IRB 101
An Introduction to the WCM IRB

Office of Human Research Compliance
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https://research.weill.cornell.edu/

Today's Topics

- Office of Human Research Compliance & Protections
- 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
Office of Human Research Compliance & Protections
Organizational Chart

Is IRB Review Required?
Preparing and Submitting to the IRB
Things to Know About iRIS
What Kind of Review?
Common Causes of Delays
Post Approval Process

Topic #1
Topic #2

IRB review is required for research involving human subjects
What is Research?

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 in which a drug is administered or dispensed to, or used involving, one or more human subjects. For the purposes of this part, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice.
- Investigation means a clinical investigation or research involving one or more subjects to determine the safety or effectiveness of a device.

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 investigational new drug 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 an investigational device 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)]
Office of Human Research Affairs Organizational Chart

Is IRB Review Required?

Preparing and Submitting to the IRB

Things to Know About iRIS

What Kind of Review?

Common Causes of Delays

Post Approval Process

Elements of a Successful Submission

- Well planned protocol
- Completed COI disclosure
- Completed CITI training
- Appropriate informed consent process
- Accurate IRB application
- Approval
- Post-approval compliance
Planning a Protocol

- Every new submission requires a protocol
- Resources to develop an appropriately detailed protocol:
  - WCM IRB’s Protocol Elements Checklist COMING SOON
  - Peer-reviewed SPIRIT 2013 guidelines https://www.spirit-statement.org/
- Be aware of IRB policies https://research.weill.cornell.edu/compliance/human-subjects-research/institutional-review-board/irb-policies-and-procedures

Conflict of Interest

- All researchers/investigators engaged in human subjects' research must file a financial COI disclosure with their protocol
- COI disclosures must be submitted when additional Investigators join a study
- COIs are submitted to the WCM COI office:
  - https://research.weill.cornell.edu/conflict-interest-office
Educational Requirements

- CITI Basic Course in Human Subjects Research
  - Refresher course needed after 3 years
- CITI Course in Good Clinical Practice (GCP);
  - Academy of Physicians in Clinical Research;
  - FDA Investigator Course;
  - TransCelerate BioPharma, Inc. approved courses;
  - National Institute of Allergy and Infectious Disease (NIAID) Program;
  - GCP courses offered by ACRP or SOCRA
  - Refresher course needed after 3 years

Informed Consent Process

- 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 (oral consent)
  - Waiver of Informed Consent (e.g., for chart reviews)
Oral Consent and Waivers

- A **waiver** of signed documentation or a full waiver of consent is permitted under the regulations in certain circumstances for minimal risk research.

- When **oral consent** is obtained, the research record should still contain documentation of the consent process, including the date and time.
  - The JCTO has an oral consent template.
  - IRB approval of the oral consent or waiver is required.

Accurate IRB Application

- The application must reflect the research and be consistent with information presented in the other submission components (e.g., protocol, consent documents, etc.)

- The application operates via dynamic branching logic, which means that it may be used to submit for determinations of:
  - Exemption
  - Expedited review
  - Full board review
  - Other determinations (e.g., not human subjects research, etc.)
IRB Review and Decision

Elements of a Successful Submission
- Well planned protocol
- Completed COI disclosure
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Plan/Draft Protocol
Complete & Submit IRB Application
Received by IRB for pre-review
Formal IRB Review
Approval!

Plan/Draft Consent(s)

Returned for stipulations (revisions)

Topic #4

Office of Human Research Affairs Organizational Chart
Is IRB Review Required?
Preparing and Submitting to the IRB

Things to Know About WRG-HS
What Kind of Review?
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Post Approval Process
WRG-HS Electronic Submission System

- All protocols for review by the IRB must be submitted through the Weill Research Gateway 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)
- **WRG Comprehensive Job Aid**

Before submitting to WRG-HS…

You **must** ensure that:

- The PI and **all** other key personnel (i.e., additional investigators and research support staff) have completed:
  - CITI Biomed and GCP training;
  - COI financial (when applicable)
  - COI Survey (ensure it is on file with the Conflict of Interest Office)

Contact omp2002@med.cornell.edu with any questions about COI
Topic #5

Office of Human Research Affairs Organizational Chart

Is IRB Review Required?

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Post Approval Process

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Categories of Review and Submission Timing

*Meeting dates are on our webpage*

<table>
<thead>
<tr>
<th>Degree of Risk</th>
<th>Category of Review</th>
<th>WCM IRB Form</th>
<th>Submission Deadline</th>
<th>Typical Turnaround*</th>
</tr>
</thead>
<tbody>
<tr>
<td>minimal</td>
<td>Exempt</td>
<td>WRG-HS</td>
<td>Rolling</td>
<td>~2 weeks</td>
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<tr>
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<td>Full</td>
<td>WRG-HS</td>
<td>Rolling</td>
<td>~2 weeks</td>
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*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*
Exempt Research

**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.
- 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.

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Expedited Review

- Research involves no more than minimal risk and procedures listed in one or more of the federally defined categories.
- Protocol is reviewed by one 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 it should have full committee review.
Full Board 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;
• Research that involves the randomization of standard of care

How Does Full Board Review Work?

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 are asked to recuse themselves
4. Further discussion followed by a vote to approve (full approval or provisional (with modifications), disapprove the protocol
5. PI is notified of outcome and any required changes for approval
Full Board Determinations

• **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!

Note:

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

*No expiration date in the stamp for PAM-AR eligible...
Approval/Expiration Dates

Protocol
• non-Exempt: 1 year
• Exempt/Expedited: no expiration
• Re-approval after any changes are made (via amendment)
• Do not let your approval lapse!
  – Submit your renewal at least 45 days before your expiration date

Informed Consent
• First page is “stamped”, showing:
  – Approval date (from)
  – Expiration date (to) *
• Most recently approved document must be used at all times
  – Available in WRG-HS

Topic #6

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Where Is My Study?

Submission Tracking

- Draft (Start here)
- Pending - Submitted for Initial Review
  - Returned for stipulations (revisions)
  - Received by IRB & Pre-reviewed
  - Formal IRB Review
- Awaiting Execution of Contract
- Approval!

Note: This includes several pre-IRB steps including: PI, chair, and other sign-offs, plus CITI Basic and GCP verification, and COI review. Track submission progress!
Common Causes For Delays

• Submission not fully submitted  
  o e.g., still in draft, signature routing not completed correctly, etc.
• Required signoffs missing
• CITI not current for key personnel
• COI not current for key personnel, if applicable

• Incomplete/inaccurate submission
• Slow responses to stipulations
• Common WRG errors:
  o 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!

Topic #7

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Post Approval Process
Ongoing (Post-Approval) Requirements

- 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

- On-going research must be re-reviewed at intervals appropriate to the degree of risk, at least once per year
- Re-review is to be as diligent as initial review
- 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!
- Notice of lapses in approval is issued to the PI, Department Chair, and Dean
Reportable Events Policy

Events must be reported to the IRB within 5 business days:

- Unanticipated Problems
- A Protocol Deviation
- Deviation from the IRB Informed Consent Policy
- Non-compliance
- Systematic data collection error
- Breach of confidentiality
- Other events listed in the policy, found [here](#)

What We Covered

- Human Research Protections and Compliance Organizational Chart
- Is IRB Review Required?
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- The Informed Consent Process
- Things to Know About iRIS
- What Kind of Review?
- Common Causes of Delays
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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

- Policies and Procedures
- Submission Guidelines
- Educational Materials
- Staff listing