be in the consent and protocol
- The provisions for storage and future use of data or specimens should match across all documents.
- Study procedures should be listed across all documents.

Analyst Pre-Review Considerations

Committee	Acronym	Phone	Email
Radiation Safety Committee	RSC	(646) 962-7233	mhp@med.cornell.edu
Conflict of Interest	COI	(646) 962-8200	conflicts@med.cornell.edu
Institutional Biosafety Committee	IBS	(646) 962-7233	ibc@med.cornell.edu
Protocol Review and Monitoring Committee	PRMC	(646) 962-8215	GeneralPRMC@med.cornell.edu
Protocol Review and Monitoring Committee – Cancer	PRMC-C	----------	CancerPRMC@med.cornell.edu
Privacy Office		(646) 962-6930	privacy@med.cornell.edu
Clinical & Translational Science Center	CTSC	(646) 962-8302	ctsc@med.cornell.edu
Office of Sponsored Research Administration	OSRA	(646) 962-8290	osra-contracts@med.cornell.edu
Artificial Intelligence Working Group		----------	yiz2014@med.cornell.edu
Digital Health Technology	DHT	----------	ri-review@med.cornell.edu

Analyst Pre-Review Considerations

Are all applicable Federal Regulations satisfied?

- New Common Rule (2018)
- Health Insurance Portability and Accountability Act (HIPAA)
- Subpart B – Pregnant Women/ Fetuses
- Subpart C – Prisoners
- Subpart D – Minors
- Department of Defense (DOD) / Department of Education (DOE)
- Food and Drug Administration (FDA)
- Family Education and Rights and Privacy Act (FERPA) / Protection of Pupil Rights Amendment (PPRA)

Helpful Tips when submitting

- Consistency
- Complete answers
- Think of the IRB as someone unfamiliar with your field, office, or clinic.
  - Include charts or diagrams
- Only what is in the application
- Please reach out to the IRB if you have questions

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Criteria for Approval

Approval Criteria

- If a study is non-exempt human subjects research, it *must* meet the Criteria for Approval (".111 Criteria") (45CFR46.111, 21CFR56.111).
- **IRB Analyst considers whether enough information has been included for the IRB members to determine that these criteria are satisfied.**
  - "Pre-Review Modifications" required if additional information is required.

Approval Criteria (45 CFR 46.111/ 21 CFR 56.111)

1. **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.

IRB Analysts look for:

- **Descriptions of the procedures being used for research purposes and/or being used clinically.**
- **Descriptions of any risks that subjects are being exposed to and plans for mitigating those risks.**
- **Rationale for all risks.**

Approval Criteria (45 CFR 46.111/ 21 CFR 56.111)

2. **Risks 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.**

IRB Analysts look for:

- **Descriptions of any benefit to the participants.**
- **Descriptions of any future benefits to other patients or society at large.**

Approval Criteria (45 CFR 46.111/ 21 CFR 56.111)

3. **There are adequate provisions to protect the privacy of subjects.**

IRB Analysts look for:

- **Descriptions of how privacy of subjects will be protected:**
  - **Location**
  - **Security**

Approval Criteria (45 CFR 46.111/ 21 CFR 56.111)

4. **There are adequate provisions to maintain the confidentiality of data.**

IRB Analysts look for:

- Description of how data will be protected
  - Where it will be stored
  - Who will have access
  - When it will be destroyed
  - Code “key”

Approval Criteria (45 CFR 46.111/ 21 CFR 56.111)

5. **The informed consent process is adequate.**

IRB Analysts look for:

- Description of how informed consent will be obtained
  - When and where potential subjects approached
  - Who will approach
  - Opportunity for questions
  - Opportunity to consult

Approval Criteria (45 CFR 46.111/ 21 CFR 56.111)

6. **The documentation of informed consent is adequate.**

IRB Analysts look for:

- Required elements
- Reading level
- Appropriate wording
- Signatures

Let’s try our hand at it!

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Link to Quiz

Quiz Question:

A study collects survey responses and results from an MRI with contrast being conducted for research purposes only. The study team describes their plan to maintain the confidentiality of data:

All data will be coded. The data will be stored in a password-protected file on the WCM server and accessible by the study team. The key linking the codes to the identifiers collected for the subjects (MRN, name, date of birth) will be stored in a locked filing cabinet in the PI's office in a WCM building.

.111 Criteria #4: There are adequate provisions to maintain the confidentiality of data.

Is this enough information for an IRB reviewer to determine that this criteria has been satisfied?

☐ Yes ☐ No

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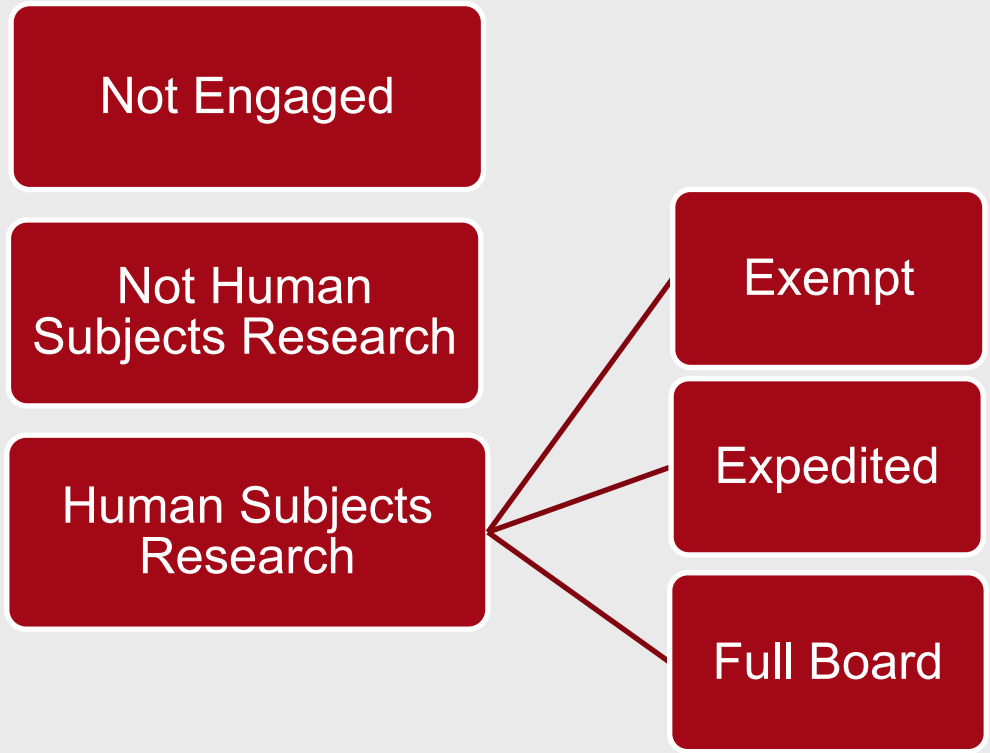
Pre-review complete

Pre-review Process



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Where does the submission go next?

- IRB analyst makes a preliminary decision regarding risk level for the study at the same times as considering if the study could be reviewed under the expedited categories.
  - Expedited submissions do not require a full board review; “Expedited” does not reflect speed of review
  - Do **all** of the study interventions/activities fall under Expedited Categories?
  - Studies reviewed expedited process must be minimal risk
    - If at any point during the rest of the review, a risk level of GTMR is suspected, the submission can no longer be reviewed expedited process

Minimal Risk vs. Greater Than Minimal Risk

Minimal Risk

The "probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests" (45 CRF 46.102(j) and 21 CFR 56.102(i)).

Examples: Saliva (buccal) swab, surveys, handwriting sample

Greater Than Minimal Risk

The probability and magnitude of harm or discomfort anticipated in the research risks are more than minimal risk.

Examples: Research biopsy, MRI with contrast

Most of the time,

- If the study seems like minimal risk, it can be reviewed via expedited process (fits the expedited categories)
- Greater than minimal risk submissions needs full board review

But my study is minimal risk!

Reasons something that may be or may seem like minimal risk is scheduled for full board review:

- **The study needs an NSR device determination**
- **Intervention or study procedure doesn't fit into any of the expedited categories**
  - Example: Blood draw volume in sick population exceeds expeditable amount. (Expedited category 2 allows for blood draws but specifies the amount of blood you can draw in an 8 week period for both healthy and unhealthy populations.)
- **A minimal risk intervention is being conducted on a population that may be at higher risk.**
  - Example: A study is conducting focus groups and administering surveys regarding suicide ideation to a group of veterans with PTSD

Let's Discuss: Determining Risk

Minimal Risk

- A study collecting body composition assessments and BMI calculations for research purposes.
- In a cohort of CrossFit members.

Greater Than Minimal Risk

- A study collecting body composition assessments and BMI calculations for research purposes.
- In a cohort of subjects with anorexia.

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IRB Member Review

Elements of a Member Review

- **Take a deeper dive into what analysts look for in pre-review**
- **Make a risk level determination**
- **Determine whether the approval criteria are met**

Pre-review vs. Review – A Deeper Dive

Pre-review

- **Analysts have expert knowledge of the federal regulations**
- **Focused on completeness of information based on regulatory and institutional requirements**
  - "Is the information present and clear?"

Member Review

- **Checklist is saved in WRG as proof of a complete and thorough review**
- **Focused on medical practicality, risks, and the overall subject experience**
  - "Is the information provided reasonable, practical, and scientifically sound? Is it good enough?"

Making a Risk Determination

- **Reviewer reviews the analyst's recommendation**
- **Reviewer assesses the risks and benefits involved in study participation**
  - Considers how the risks to subjects compare to the potential benefits of participation
  - Considers only those risks and benefits that may result from the research, not those from therapies subjects would receive clinically
- **Expedited reviewer makes a minimal risk determination independently**
- **The convened Full Board makes the risk determination**
  - Could be either minimal risk or greater than minimal risk

Assessment of Approval Criteria

- **The reviewer assesses the information provided and determines if the .111 Criteria have been satisfied.**
  - Risk v. Benefit Analysis
  - Privacy of Subjects
  - Confidentiality of Data
  - Informed Consent Process
  - Informed Consent Documentation

Exempt or Expedited Member Review

- **Agendas close at the end of each week and the assignments are made**
  - One reviewer is assigned
  - No convened meeting
  - Reviews are completed on a rolling basis
  - Reviewer considers comments by the IRB analyst after pre-review

Full Board Member Review

- **Agendas close roughly 2 weeks prior to the meeting date and assignments are made**
  - One or two primary reviewers are assigned
  - Reviewers have until the meeting to complete their review
  - Board members raise any questions or concerns for discussion

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What does an IRB meeting look like?

- **In the post-COVID era, WCM conducts IRB meetings over ZOOM.**
- **Generally attended by IRB board members and staff**
  - Board members come from varied backgrounds with experience and expertise across disciplines.
  - Students, clinical employees, and sometimes a study PI or coordinator may also attend.
- **At WCM, each convened Board meets twice a month.**
- **Meetings are scheduled for 2 hours.**
- **Full Board meeting dates**

At the IRB Meeting: Quorum

Quorum: The minimum number of members who must be present to conduct a meeting.

- Rosters for the convened board are comprised of primary and alternate board members
- Quorum is calculated by taking the number of primary members for a particular meeting, dividing in half, and adding 1
- Members who attend the meeting can be either primary members or alternates
- A non-scientist must be present at all times
- Must be maintained for the entirety of the meeting

At the IRB Meeting: Voting on a Motion

- A motion will be made and seconded, and a determination of for, against, or abstained is recorded by IRB staff
- At WCM, the majority of voting members must agree on the motion for it to pass
- Members can recuse from a discussion or vote due to a real or perceived COI

What happens after the member review?

- **For all submissions (reviewed by the expedited reviewer or the full board), the next steps are essentially the same:**
- **IRB analyst records the determination in WRG and issues the determination letter to the study team.**
  - **Modifications required**
  - **Approval**
  - **Disapproval**
- **If there are modifications required, your response is reviewed. If all required changes have been made, approval will be issued.**
  - Review of the modifications response may be done by a member or at another convened meeting.

Helpful Resources

- **WCM IRB Website**
  hrp.weill.cornell.edu
- **IRB Consultation Service**
  https://weillcornell.az1.qualtrics.com/jfe/form/SV_8B8nCOcC8q7pUN0
- **WCM IRB Office**
  irb@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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