



INSTITUTIONAL REVIEW BOARDS ACROSS BORDERS: APPROVAL PROCESSES, COMMON CHALLENGES, AND INTERNATIONAL ETHICAL STANDARDS

Understanding global research oversight,
ethical compliance, and practical advice

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**POLL: HOW
WOULD YOU
RATE YOUR IRB
EXPERIENCE?**

Novice (Don't know much about IRB processes)

Beginner (I know IRBs exist, but never had to submit a study application)

Average (I've submitted a study in the past/contributed to an IRB application)

Proficient (I regularly submit studies to IRBs as a PI)

Expert (I have submitted numerous studies in different/international contexts to a variety of different IRBs)

PRESENTATION OVERVIEW

- **Fundamentals of Institutional Review Boards (IRBs)**
- **Navigating IRB Approval Processes Internationally**
- **Common Challenges in Cross-Border IRB Approvals**
- **International Research Ethics and Standards**
- **Best Practices for Ensuring Ethical and Compliant Research Globally**



FUNDAMENTALS OF INSTITUTIONAL REVIEW BOARDS (IRBs)

TYPES OF RESEARCH REQUIRING IRB APPROVAL



Human Subjects Research

Research involving human participants requires IRB approval to protect rights and safety.

Clinical Trials

Clinical trials must undergo IRB review to ensure ethical standards and participant safety.

Behavioral Studies

Behavioral research involving human subjects requires IRB approval to maintain ethical conduct.

Biomedical Investigations

Biomedical research involving human subjects must be reviewed by an IRB for ethical compliance.



WHY DO I NEED AN IRB?



Protecting Research Participants

IRBs ensure the rights and welfare of participants are safeguarded throughout the research process.

Reviewing Study Protocols

IRBs carefully review research protocols to verify ethical compliance and minimize potential risks.

Dissemination Requirements

Many publications require IRB approval for publishing of research studies.



BASIC STRUCTURE AND FUNCTIONS OF IRBs



Multidisciplinary Membership

IRBs consist of members from various professional backgrounds to ensure comprehensive ethical review.

Research Proposal Review

IRBs critically assess research proposals to ensure ethical standards and participant safety are upheld.

Monitoring and Compliance

IRBs monitor ongoing studies and enforce adherence to ethical and legal research requirements.



NAVIGATING IRB APPROVAL PROCESSES INTERNATIONALLY

TYPICAL STEPS IN IRB APPROVAL ACROSS DIFFERENT REGIONS

Project Scope

What is the project asking of participants? Does the proposed project include vulnerable groups? Might the research be considered EXEMPT?

Initial Submission

The process begins with submitting the research proposal to the IRB for consideration and review.

Scientific and Ethical Review

The proposal undergoes scientific and ethical evaluation to ensure sound methodology and participant protection.

Requested Revisions

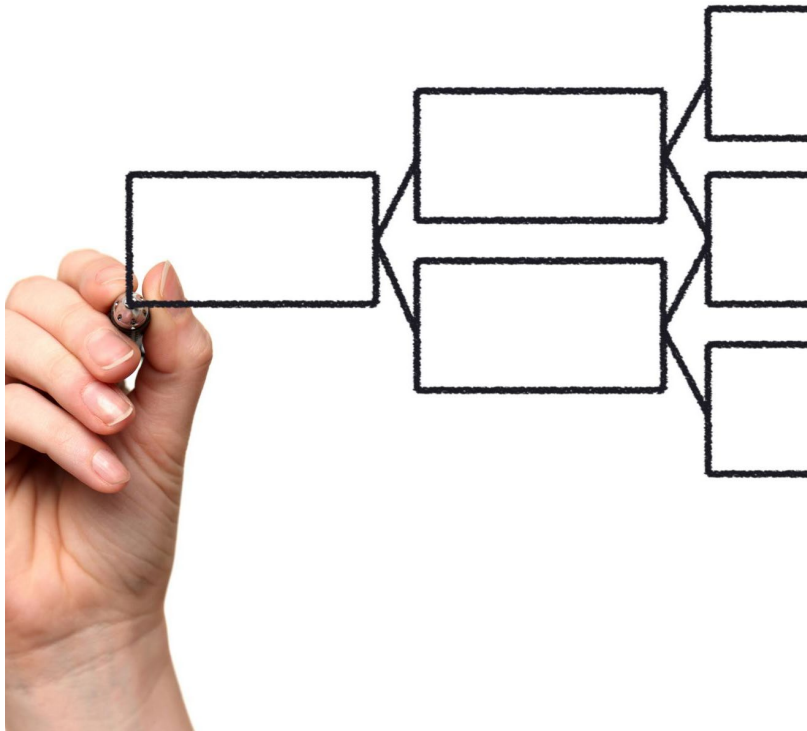
Researchers may be asked to revise their proposal addressing concerns raised during the review.

Final Approval

Once revisions satisfy the IRB, the research receives official approval to proceed.



SELECTING THE RIGHT INSTITUTIONAL REVIEW BOARD (IRB)



- Identify which IRBs the project has access to
- Understand the institutional requirements of participating project members' organizations
- Consider the IRB's accreditation and regulatory compliance
- Evaluate the IRB's review timelines and responsiveness
- Review the costs and fees associated with the IRB services
- Check the IRB's experience with international or cross-border studies
- Ensure the IRB's commitment to ethical standards and participant protection



A magnifying glass is positioned over a document, focusing on a stamp that reads 'Ending Balance' and '\$3,770.13'. The background is a blurred stack of papers.

DOCUMENTATION AND SUBMISSION REQUIREMENTS

Researcher Qualifications

Participating researchers must need to share their educational background and experience as well as their human subjects training/certification or may need to complete specific IRB training requirements. Likely need to identify all individuals who will be collecting and/or analyzing data as researchers.

Detailed Research Protocols

Researchers are required to submit comprehensive research protocols to outline study design and methodology clearly.

Informed Consent Forms

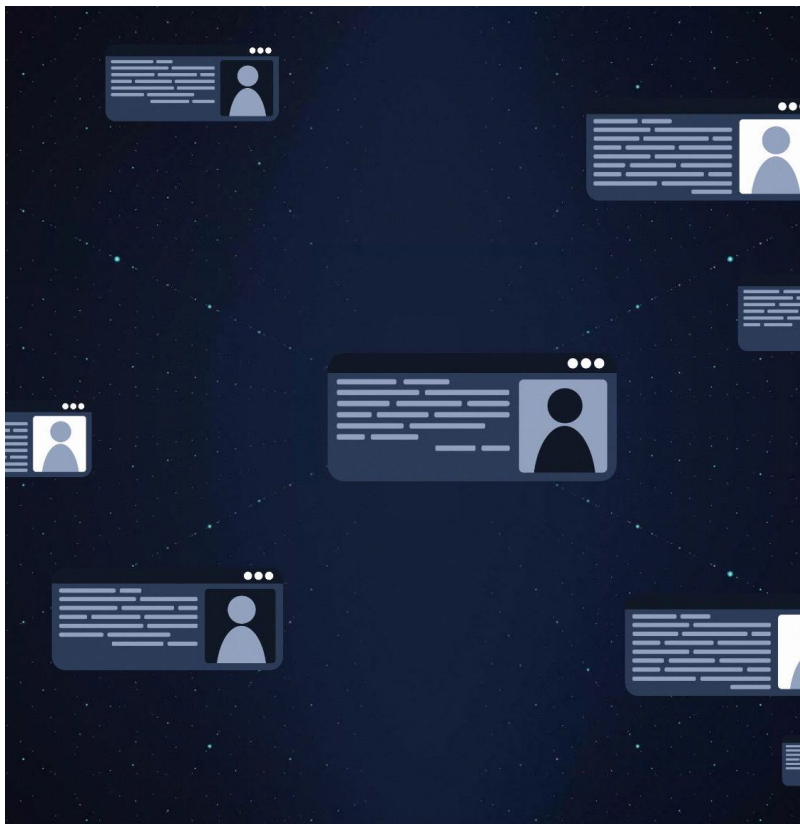
Informed consent forms must be prepared carefully to ensure participant understanding and compliance with ethical standards.

International IRB Adaptation

Documents often require adaptation to satisfy varying requirements of international Institutional Review Boards (IRBs).



TIMELINES AND COMMUNICATION WITH IRBs ABROAD



Variable Approval Timelines

Approval timelines for research projects differ significantly between countries and institutions.

Importance of Clear Communication

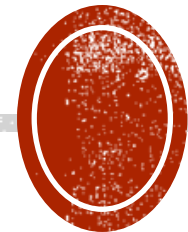
Clear communication with IRBs helps promptly resolve queries and ensures project progress.



FEE-BASED IRBs

- Solutions IRB
<https://www.solutionsirb.com/>
- Tempus IRB
<https://www.tempusirb.com/>

IRB costs usually allocated as indirect costs on large grants or institutional projects but can be done as direct costs for subcontractors or smaller projects.



COMMON CHALLENGES IN CROSS-BORDER IRB APPROVALS

REGULATORY DIFFERENCES AND CONFLICTING GUIDELINES



Diverse National Regulations

Different countries have varying regulations affecting multinational study approvals and compliance.

Ethical Guideline Conflicts

Conflicting ethical standards across countries create challenges in harmonizing research protocols.

Challenges in Unified IRB Approval

Regulatory differences complicate the process of obtaining unified Institutional Review Board approvals.



LANGUAGE BARRIERS AND TRANSLATION CONCERNS



Importance of Accurate Translation

Precise translation ensures participants fully understand study details and consent forms to make informed decisions.

Ensuring Participant Understanding

Clear communication reduces misunderstandings and enhances compliance with study protocols among diverse participants.

Compliance with IRB Requirements

Accurate translations are required for ethical approval by IRBs to protect participant rights and welfare.



COORDINATION BETWEEN MULTIPLE IRBs AND INSTITUTIONS



Effective Coordination

Successful management depends on coordinating across IRBs to ensure review consistency and efficiency.

Aligned Standards

Aligning review standards helps streamline approval processes between different institutions.

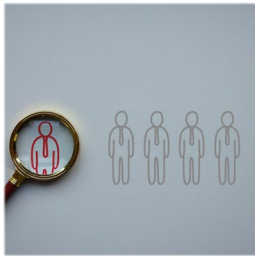
Communication & Timelines

Clear communication and synchronized timelines are crucial to managing multi-IRB approvals effectively.



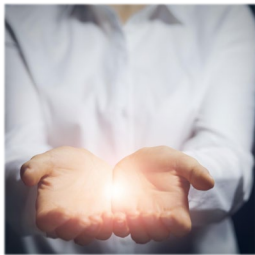
INTERNATIONAL RESEARCH ETHICS AND STANDARDS

UNIVERSAL ETHICAL PRINCIPLES IN RESEARCH



Respect for Persons

This principle emphasizes treating individuals as autonomous agents and protecting those with diminished autonomy.



Beneficence

Researchers must maximize benefits and minimize harm to participants, ensuring well-being throughout studies.



Justice

Fairness in distribution of research benefits and burdens is essential to uphold ethical standards.





CULTURAL CONSIDERATIONS AND LOCAL CONTEXT

Importance of Cultural Norms

Understanding cultural norms is essential to design research that respects community values and beliefs.

Local Context Awareness

Considering local context helps adapt research methods to fit specific environmental and social conditions.

Ethical Research Practices

Incorporating cultural and local knowledge ensures ethical relevance and acceptance of research findings.



BEST PRACTICES FOR ENSURING ETHICAL AND COMPLIANT RESEARCH GLOBALLY

PERSONAL DISPOSITIONS FOR IRB-COMPLIANT RESEARCH

- Start early and be reflective about the burden the proposed study will have on participants as well as researchers
- Maintain integrity and honesty throughout the research process.
- Demonstrate cultural sensitivity and respect for participants.
- Exhibit patience and persistence in navigating IRB requirements.
- Practice transparency in reporting methods and findings.
- Show empathy towards participant concerns and ethical considerations.
- If something changes during the study, consider the IRB implications.
- Stay open to feedback and continuous learning about ethical standards.
- Ask questions. Be proactive, rather than reactive.





EFFECTIVE COMMUNICATION WITH INTERNATIONAL IRBs

Clear Communication Importance

Clear communication ensures that all IRB requirements are understood, reducing delays in approval processes.

Respectful Interaction

Respectful dialogue between international partners builds trust and encourages cooperation during IRB reviews.

Timely Responses

Providing timely responses helps maintain momentum and ensures a smoother IRB approval process.





BUILDING COLLABORATIVE RELATIONSHIPS

Partnerships with Local Institutions

Collaborations with local institutions foster mutual understanding and strengthen community ties.

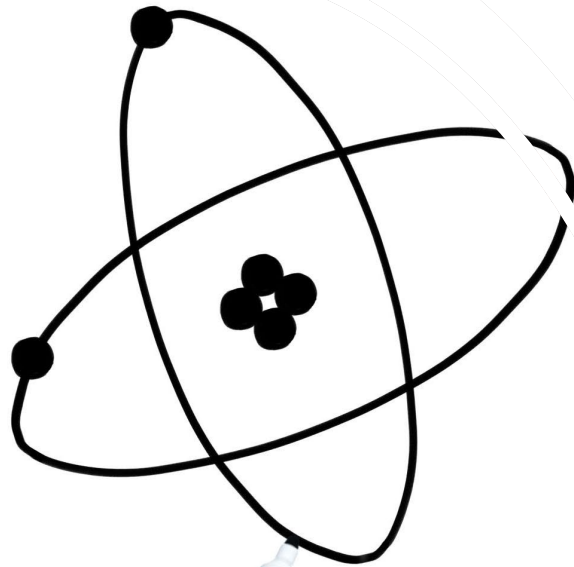
Resource Sharing Benefits

Sharing resources enhances efficiency and supports joint project success.

Ethical Oversight Consistency

Joint ethical oversight ensures consistent standards and protects participant rights.





CONTINUOUS TRAINING AND STAYING UPDATED ON GLOBAL REGULATIONS

Importance of Ongoing Education

Continuous training helps researchers stay informed about changing international guidelines and maintain compliance.

Maintaining Ethical Standards

Staying updated ensures researchers uphold ethical standards in their work and avoid regulatory violations.



CONCLUSION

Understand Diverse Regulations

Comprehending varied international IRB rules is crucial for smooth cross-border research approvals.

Overcome Communication Challenges

Effective communication across cultures and languages ensures clear understanding in multinational research.

Adhere to Ethical Standards

Following international ethical guidelines is vital for responsible and trustworthy global research practices.

Apply Good Habits of Practice

Be conscientious, empathetic, and reflective.

START EARLY!!!



RESOURCES

- [NSF FAQ on Research on Human Subjects](#)
- [International Compilation of Human Research Standards 2024 Edition](#)
- [Ethics in Human Subjects Research](#)
- [Consent Form Examples](#)
- [Consent Form Examples 2](#)
- [ASTRO ACCEL IRB](#)



QUESTIONS?



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<https://astroaccelcommons.org/en/profile/2067/>