

# IRB (Institutional Review Board)

Authored by  
**mohammad looti**

September 29, 2025

## RECOMMENDED CITATION

mohammad looti (2025). *IRB (Institutional Review Board)*. PSYCHOLOGICAL SCALES.  
Retrieved from <https://scales.arabpsychology.com/?p=31371>

## IRB (Institutional Review Board)

**Primary Disciplinary Field(s):** Research Ethics, Bioethics, Public Health, Social Sciences, Clinical Research

### 1. Core Definition and Nomenclature

An **Institutional Review Board** (IRB) is a formally constituted committee specifically designated within an institution, primarily in the United States, with the critical responsibility of overseeing ethical considerations in research. Its fundamental role is to safeguard the rights, welfare, and well-being of human participants involved in research studies. This oversight encompasses a broad spectrum of research activities, ranging from biomedical investigations to behavioral science inquiries. The IRB serves as an essential ethical gatekeeper, ensuring that all research conducted under its purview adheres to stringent ethical principles and regulatory requirements.

While the term "Institutional Review Board" is prevalent in the United States, similar entities exist globally under various names, all sharing the core mission of ethical research review. These include the **Independent Ethics Committee** (IEC), the **Ethical Review Board** (ERB), or the **Research Ethics Board** (REB) in other countries and international contexts. Regardless of the specific nomenclature, these committees are united by their common objective: to provide an independent, expert review of research protocols to prevent harm and uphold the dignity of individuals participating in scientific inquiry. Their existence is a testament to the evolving understanding of ethical responsibilities in scientific advancement, moving beyond mere scientific validity to encompass profound moral obligations to human subjects.

The establishment and functioning of IRBs underscore a societal commitment to responsible scientific conduct. They are structured to bring diverse perspectives to the ethical review process, typically including scientists, non-scientists, and community representatives. This multidisciplinary composition is crucial for a comprehensive assessment of research proposals, ensuring that both scientific merit and humanistic concerns are adequately addressed. The ultimate goal is to foster an environment where groundbreaking research can flourish without compromising fundamental ethical standards, thereby maintaining public trust in the scientific enterprise.

### 2. Historical Development and Ethical Underpinnings

The concept of formal ethical review boards like the IRB emerged from a series of profound ethical transgressions in research involving human subjects during the 20th century, which led to a global call for greater accountability and protection. Landmark cases, such as the horrific experiments conducted by Nazi physicians during World War II, which culminated in the creation of the Nuremberg Code in 1947, provided the initial ethical framework stipulating voluntary consent and

the minimization of harm. This code, though not legally binding, laid foundational principles for ethical human experimentation. Subsequent international efforts, notably the Declaration of Helsinki developed by the World Medical Association in 1964, further elaborated on ethical guidelines for medical research involving human subjects, emphasizing the welfare of the research subject over the interests of science and society.

In the United States, the catalyst for the widespread implementation of IRBs was largely the exposure of the Tuskegee Syphilis Study, a notorious clinical study conducted between 1932 and 1972 where African American men with syphilis were deliberately left untreated to observe the natural progression of the disease, without their informed consent. The profound ethical breaches of this study, alongside other controversial research, spurred public outrage and governmental intervention. In response, the U.S. Congress passed the National Research Act in 1974, which mandated the establishment of IRBs at all institutions receiving federal funding for human subjects research. This legislative action was a pivotal moment, institutionalizing the ethical review process and formally recognizing the need for robust oversight.

Following the National Research Act, the Belmont Report was published in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This seminal document articulated three core ethical principles that continue to underpin all human subjects research and IRB review: **Respect for Persons**, **Beneficence**, and **Justice**. Respect for Persons acknowledges the autonomy of individuals and demands protection for those with diminished autonomy. Beneficence requires that researchers strive to do no harm and maximize potential benefits while minimizing potential risks. Justice mandates that the burdens and benefits of research be distributed fairly. These principles provide the philosophical bedrock upon which all IRB decisions are made, ensuring a systematic and principled approach to protecting research participants.

### 3. Mandate and Scope of Review

The primary mandate of an IRB is to review, approve, monitor, and provide continuing review for all biomedical and behavioral research involving human subjects. This comprehensive oversight ensures that every stage of a research project, from its initial conception to its conclusion, adheres to the highest ethical and regulatory standards. "Biomedical research" typically involves studies concerning health and disease, including clinical trials of drugs and medical devices, genetic research, and studies involving biological samples. "Behavioral research" encompasses studies in psychology, sociology, anthropology, and education, which might involve surveys, interviews, observations, or experimental manipulations of social environments. The scope is deliberately broad to cover any investigation that collects data from or about living individuals.

The review process itself is multifaceted. Before any research involving human subjects can

commence, a detailed protocol must be submitted to the IRB. This protocol outlines the research questions, methodology, participant recruitment strategies, data collection procedures, potential risks and benefits, and plans for ensuring participant confidentiality and data security. The IRB critically evaluates whether the proposed research is ethically sound, scientifically valid, and minimizes risks to participants while maximizing potential benefits. Approval is granted only when the board is satisfied that all ethical requirements have been met and that participants' rights and welfare are adequately protected. This initial approval is a crucial gatekeeping function, preventing potentially harmful or unethical studies from ever beginning.

Beyond initial approval, the IRB's mandate extends to continuous monitoring of ongoing research. This includes requiring regular progress reports, reviewing any proposed modifications to the study protocol, and assessing adverse events or unanticipated problems that arise during the research. If concerns emerge about participant safety, ethical conduct, or adherence to the approved protocol, the IRB has the authority to suspend or terminate a study. This ongoing oversight is vital to ensure that ethical standards are maintained throughout the entire research lifecycle, adapting to unforeseen circumstances and ensuring sustained protection for human subjects. The rigorous nature of this monitoring is what ultimately distinguishes ethically approved research from potentially exploitative practices, reinforcing integrity and accountability in scientific inquiry.

#### 4. Key Principles of Ethical Review

The operational framework of an IRB is firmly anchored in the three core ethical principles outlined in the Belmont Report: **Respect for Persons**, **Beneficence**, and **Justice**. The principle of **Respect for Persons** necessitates treating individuals as autonomous agents capable of making their own choices, and it requires protecting those with diminished autonomy. In practice, this primarily translates to ensuring robust informed consent. Researchers must provide potential participants with comprehensive information about the study's purpose, procedures, risks, benefits, and their right to withdraw at any time without penalty, allowing them to make a truly voluntary decision to participate. For vulnerable populations such as children, prisoners, or individuals with impaired cognitive abilities, additional protections and safeguards, often involving consent from legal guardians and assent from the participants themselves, are rigorously applied to ensure their rights are not exploited.

The principle of **Beneficence** guides the IRB to ensure that research minimizes potential harms to participants and maximizes potential benefits to both individuals and society. This involves a meticulous risk-benefit analysis. The IRB evaluates whether the potential benefits of the research (e.g., advancing scientific knowledge, improving public health) outweigh the foreseeable risks to participants (e.g., physical discomfort, psychological distress, breach of privacy). Researchers are expected to design studies that incorporate measures to minimize risks, such as using the least invasive procedures possible, ensuring data confidentiality, and providing support services if

emotional distress is anticipated. If the risks are deemed excessive relative to the potential benefits, or if they can be further mitigated, the IRB will require modifications to the protocol before granting approval.

Finally, the principle of **Justice** addresses the equitable distribution of the burdens and benefits of research. This means that particular populations should not be unfairly burdened with the risks of research simply because they are easily accessible or socioeconomically disadvantaged, while other populations disproportionately reap the benefits. The IRB scrutinizes recruitment strategies to ensure that the selection of research participants is fair and that research subjects are not chosen based on convenience rather than scientific necessity. It also considers whether the results of the research will be accessible and beneficial to the communities and populations that contributed to the study, especially if they bore significant risks. Adherence to these three principles collectively ensures that research is not only scientifically sound but also morally justifiable and respectful of human rights.

## 5. Operational Structure and Composition

The operational effectiveness of an IRB largely depends on its structure and the diverse composition of its members, which are typically mandated by federal regulations such as the Common Rule in the United States. A standard IRB is designed to include a variety of perspectives to ensure a comprehensive and balanced ethical review. This usually entails a mix of scientific and non-scientific members, along with individuals not affiliated with the institution. Scientists bring expertise in research design, methodology, and the technical aspects of the proposed study, allowing for an informed assessment of scientific validity and risk. Non-scientists, such as ethicists, lawyers, or clergy, contribute perspectives on ethical norms, community values, and legal considerations, ensuring that the humanistic implications of the research are thoroughly considered.

Furthermore, federal regulations require that at least one member of the IRB be unaffiliated with the institution conducting the research and not be an immediate family member of someone affiliated with the institution. This independent member is crucial for introducing an external, unbiased viewpoint, helping to prevent institutional conflicts of interest or undue pressure on the review process. Additionally, whenever research involves a vulnerable population, such as prisoners, children, or individuals with disabilities, the IRB must include members who are knowledgeable about and experienced in working with that specific population. This ensures that the unique needs and vulnerabilities of these groups are properly understood and addressed during the review.

IRBs also employ different levels of review depending on the perceived risk associated with the research. Full board review is required for research involving more than minimal risk to

participants, such as clinical trials of new drugs or invasive procedures. This typically involves a meeting of the full committee to discuss and vote on the protocol. Expedited review is possible for certain categories of research involving no more than minimal risk, such as studies collecting routine physiological data or minor changes to previously approved research. This review can be conducted by a single experienced IRB member or a small subset of the board. Finally, some research activities, like certain educational practices or analyses of existing publicly available data, may qualify for exempt review, meaning they are considered to fall outside the direct regulatory oversight of the IRB due to extremely low risk, though a determination by the IRB or a qualified institutional official is usually still required. These varied review pathways allow IRBs to efficiently manage their workload while ensuring appropriate scrutiny for different risk profiles.

## 6. Significance in Research Integrity and Public Trust

The IRB plays an absolutely pivotal role in ensuring research integrity and fostering public trust in scientific endeavors, which are highlighted as essential steps in publishing research. By mandating rigorous ethical review, IRBs serve as a bulwark against misconduct and ensure that studies are not only scientifically sound but also conducted with the utmost ethical responsibility. The source content explicitly states that the IRB's purpose is to "assure that published studies are authentic, properly conducted, and reflect the current state of research." This speaks directly to the core tenet of academic integrity: that all research should be honest, transparent, and reproducible. Without such oversight, the scientific literature could be vulnerable to falsified results, erroneous conclusions, and unethical methodologies, which could severely mislead genuine studies and undermine the entire edifice of scientific knowledge.

The protection of research participants from harm or distress is the most profound aspect of the IRB's significance. By meticulously reviewing protocols for potential risks, ensuring robust informed consent processes, and continuously monitoring ongoing studies, IRBs actively prevent the exploitation and mistreatment of individuals for scientific gain. This ethical safeguarding is paramount for maintaining the public's willingness to participate in research. Historical instances of ethical breaches eroded public confidence in scientific institutions, demonstrating that without trust, participation in vital research, particularly in areas like public health and medicine, would diminish significantly. The existence of IRBs signals to the public that their well-being is prioritized, thereby encouraging participation and facilitating the advancement of knowledge that ultimately benefits society.

Furthermore, the IRB's role extends to upholding the ethical reputation of academic and research institutions. An institution with a robust and respected IRB signals its commitment to ethical conduct, attracting credible researchers and ethical funding opportunities. Conversely, institutions lacking stringent ethical oversight risk reputational damage, legal liabilities, and the loss of federal funding. By ensuring that research adheres to established ethical guidelines and regulatory

requirements, IRBs contribute to a culture of accountability and responsibility within the scientific community. This not only protects individual participants but also safeguards the broader scientific enterprise, ensuring that its pursuit of knowledge remains credible, ethical, and worthy of public support.

## 7. Consequences of Non-Compliance and Ethical Lapses

The absence or circumvention of IRB review carries severe and multifaceted consequences, as directly articulated in the source content: "Without this step it would be possible to print falsified results, state erroneous conclusions, use unethical methodology, or any number of other research fallacies that could mislead or pervert genuine studies." These potential outcomes represent a grave threat to the integrity of science and the welfare of society. Falsified data and erroneous conclusions not only waste valuable resources but can also lead to misinformed clinical practices, ineffective public policies, and the misdirection of future research, ultimately harming public health and trust in scientific findings. Unethical methodologies, such as coercing participants or exposing them to unacceptable risks, directly violate human rights and can cause profound physical, psychological, or social harm to individuals.

For researchers, non-compliance with IRB regulations or engaging in unethical practices can result in severe professional repercussions. These may include immediate termination of the research project, revocation of research privileges, loss of academic positions, and disqualification from future grant funding. In more serious cases, researchers could face professional sanctions, legal penalties, or even criminal charges, particularly if their actions lead to significant harm to participants. The damage to a researcher's reputation can be irreparable, effectively ending their career in academia or clinical practice. Such consequences serve as a powerful deterrent, reinforcing the importance of strict adherence to ethical guidelines and IRB protocols.

Institutions are also subject to significant penalties for failures in IRB oversight. Federal agencies, such as the Office for Human Research Protections (OHRP) in the U.S., have the authority to suspend or withdraw federal funding for research involving human subjects from institutions found to be non-compliant. This can have devastating financial implications, particularly for large research universities heavily reliant on federal grants. Beyond financial penalties, an institution's reputation can be severely tarnished, leading to a loss of public trust, difficulty attracting top talent, and challenges in recruiting research participants. The collective impact of non-compliance underscores the critical role of IRBs not just as ethical gatekeepers, but as essential components of institutional risk management and reputation protection.

## 8. Debates and Criticisms

Despite their indispensable role, IRBs are not without their share of debates and criticisms, which

often focus on their practical implementation and potential unintended consequences. One common critique revolves around the perception of IRBs as bureaucratic hurdles that can significantly delay research progress. Researchers often report lengthy review periods, extensive requirements for modifications, and a perceived lack of flexibility, which can impede time-sensitive studies or those involving rapidly evolving fields. This bureaucratic burden, sometimes labeled as "ethics creep," refers to the tendency for ethical oversight to expand beyond its original scope, potentially stifling innovation and increasing administrative overhead without always commensurately enhancing ethical protection.

Another area of concern relates to the consistency and expertise of IRB reviews. Critics argue that decisions can vary significantly between different IRBs, leading to frustration for researchers who conduct multi-site studies or apply to multiple institutions. Furthermore, while IRBs are designed to be multidisciplinary, individual board members may lack specialized expertise in highly niche or complex scientific fields, making it challenging for them to fully grasp the nuances of a research protocol. This can sometimes lead to overly cautious decisions, or conversely, an oversight of risks that are highly specific to a particular discipline, thus compromising the quality of the ethical review.

Finally, there is an ongoing debate about the balance between process-oriented compliance and genuine ethical reflection. Some critics contend that IRBs have become overly focused on checking off regulatory requirements and ensuring adherence to specific forms and procedures, rather than engaging in deep, substantive ethical deliberation. This emphasis on compliance can, ironically, distract from the core ethical principles of respect, beneficence, and justice, transforming the review process into a box-ticking exercise rather than a thoughtful ethical dialogue. Addressing these criticisms requires continuous efforts to streamline processes, enhance reviewer training, and foster a culture where ethical principles are genuinely understood and applied, rather than merely complied with.

## Further Reading

[Belmont Report](#)

[Nuremberg Code](#)

[Declaration of Helsinki](#)

[Tuskegee Syphilis Study](#)

[Institutional Review Board](#)

[Informed consent](#)

[Risk-benefit analysis](#)

[Vulnerable populations](#)

[Research integrity](#)