Welcome!

• The session will begin shortly; please take a moment to make sure your microphone is muted.
• The presentation portion of this session will be recorded.
Understanding the IRB Review Application (IRA)

How to Craft a Thorough and Well-Structured IRA

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Today’s Topics

- The IRB
- Evolution of our IRB Application
- IRA Sections and Corresponding Approval Criteria
- Resources
The IRB
It's role and requirements
The Purpose of an IRB
Institutional Review Board (IRB)

Headed by scientists/nonscientists in any institution/agency conducting research with human participants

1. Minimization of risks to participants
2. Reasonable risk in relation to benefits
3. Equitable selection
4. Informed consent
5. Documentation of informed consent
6. Data monitoring
7. Privacy and confidentiality

IRB review is required for research involving human subjects
Applicable Regulations May Include

1. Declaration of Helsinki
2. Good Clinical Practice (GCP)
3. Food and Drug Administration (FDA) Regulations
4. Health Insurance Portability and Accountability Act (HIPAA)
5. Family Educational Rights and Privacy Act (FERPA)
6. International Conference on Harmonization (ICH) Guidelines
7. National Institutes of Health (NIH) Policies
8. State and Local Regulations
Commonly Accepted Ethical Standards

• Informed Consent
• Voluntariness
• Privacy and Confidentiality
• Beneficence
• Non-Maleficence
• Justice
• Respect for Persons
Evolution of our IRB Application
Our Old IRB Application

Many returns for clarifications

- Repetitive
- Out of order
- Unclear questions

Backlog

Upset researchers

Frustrated staff
How does the IRA streamline the submission process?

IRAs account for information about:

• General Study Design
• Retrospective and/or Prospective
• Cost, Reimbursement, or Compensation
• Risks and Risk Minimization
• Benefits
• Privacy and Confidentiality
• Informed Consent, Minor Assent, and Parental/Guardian Permission

WRG-HS's initial application now ONLY collects:

• Personnel (WCM/NYP)
• Non-Affiliated (Non-WCM/NYP) Personnel
• Review & Approval
• Sponsors and Entities
• Attachments
IRA and Corresponding Approval Criteria
Use this IRB Review Application if you have completed the "Therapeutic Studies JCTO Protocol template" and/or have a study which will use a de-identified or implement a clinical trial. If you are submitting a biorepository, complete the IRB Review Application - Biorepository. Please delete the instructions and sample text after you complete each section. Do not delete the section headings. If the heading does not relate to your research insert N/A.

First-time users of this form are encouraged to set up a walkthrough consultation with the IRB. Contact irb@med.cornell.edu or irb@med.cornell.edu or irb@med.cornell.edu with any questions.

You may also view the "Therapeutic JCTO Protocol Guidance Document" for additional information to assist in completing this application.

Title:

Version Date:

Funding Source(s):

Principal Investigator:

Study Sponsor:

INDBIE Number:

Participating Sites/Collaborators:

IRB (WRG number):

Background/Purpose/Study Aims:

Briefly and clearly state the overall purpose of the study in a few sentences. Provide a non-technical explanation in lay terms to justify why the research needs to be done and what its relevance will be. Describe the relevant prior scientific or scholarly literature and gaps in current knowledge. Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge. If applicable, describe any relevant preliminary data. Include references at the end of this protocol. List research objectives, specific aims, and state the hypotheses to be tested.

Describe the primary and secondary endpoints, including safety endpoints.

Study Population:

Describe the participant population such as age range, gender, and ethnic background. List the inclusion/exclusion criteria that people must have to be included in or excluded from participating in the research. Justify the reasons for exclusions. Note that if you have an inclusion/exclusion criteria, please explain the screening process in the Screening Procedures section. If your study is aimed at addressing issues that affect a certain community or group, set up a consultation with the IRB to review what is required. The IRB will work with you to confirm if the target community needs to be involved in the design and conduct of the study.

Vulnerable Populations:

(See list above and confirm details are in line with information under JCTO protocol section 4.6, if used.) Outline how researchers are ensuring that appropriate steps are taken for their consent and additional safeguards that have been included to protect the rights and welfare of these populations. If your study involves pregnant individuals, fetuses, neonates of uncertain viability, or neonates, set up a consultation with the IRB to review what is required. Reference IRB policies for information about various populations.

Recruitment Process:

Describe the plan (when, where, how) to identify potential participants, including database review and data sources if applicable. Indicate who will make initial contact and how, and if physicians or staff refer participants. Specify if any advertising/recruitment materials will be used, including verbal/electronic announcement of the research. Upload recruitment material(s) as supporting documents with your submission.

Screening Procedures:

Describe the screening process (how researchers will confirm that potential participants meet inclusion/exclusion criteria) and what will happen to screening eligibility data for individuals who are not eligible to participate.

<table>
<thead>
<tr>
<th>Population</th>
<th>Included</th>
<th>Excluded</th>
<th>Justification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults unable to consent</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Individuals who are not yet adults (infants, children, teenagers)</td>
<td>Included</td>
<td>Excluded</td>
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<tr>
<td>Pregnant individuals</td>
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<tr>
<td>Prisoners</td>
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<tr>
<td>Adults with diminished capacity to consent</td>
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<tr>
<td>Individuals who are not able to clearly understand English</td>
<td>Included</td>
<td>Excluded</td>
<td></td>
</tr>
</tbody>
</table>
Background/Purpose/Study Aims:

Does this study constitute as research defined by the Revised Common Rule

"Research is as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."
Study Population

- Age range, gender and ethnic background
- Inclusion/exclusion criteria

IRB Approval Criteria 46.111
Risks to subjects are minimized
Vulnerable Populations
If you are not targeting the population, do NOT list it.

- Adults Unable to Consent
- Children/Minors
- Pregnant Individuals
- Prisoners
- Adults with Diminished Capacity
- Non-English Speakers

IRB Approval Criteria 46.111
Informed consent
Recruitment Process

- Describe the plan to identify potential participants

IRB Approval Criteria 46.111 Selection of subjects is equitable
Screening Procedures

• Describe the screening process and
• Plan for screening/eligibility data for individuals who are not eligible
Informed Consent Process

Will you be obtaining consent or requesting a waiver?

46.116 General requirements for informed consent
Elements of Consent

- Statement that it is research.
- Explanation of the purposes, duration, and procedures of the research and of the subject's participation.
- Description of any reasonably foreseeable risks.
- Description of any benefits to the subject or to others.
- Description of how confidentiality will be maintained.
- Information of whom to contact for answers about the research and research subjects' rights.
- Statement that participation is voluntary and that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.
HIPAA Authorization

HIPAA only applies if you are accessing medical records from a covered entity

Authorization is required

You may request a waiver of authorization or a partial HIPAA Waiver (screening, recruitment only)
Data Collection Procedures

Describe the project procedures, interventions, assessments, and participant activities

• What is Standard of Care?
• What is being done for research only?
• Are there any data collection documents attached?
• Were all research study materials attached for review?
Dosing and Administration
Study Locations

• List name of all sites/locations
• If you will be receiving/sending data to and from another institution, indicate which institution

*Note, the IRB does not determine whether a Data Use Agreement is necessary.
Participant Compensation

IRB Approval Criteria
46.111 Data Monitoring
International Research
Economic Burden to Participants
Lifestyle Considerations
Risk to Participants
Benefits to Participants

• The IRB considers only the benefits that may result from the research
Privacy of Participants

- Privacy concerns people, whereas confidentiality concerns data.
Data Management and Confidentiality

Considerations for securely storing data include:

• Paper records are locked in a secure location.
• Electronic records are stored on password protected or encrypted computer as appropriate based on sensitivity of data.
• Identifiers are stored separately from project data.
• For identifiable data, a coding process will be used to store data without identifiers, the link stored separately from all other project records.
Provisions to Monitor the Data to Ensure the Safety of Participants

- Who will monitor the data for safety concerns?
- What data will be reviewed?
- How often will the monitoring occur?
- What are the reporting mechanisms?
Data and Specimen Banking
Sharing of Results with Participants
Withdrawal of Participants
Sample Size

- Note, once IRB approves your study, you may not enroll beyond your sample size without first obtaining IRB approval.
Approach to Analysis
Resources Available
Forms & Applications

IRB Review Application (IRA) Forms

For all new initial applications submitted to WRG-HS, a supplemental IRB Review Application (IRA) must be attached. Please select and fill in the applicable IRB Review Application (IRA) linked below. Once complete, please upload it to WRG as part of your new submission.

- Biomedical IRA: Use this IRB Review Application if you have completed the Therapeutic Studies JCTO Protocol template and/or have a study which will use a device/drug or implement a clinical trial.
- Biorepository IRA: This IRB Review Application template is only to be used for the establishment of a biorepository (storage and maintenance) for potential future use, not testing and research.
- Medical Education IRA: Use this IRB Review Application if your study is minimal risk and qualifies under exempt category 1 only: Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students’ opportunities to learn required educational content or the assessment of educators who provide instruction.
- Social-Behavioral and Educational Research (SBER) and Records IRA: Use this IRB Review Application if you have completed the Non-Therapeutic Studies or Tissue Use/Chart Review JCTO template, the Education Protocol Template and/or have a study which will use conduct social, behavioral, or educational research.
Where are the IRAs located?
Tips for Effective Communication with the IRB

- Respond to feedback and address any concerns raised during the review process
- Request a call with your pre-reviewer
- Request a Consultation before your next IRB submission.
Resources
Resources

Office of Human Research Protections website
https://hrp.weill.cornell.edu
Includes: Policies and Procedures
Submission Guidelines
Educational Materials
Staff Directory

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

Need help? We are here for you!

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