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The Institutional Review Board (IRB): What It Is and Why You Need One

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The Institutional Review Board, or IRB for short, is also known as an independent ethics committee (IEC), ethical review board (ERB), or research ethics board (REB). It generally consists of a formally designated committee that reviews and monitors research projects that intend to use human beings as the research objects. For a comprehensive look at IRBs in question and answer format, please click here. The IRB is in place to protect the rights and well being of human research participants from both physical and psychological harm. It also serves to assure that whatever harm involved is explicitly described and that the subjects 1) understand the risks, and 2) agree to participate of their own volition. The IRB may be sponsored within the institution conducting the research or it may be an independent entity tasked with performing IRB functions. If you are interested in conducting prospective clinical research, IRB approval is required and must be obtained from your university or hospital IRB or a commercial entity.

IRBs were created in response to explicit harms that came to participants in research done in the United States (the infamous Tuskegee Syphilis Study, for example, or radiation experiments done by the military) and in Europe as part of Nazi "research." The Belmont Report identified three key ethical principles of human research: 1) respect for persons, 2) beneficence, and 3) justice. An IRB may only approve research for which the risks to subjects are balanced by potential benefits to society, and for which the selection of subjects presents a fair or just distribution of risks and benefits to eligible participants. For more information on the IRB, click here.

Even retrospective studies, if involving humans, as is common in retrospective case reviews, may benefit from an IRB-approved exemption. Research involving the analysis of existing data and other materials if they are already publicly available, or where the data can be collected such that individual subjects cannot be identified in any way, does not require IRB approval. Click here for a detailed overview of these issues (Parker GE. A framework for navigating Institutional Review Board (IRB) oversight in the complicated zone of research. *Cureus*. 2016; 8(10):e844. doi:10.7759/cureus.844). Commercial IRBs are acceptable alternatives to standard hospital- or university-based review boards.

It is good and established practice for medical journals to avoid publishing research that has not met IRB standards. The following requirements are important to keep in mind if you are considering research that involves human participants. You must

- Obtain prior approval for human subjects research by an IRB or equivalent ethics committee(s).
- Declare compliance with ethical practices upon submission of a manuscript.
- Report details on how informed consent for the research was obtained (or explain why consent was not obtained).
- Submit, upon request from the journal, documentation from the review board or ethics committee confirming approval of the research.
- For clinical trials, provide trial registration details, the study protocol, and CONSORT documentation (which is a standard evidence-based, minimum set of recommendations for reporting randomized trials; for more information, click here).
- Confirm that an identified individual has provided written consent for the use of that information.

Member Resource: A Commercial IRB

Pearl IRB
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Indianapolis, IN 46225
www.pearlirb.com/

Pearl IRB is an independent institutional review board, fully accredited by the Association for the Accreditation of Human Research Protection Program Inc. (AAHRPP). Pearl IRB manages the local and central IRB needs for large and small institutions, principal investigators, CROs, and sponsors. Its vision is to improve the clinical research process which will lead to delivering therapeutics and diagnostics to patients sooner. Whether the research is a small single site project or a complex multi-center study, Pearl IRB can help. If you are interested, contact Pearl IRB for its fee schedule.

If you're unsure how your study may be classified for review, the Office for Human Research Protections (OHRP) has some helpful resources. Click here to review their online decision trees. These charts are designed to help you decide if an activity is research involving human subjects that must be reviewed by an IRB and whether informed consent, or documentation of informed consent, can be waived.

Pearl IRB board review turnaround times are 1-3 business days for exempt or expedited reviews, and 8-10 business days for a full board review.