

What is an IRB? The Role of Ethics Committees in Research

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Executive Summary

Institutional Review Boards (IRBs), also known as Independent Ethics Committees (IECs), play a pivotal role in overseeing [clinical trials](#) involving human participants. Their primary responsibility is to safeguard the rights, safety, and welfare of research subjects, ensuring that studies comply with ethical standards and regulatory requirements (^[1] [ichgcp.net](#)) (^[2] [www.law.cornell.edu](#)). This report examines the comprehensive legal, historical, and practical framework governing IRBs/IECs, highlighting their composition, review processes, and decision-making criteria. We analyze how protocols are submitted, reviewed, and approved (or disapproved), and discuss emerging trends such as single IRB mandates and international harmonization. Case studies illustrate both successes and failures of the ethics-review system, including notable controversies of falsified approval (e.g., the IHU-Méditerranée Infection case) (^[3] [pmc.ncbi.nlm.nih.gov](#)). Quantitative data on review times and approval rates reveal significant variability among IRBs (^[4] [pmc.ncbi.nlm.nih.gov](#)). We also explore perspectives of researchers, ethicists, and regulators. Finally, the report identifies challenges (e.g., administrative burdens, inconsistent standards) and proposes future directions such as enhanced training, digital review platforms, and global ethics coordination. All conclusions and assertions are supported by authoritative sources, including regulatory texts (e.g. U.S. CFR, ICH-GCP guidelines) and peer-reviewed studies.

Introduction and Background

The modern system of ethical oversight in human research has evolved through a series of historical milestones. In the aftermath of World War II, revelations of Nazi medical experiments led to the 1947 Nuremberg Code, which articulated basic principles such as voluntary informed consent. Subsequent decades saw further calamities – notably the Tuskegee Syphilis Study (1932–1972) and the thalidomide tragedy of the 1950s–1960s – that spurred public demand for formal safeguards. These events culminated in the U.S. National Research Act of 1974 and the Belmont Report (1979), which codified ethical foundations: **Respect for Persons**, **Beneficence**, and **Justice**. Collectively, these principles underpin the responsibilities of IRBs/IECs to protect human subjects (^[5] [pmc.ncbi.nlm.nih.gov](#)) (^[6] [www.wma.net](#)). Concurrently, international declarations (e.g., the World Medical Association's Declaration of Helsinki, 1964 and its later revisions) have detailed expectations for ethics committees worldwide to approve research protocols before studies begin (^[7] [www.wma.net](#)).

Today, virtually all clinical research involving human participants must receive prior IRB/IEC approval as a condition of publication, funding, and regulatory compliance. Regulatory frameworks vary by country and region. In the United States, the federal **Common Rule** (45 CFR 46) and [FDA regulations \(21 CFR Parts 50 and 56\)](#) provide the legal requirements for IRBs. In Europe, the Clinical Trials Regulation (EU No. 536/2014) and national laws govern ethics committees (often termed "Institutions Ethics Committees" or "Research Ethics Committees"). Globally, the **International Council for Harmonisation (ICH) Good Clinical Practice (GCP)** guideline E6(R2) sets international standards for IRB/IEC operations (^[1] [ichgcp.net](#)) (^[8] [ichgcp.net](#)). Additionally, the World Health Organization and industry bodies issue guidance (e.g. CIOMS guidelines) to harmonize ethical review standards internationally.

The IRB/IEC process fundamentally involves *independent* experts reviewing study protocols, informed consent forms, and related materials to ensure that risks are minimized, participant selection is equitable, and consent is properly obtained. Per regulatory guidance, an IRB has the authority to **approve**, **request modifications**, or **disapprove** research (^[9] [www.fda.gov](#)) (^[1] [ichgcp.net](#)). In practice, most protocols are initially approved or approved with conditions (e.g., clarifications, consent form edits). A minority are deferred or rejected due to serious ethical concerns or inadequate subject protection.

The remainder of this report is structured as follows. Section 1 provides historical context and the evolution of IRBs/IECs. Section 2 details the legal and regulatory frameworks (U.S. and international) that define ethics committees' powers and

responsibilities. Section 3 examines IRB/IEC composition, including necessary expertise and independence. Section 4 outlines the full review process: submission, review categories (exempt/expedited/full-board), decision outcomes, and post-approval oversight. Section 5 analyzes empirical data on IRB operations (e.g. review durations, common modifications requested). Section 6 presents case studies illustrating real-world functioning and challenges of IRBs. Section 7 discusses criticisms, reform efforts, and future directions (e-IRBs, central reviews, etc.). The conclusion synthesizes key findings about how ethics committees safeguard research subjects.

1. Historical and Ethical Foundations

1.1 Early Ethical Codes and Their Impact

The imperative for ethical oversight in human experimentation can be traced to landmark events. The **Nuremberg Code** (1947) arose from the Nazi doctor trials and emphasized voluntary consent and benefit-risk analysis. It laid the groundwork by stating that *“the voluntary consent of the human subject is absolutely essential”*. Following decades saw abuses such as the Tuskegee Syphilis Study (1932–1972), where treatment was deceptively withheld, and the Willowbrook hepatitis experiments (1956–1970s) on institutionalized children, each highlighting egregious violations of consent and welfare. Public outrage from these scandals prompted U.S. Congress to create the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, whose 1979 **Belmont Report** articulated three core principles:

- **Respect for Persons:** honoring autonomy and requiring informed consent.
- **Beneficence:** maximizing benefits and minimizing harms.
- **Justice:** ensuring fair distribution of research burdens and benefits.

The Belmont Report explicitly recommended that institutions conducting human research establish review bodies (IRBs) to implement these ethical principles (^[5] [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov/)).

Alongside these, professional associations issued ethical declarations. The World Medical Association’s **Declaration of Helsinki** (first adopted 1964, with [eight subsequent revisions through 2024](#)) mandates that *“research protocols must be submitted for consideration, comment, guidance, and approval to the concerned research ethics committee before the research begins”* (^[7] www.wma.net). The declaration further emphasizes that ethics committees must function transparently and independently, resistant to undue influence, and include lay members familiar with local context (^[7] www.wma.net). These global codes framed the expectation that all medical research be reviewed by an independent committee.

1.2 Establishment of Formal IRBs/IECs

In the U.S., federal regulations were enacted to operationalize these ethical mandates. The **Department of Health, Education, and Welfare (DHEW)** Federal Policy for Protection of Human Subjects (codified as 45 CFR 46 in 1974, later known as the “Common Rule” when adopted by multiple agencies) set baseline requirements for IRBs: composition, scope, and review criteria. It required institutions to sign assurances of compliance (written agreements with the government) and to establish IRBs. Similarly, the **Food and Drug Administration** defined IRBs in 21 CFR Part 56 and required registration for any IRB reviewing FDA-regulated research (^[10] www.fda.gov). Over time, additional subparts of 45 CFR 46 addressed special populations (pregnant women, prisoners, children, etc.) and strengthened ethics codes.

Internationally, the concept of ethics committees spread. The **Council for International Organizations of Medical Sciences (CIOMS)** and **World Health Organization (WHO)** produced guidelines (e.g. CIOMS Guidelines, 2002 and 2016) that specifically discuss IRB/REC (Research Ethics Committee) responsibilities in health research. The ICH’s Good

Clinical Practice guideline E6(R2), promulgated (and periodically updated; the successor [E6\(R3\) was finalized in January 2025](#) and adopted by the [FDA in September 2025](#)) by major pharmaceutical regulators in the US, EU, and Japan, standardized IRB/IEC duties in the context of drug trials (^[1] [ichgcp.net](#)) (^[8] [ichgcp.net](#)). Notably, ICH E6(R2) stipulates that an IRB/IEC “should safeguard the rights, safety, and well-being of all trial subjects” and lists the documents and issues an ethics committee must review (^[1] [ichgcp.net](#)).

In sum, the current ethics-review system is the product of historical abuses, moral philosophy, and regulatory codification. It rests on the conviction that independent, knowledgeable committees can protect participants better than investigators alone.

2. Regulatory and Legal Frameworks

2.1 United States Regulations

2.1.1 Federal Policy (45 CFR Part 46) – The Common Rule

In the U.S., the federal **Common Rule** (45 CFR Part 46), most recently revised in 2018, sets forth uniform ethics requirements for research funded or conducted by constituent agencies (e.g. HHS, NIH) (^[2] [www.law.cornell.edu](#)). Key provisions include:

- **Definition of IRB:** A board established by an institution to review research activities (^[9] [www.fda.gov](#)). (FDA similarly defines IRB in 21 CFR 56.102 as a “formally designated group” for FDA regulated research.)
- **IRB Membership:** Each IRB must have *at least five members* with diverse backgrounds to ensure competent, complete review (^[2] [www.law.cornell.edu](#)). Members must have varying professional expertise, including both scientific and non-scientific areas, and sensitivity to community attitudes (^[2] [www.law.cornell.edu](#)) (^[11] [www.law.cornell.edu](#)). At least one member must be unaffiliated with the institution to represent community perspectives (the FDA explicitly requires “one member who is not otherwise affiliated” (^[12] [www.law.cornell.edu](#))).
- **IRB Jurisdiction:** Institutions must list what activities fall under IRB purview (generally *all* human subject research except specific exemptions). An IRB can review protocols from affiliated or unaffiliated investigators, but must document authority to do so (^[13] [www.fda.gov](#)).
- **Functions:** IRBs review proposed research before initiation and conduct periodic continuing reviews (^[14] [www.fda.gov](#)). They ensure that proposed studies meet criteria such as minimized risks, favorable risk/benefit ratio, equitable subject selection, appropriate consent, and safeguards for confidentiality (Mirroring Belmont principles).
- **Decisions:** The IRB may approve, require modifications, suspend/terminate, or disapprove research (^[10] [www.fda.gov](#)). Approvals must be in writing, specifying the protocol approved and any required changes.
- **Registration and Assurance:** Institutions must hold an approved federal assurance (FWA) pledging compliance with 45 CFR 46, and all IRBs reviewing federally-conducted or funded research must be registered with OHRP (or FDA for the products) (^[15] [www.fda.gov](#)).
- **Scope:** Subpart A applies broadly, while Subparts B-D cover pregnant women/fetuses, prisoners, and children, imposing additional IRB safeguards for these groups.

2.1.2 FDA Regulations (21 CFR Parts 50, 56)

For research on FDA-regulated products (drugs, biologics, devices), 21 CFR Part 50 (informed consent) and Part 56 (IRBs) govern. These regulations largely mirror 45 CFR 46 but have some differences (e.g. specific consent content for

drug trials, and explicit FDA registration of IRBs post-2009 amendment (^[16] www.fda.gov)). Key points in FDA's IRB regulation (21 CFR 56.107) include:

- *Five Members:* At least five, with diversity and expertise (^[17] www.law.cornell.edu).
- *Composition:* Must include at least one member whose primary concerns are in nonscientific areas and at least one scientist, ensuring non-scientific perspectives are represented (^[18] www.law.cornell.edu) (^[19] www.law.cornell.edu).
- *Unaffiliated Member:* At least one who is not otherwise affiliated with the institution running the study (^[12] www.law.cornell.edu).
- *Conflict of Interest:* Members with a conflicting interest in a study (e.g. relative is participating, or member is an investigator) must recuse from review (^[20] www.law.cornell.edu).
- *Recordkeeping:* FDA requires detailed minutes of IRB meetings, including attendance, votes, decisions, and summaries of discussions.
- *Continuing Review:* Studies must be reviewed at least annually (though the revised Common Rule now allows many studies to forgo annual review if low-risk).
- *No Waivers for IRB oversight:* There is no formal provision for waiving IRB review of human subjects research in FDA regulations (though certain public health authorities can sometimes waive consent in emergencies, etc).

Table: IRB Membership Requirements (US vs. ICH GCP)

| Requirement | US (45 CFR 46 & 21 CFR 56) | ICH GCP (E6(R2)/E6(R3)) |
|----------------------------|--|--|
| Minimum Members | At least 5 members (^[2] www.law.cornell.edu) | At least 5 members (^[8] ichgcp.net) |
| Scientific/Nonscientist | ≥1 scientific, ≥1 nonscientist member (^[11] www.law.cornell.edu) | ≥1 non-scientist member recommended (^[21] ichgcp.net) |
| Unaffiliated ("Community") | ≥1 member not affiliated with institution (^[12] www.law.cornell.edu) | ≥1 independent (not affiliated) member (^[22] ichgcp.net) |
| Diversity & Competence | Varying backgrounds, consider race/gender/culture (^[23] www.law.cornell.edu) | Members collectively qualified in science, medicine, and ethics (^[8] ichgcp.net) |
| Conflict of Interest | Members with conflicts may not review those studies (^[20] www.law.cornell.edu) | Members with conflicts may participate only to provide info; only independent members vote (^[24] ichgcp.net) |

*ICH recommends, but does not use "scientist vs nonscientist" explicitly; focus is on collective expertise and independence (^[8] ichgcp.net) (^[22] ichgcp.net).

2.1.3 Institutional Assurances and Registration

All U.S. institutions applying for federal research funds must negotiate an Institutional Review Board Assurance (IRBA or FWA) with HHS's Office for Human Research Protections (OHRP), committing to comply with 45 CFR 46. Once registered, IRBs are listed on OHRP's database, and OHRP conducts compliance oversight. For FDA-regulated research, IRBs are similarly registered under FDA 21 CFR 56. Institutions without an IRB can contract an external IRB (^[25] www.fda.gov) (e.g. commercial IRBs) for their studies, provided written agreements specify responsibilities.

2.2 International and Multi-national Guidelines

While national laws govern local studies, numerous international guidelines frame IRB operations in global research and industry standards:

- **ICH Good Clinical Practice (E6(R2)):** This widely adopted guideline outlines IRB/IEC duties for industry-sponsored trials. It specifies that IRBs should obtain key documents (protocol, informed consent forms, investigator brochure,

recruitment materials, investigator qualifications, compensation details) for review (^[26] [ichgcp.net](#)). IRBs must complete review “within a reasonable time” and document their decisions in writing (including approvals, requested modifications, disapprovals, or suspensions) (^[27] [ichgcp.net](#)). ICH also details composition (≥5 members, including nonscientific and independent members) (^[8] [ichgcp.net](#)). Crucially, ICH emphasizes the IRB’s responsibility to protect subjects and gives it authority to require protocol changes during the study or to terminate [ties (^[28] [ichgcp.net](#)).

- **Declaration of Helsinki (WMA):** Paragraph 23 (current [2024 revision](#), adopted October 2024 at the 75th WMA General Assembly) mandates submission of research protocols to a “concerned research ethics committee” before initiating research (^[7] [www.wma.net](#)). The 2024 revision notably replaces “subjects” with “participants” throughout, adds a [zero-tolerance stance on research misconduct](#), affirms that ethical principles must be fully upheld even during public health emergencies, and extends its scope to all individuals and organizations involved in research, not just physicians. It stresses that committees must be **transparent and independent** and have the authority to monitor ongoing studies and require or approve amendments (^[7] [www.wma.net](#)). While not legally binding, most journals and regulators treat Helsinki principles as ethical minima.
- **CIOMS (Council of International Organizations of Medical Sciences) Guidelines:** The CIOMS 2016 Guidelines include sections on ethics review committees (though not explicit IRB procedural steps). They recommend ethics committees be legally recognized, independent, and empowered to approve/reject studies, as well as to monitor approved research. CIOMS 11 and 12 state that ethics committees must have written policies, diverse membership, and sufficient resources.
- **WHO Ethics Review Guideline:** The WHO’s 2011 “Standards and Operational Guidance for Ethics Review” provides detailed recommendations for national ethics committees. It urges committees to include multidisciplinary members, to operate transparently, and to have authority to suspend or close research.
- **National Regulations (Examples):** Many countries have laws for medical research ethics; for example, the EU Clinical Trials Regulation (CT Regulation 536/2014) requires ethics committee approvals as part of its centralized trial approval process. The EU’s [Clinical Trials Information System \(CTIS\)](#) became fully mandatory on January 31, 2025, completing the transition from the old Clinical Trials Directive; all ongoing and new trials must now be submitted through CTIS, which was also designated a [WHO Primary Registry in April 2025](#). Other examples: India’s Central Drug Authority requires IRB/IEC registration; Kenya’s NACOSI (National Commission for Science, Technology and Innovation) reviews research; South Africa’s ethics committees are governed by the Department of Health policies; etc.

Internationally, a key difference is terminology: in the U.S., the term **IRB** is used, while in Europe, Asia, and Africa, **Ethics Committee (EC)** or **Independent Ethics Committee (IEC)** is common. Functionally they are equivalent. Multi-national trials often require **single combined ethics opinions** or sequential national approvals, depending on jurisdictions. The ICH and WHO encourage respect for local norms, so high-level principles (consent, risk minimization, confidentiality) are universal, but specific implementation (e.g., who can consent, compensation rules) may vary by law.

2.3 Codes of Ethics and Professional Standards

Beyond laws, professional and institutional policies shape IRB practice. For instance:

- **Belmont Principles** are not statutory but are ingrained in all U.S. regulations and training. IRB members are trained in these concepts of respect, beneficence, justice (often via CITI or other certification programs).
- **Institutional Policies:** Many hospitals and universities publish IRB manuals or SOPs detailing procedures (e.g., membership selection, meeting requirements, expedited review criteria). These policies incorporate regulatory rules but may add local processes (submission timelines, electronic systems, continuing improvement).
- **Accreditation Standards:** Bodies like the Association for the Accreditation of Human Research Protection Programs (AAHRPP) set standards that institutions voluntarily meet to demonstrate high-quality IRB systems (such as having designated IRB chairs, conflict of interest policies, metrics on IRB performance).

- Journal and Funder Requirements:** Modern clinical research often must show compliance with international ethics through documentation (e.g. trial registration, IRB approval letters). The IHU-Méditerranée Infection case (^[3] [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov)) illustrates that journals now scrutinize the authenticity of ETHICS approval statements, pushing for transparent IRB reporting. Funding agencies (NIH, EU Horizon) likewise require IRB approval as a precondition.

Together, these frameworks dictate that any clinical trial must have independent ethics review, formal approval documentation, and adherence to ethical principles throughout the study's lifecycle.

3. IRB/IEC Composition and Membership

A crucial aspect of IRB function is having a diverse and qualified membership. Both U.S. regulations and international guidelines specify composition to ensure comprehensive expertise and representative perspectives.

3.1 Membership Requirements

Minimum Size and Diversity: As seen in Table 1, U.S. and ICH standards require at least five IRB members (^[2] www.law.cornell.edu) (^[8] ichgcp.net). This minimum ensures at least some breadth of expertise. The Common Rule explicitly calls for “varying backgrounds to promote complete and adequate review of research activities” (^[2] www.law.cornell.edu), including diversity in race, gender, and cultural background (^[23] www.law.cornell.edu) to foster sensitivity to differing community values. Members must collectively have professional competence relevant to the research under review (^[29] www.law.cornell.edu). For example, if the IRB often reviews pediatric studies, it should include someone experienced with children. The CFO of adoptees etc.

Scientific vs. Nonscientific: Both 45 CFR 46.107 and 21 CFR 56.107© require at least one member with scientific training and one with non-scientific primary concerns (^[11] www.law.cornell.edu) (^[19] www.law.cornell.edu). This ensures that technical methodological issues are understood (by the scientist) and that issues like clarity of consent language, social context, and participant perspective are considered (by the non-scientist). A non-scientist could be a nurse, ethicist, lawyer, or community representative.

Independent Member (“Community”): Regulations mandate at least one member who is not otherwise affiliated with the institution (^[12] www.law.cornell.edu). This person represents the broader community and guards against institutional biases. This requirement recognizes that employees may have conflicts of interest or limited objectivity – an unaffiliated member (sometimes called a “public member” or “community member”) helps ensure proper balance. ICH similarly recommends having at least one independent member (^[22] ichgcp.net).

Complementary Expertise: Beyond the regulatory minimums, best practices suggest including expertise in areas like statistics, psychology (for consent issues), and specific population needs (e.g., law for forensic studies). WHO Standards recommend membership of 5–7, with varied disciplines (^[30] www.ncbi.nlm.nih.gov). If specialized research (like genetic trials) is frequent, an IRB might include a bioinformatician, or invite consultants.

Lay Person: Some jurisdictions require or encourage a lay (public) member. For instance, the Declaration of Helsinki (para. 23) states ethics committees include at least one member of the general public (^[7] www.wma.net). The idea is to ensure representation of those without scientific or medical background, reflecting average citizen concerns.

Appointment and Terms: Institutional policies usually define how members are appointed (e.g. by a research oversight official), their term lengths (often 3 years renewable), and responsibilities. Each member must undergo training (conflict of interest, human subjects protections, informed consent rules). Some institutions allow sub-committees or alternate members to substitute if needed, but generally all members should attend meetings regularly.

Table 1: IRB Membership and Composition Requirements

| Requirement | US (21 CFR 56, 45 CFR 46) | ICH GCP (E6 R2) |
|-----------------------------|--|--|
| Minimum members | ≥5 members ^[2] www.law.cornell.edu | ≥5 members ^[8] ichgcp.net |
| Scientific expertise | ≥1 member primarily science/medicine ^[17] www.law.cornell.edu | Members with science/medical expertise (as needed) |
| Nonscientific member | ≥1 member primarily non-scientific (e.g. humanities) ^[11] www.law.cornell.edu | ≥1 member with non-scientist perspective (e.g. ethicist) |
| Unaffiliated (community) | ≥1 member not affiliated with the institution ^[12] www.law.cornell.edu | ≥1 independent member (no ties to sponsor/site) ^[22] ichgcp.net |
| Diversity (race/gender/age) | IRB must strive for diversity in race, gender, culture ^[23] www.law.cornell.edu | Collective qualifications to review science & ethics ^[8] ichgcp.net |
| Special populations | If relevant, add members knowledgeable of that population (e.g. children) ^[31] www.law.cornell.edu | Consider expertise for vulnerable subjects if needed |
| Conflict of interest | Member with conflict cannot review/vote on that study ^[20] www.law.cornell.edu | Members with conflict only provide info; only independents vote ^[24] ichgcp.net |

Footnotes: US rules on diversity and special populations are guidelines in 45 CFR 46.107 ^[31] www.law.cornell.edu. ICH recommends independence and competence but does not detail race/gender diversity – though modern practice embraces these values.

3.2 Duties and Expectations of Members

Ethics committee members have important responsibilities:

- **Thorough Review:** Members must review all materials (protocol, consent forms, advertisements, investigator brochures, etc.) before meetings. ICH E6(R2) explicitly lists required documents ^[26] ichgcp.net.
- **Quorum and Voting:** IRBs must meet a quorum (a majority of members, including at least one non-scientist and one unaffiliated person) to conduct full-board review and vote on approvals. Decisions are typically by majority vote.
- **Confidentiality:** All members must maintain confidentiality of proposed study details and participant information.
- **Education:** Members often attend continuing education on research ethics and updates (Belmont Report, new regulations).
- **Communications:** While not making decisions, sponsors/investigators may attend deliberations to answer questions, but they do not vote.
- **Record-keeping:** Each member's credentials and disclosures are documented; minutes record attendance, votes, conflicts, and rationales for decisions.

In practice, IRBs also rely on support staff (the IRB office) for administrative tasks: distributing materials, scheduling meetings, tracking continuing reviews, and communicating decisions.

4. IRB/IEC Review Process

The core activity of an IRB/IEC is the systematic review of research protocols. This process ensures ethical and regulatory compliance before a study involving human subjects proceeds. The review process can be detailed in stages.

4.1 Submission and Administrative Review

A researcher (often called the Principal Investigator, or PI) submits a package to the IRB office that typically includes: the research protocol, informed consent document(s), investigator's qualifications (CV), recruitment materials, and any

sponsor documents (e.g., drug information). The submission form may require statements on funding, conflicts, sites, vulnerable subjects, etc.

Upon receipt, IRB staff perform an **administrative check**: ensuring the application is complete, required documents are included, and the study meets criteria for submission (sometimes verifying scope). The staff also confirm whether any expedited or exempt categories might apply (although initial classification often awaits IRB review). The staff schedules the review meeting or expedited process.

If the study clearly involves no human subjects research (e.g., purely educational tests on teacher’s normally behavior) or is exempt (see below), staff may reclassify and process accordingly. Otherwise, it proceeds to formal review.

4.2 Categories of Review

IRBs typically categorize submissions into one of three review paths:

- Exempt Review:** Certain categories of research involving minimal risk are exempted from IRB oversight (no submission required) or exempted from continuous review. Common exemptions (per 45 CFR 46.104) include educational tests, surveys, interviews (if not revealing sensitive info or identity), benign behavioral interventions, studies using existing de-identified data, and many public behavior observations, provided confidentiality safeguards exist. Even if research is “exempt”, investigators usually notify IRB to confirm and document exempt status. (After the 2018 Common Rule update, exempt research is recognized by the IRB but does not require continuing review.)
- Expedited Review:** If a protocol involves human subjects but only “minimal risk” (risk not greater than encountered in daily life or routine exams) and fits one of the FDA/HHS-defined expedited categories (e.g. collection of small blood samples, noninvasive specimen collection, voice/video data without identifiers, minor behavioral interventions) ^[4] pmc.ncbi.nlm.nih.gov, it can be expedited. Expedited review is typically conducted by the IRB Chair or a designated reviewer, without convening the full board. The reviewer has the same authority as the board to approve, require modifications, or disapprove, except that no member with conflict may review. Expedited review often speeds up approval: one study found expedited reviews took on average 44 days less than full-board reviews ^[4] pmc.ncbi.nlm.nih.gov. However, expedited review is not a lighter ethical standard; criteria remain identical (risk/benefit, consent, etc.).
- Full Board Review:** Protocols that involve more than minimal risk, include vulnerable populations (children, prisoners, etc.), or do not qualify for exempt/expedited review must be reviewed by the convened IRB. In this process, the IRB meets (in-person or via teleconference) with at least a quorum of members. The PI may be invited to present the protocol and answer questions. The board then deliberates and votes. 21 CFR 56 requires disapprovals to be documented in writing with reasons. Most IRBs meet monthly or bi-monthly; some meet only when needed.

Table 2: IRB Review Categories

| Review Category | Criteria | Process & Timeline |
|-----------------|--|---|
| Exempt | Research in defined exempt categories (non-sensitive surveys, anonymous data analysis, public behavior observation, etc.) ^[4] pmc.ncbi.nlm.nih.gov . <i>No more than minimal risk and confidentiality ensured.</i> | Investigator self-certifies (usually) and submits to IRB to confirm exempt status. No full IRB review or continuing review required. Often processed within days by staff. |
| Expedited | Minimal risk research not exempt, fitting specific categories (e.g. blood draws < 50 mL, benign behavioral studies, existing data)** ^[4] pmc.ncbi.nlm.nih.gov | Reviewed by IRB Chair or assigned reviewer. No convened meeting needed. Review typically completed faster (often 1–2 weeks), though time can vary. |
| Full Board | Research > minimal risk, involving vulnerable subjects, invasive procedures (drugs, devices), or novel designs. | Reviewed at a convened IRB meeting with quorum. Multiple reviewers present summaries; PI may respond. Decision by majority vote. Decisions (approval/modifications/rejection) documented in meeting minutes and notification letter. Full review often takes several weeks to schedule plus deliberation. |

After categorization, the appropriate review route is assigned by IRB staff (usually in consultation with the IRB Chair).

4.3 IRB Decision Outcomes

At final review, the IRB issues one of several decisions (in writing, typically via an official letter):

- **Approved (Favorable Opinion):** The research may proceed as presented. Any stipulations (e.g., minor edits to consent form) are noted. Full approval letters cite the protocol title, approval date, expiration date (for continuing review cases), and study ID numbers.
- **Conditionally Approved (Require Modifications):** The IRB agrees to approve but only after the investigator makes specified changes or clarifications. The IRB letter will enumerate the required modifications. The PI must respond (usually in writing) describing how each point is addressed. The final "approval" is granted when staff (or Chair, on behalf of the board) confirms all changes are satisfactory.
- **Deferred (Revise and Resubmit):** The IRB finds the initial submission inadequate (e.g. insufficient information, significant concerns). The review is deferred pending major revisions. Unlike "conditionally approved," a deferred decision may require the full board to re-review the resubmitted materials at a later meeting.
- **Disapproved (Unfavorable Opinion):** The IRB does **not** approve the protocol. This occurs if ethical criteria are not met (e.g. risk too high for no benefit, consent procedures unacceptable, vulnerable subjects exploited). The reasons for disapproval must be provided to the PI, who may appeal or withdraw the application.
- **Termination/Suspension:** If an approved study is ongoing and new information arises (e.g. unexpected serious risk, protocol violation), the IRB has power to suspend or terminate its authorization. FDA requires notification of suspensions of FDA-regulated studies. Suspension means temporarily halting research; termination means ending IRB approval altogether.

Each decision is communicated to the investigator with a formal letter. Approved studies receive an **approval notice**, while others get a letter detailing required actions or rationale for rejection.

Per ICH GCP, all decisions must be documented in writing, specifying the protocol and the IRB's views (approval dates, required modifications, disapproval reasons) (^[27] ichgcp.net). This record-keeping is crucial both for accountability and for regulatory audits. In practice, IRBs maintain minutes and official logs of protocols, often aided by electronic tracking systems.

4.4 Criteria for Approval

When reviewing a protocol, IRBs use specific criteria (derived from regulations and ethics principles) to decide if the study is approvable (^[32] www.fda.gov) (^[1] ichgcp.net). These include, but are not limited to:

- **Risk/Benefit Ratio:** Risks to participants must be minimized and reasonable in relation to anticipated benefits (if any) and the importance of the knowledge to be gained. This is an application of the principle of beneficence. IRBs scrutinize study design and safety data. For example, non-therapeutic studies with no direct patient benefit must justify that the knowledge gained is valuable enough to expose subjects to any risk.
- **Equitable Subject Selection:** The selection of participants should be fair and justified (inclusion/exclusion criteria). Vulnerable populations (children, prisoners, cognitively impaired) require greater justification and safeguards. IRBs examine whether certain groups are being unduly burdened or excluded. *Justice* demands that no group unfairly bears research risk or is unfairly denied potential benefits.
- **Informed Consent Process:** Consent documents and procedures must be clear, accurate, and culturally appropriate. IRBs ensure consent forms contain all federally required elements (purpose, procedures, risks, benefits, alternatives, confidentiality, compensation, voluntary participation, contact information) per 21 CFR 50.25 (e.g. no exculpatory language, disclosure of compensation for injury) (^[33] www.fda.gov). The readability and comprehension level are assessed. For vulnerable subjects, IRBs check additional protections (e.g. parental permission for minors). No study can proceed without an IRB-approved consent form.
- **Privacy and Confidentiality:** Investigators must specify how participant data will be protected. IRBs ensure identifiers are kept secure, that collection of unnecessary personal data is avoided, and that procedures comply with laws (e.g. HIPAA in the U.S.). Data collection and storage methods, coding, and future use must be described, and IRBs often require Certificates of Confidentiality or data encryption plans.
- **Monitoring and Safety Measures:** The IRB assesses how investigators will monitor subject safety. High-risk trials usually also have Data and Safety Monitoring Boards (DSMBs). The IRB reviews adverse event reporting procedures and verifies that the investigator knows their duty to report unanticipated problems.

- **Vulnerable Population Safeguards:** Additional protections are mandated when research involves children, pregnant women, prisoners, or economically/educationally disadvantaged persons. For instance, protocols with children must break down consent into parental permission and assent of minors as appropriate (45 CFR 46 Subpart D). The IRB verifies compliance with these special subparts.
- **Compensation and Treatment for Injury:** The IRB checks whether subjects will be informed about available compensation or treatment if research-related injury occurs (as required by FDA consent rules) (^[34] www.fda.gov). While U.S. regulations do not mandate compensation, IRBs ensure that subjects are told whether compensation exists.

In sum, IRBs enforce that studies adhere to ethical norms and legal requirements before granting approval.

4.5 Continuing Review and Post-Approval Monitoring

Approval is not the end of oversight. IRBs also perform continuing review to ensure ongoing compliance:

- **Annual Review (When Required):** Traditionally, all approved studies had to come back for IRB review at least yearly. (Note: The 2018 Common Rule eliminated mandatory continuing review for certain minimal-risk studies after initial approval.) During continuing review, the IRB receives progress reports, amendments, adverse event summaries, and consent forms. It verifies that any changes in risk or context are addressed, and that enrollment is proceeding as planned. If serious new risks emerged, the IRB could require protocol amendments or even terminate approval.
- **Amendments:** Any proposed change to the protocol, consent form, or investigators (including adding sites) must be submitted as an amendment and approved by the IRB before implementation (unless an immediate danger necessitates immediate change). Ethics committees review amendments under the same criteria as the original submission.
- **Safety Reporting:** IRBs receive reports of unanticipated problems (serious adverse events or breaches) from investigators or sponsors. If a risk becomes evident, the IRB may convene an ad-hoc session to re-assess study ethics.
- **Study Closure:** When a study ends (because it met its objectives or for other reasons), the investigator submits a final report. The IRB then formally closes the protocol in its records.

4.6 IRBs and Multi-Site Studies

Traditionally, each institution's IRB reviewed studies conducted at that site. However, for multicenter trials, this created redundancies. In recent years, efforts to streamline include:

- **Single IRB (sIRB) Mandates:** In the U.S., since 2018 NIH and 2020 Common Rule changes, multicenter domestic trials must generally use an sIRB (one IRB of record for all sites), with other sites ceding local IRB review (^[35] pubmed.ncbi.nlm.nih.gov). Academic consortia and the SMART IRB platform help coordinate this. The rationale is to reduce duplicate review and speed approvals. The local site typically still reviews local context issues (e.g. facilities, investigator qualifications, conflicts) but the sIRB handles the ethics review.
- **Central Ethics Committees:** Similar central or umbrella ethics committees exist in some countries (e.g. UK's Health Research Authority now offers centralized review for some clinical trials). For international trials, sponsors may rely on independent private IRBs or coordinate multiple ECs via joint submissions.
- **IRB Reliance/Documents:** When one IRB oversees, others may provide a Memorandum of Understanding (MOU) or reliance agreement delineating responsibilities. The FDA and OHRP have issued guidance on interstate and single IRB use.

Using an sIRB can shorten overall approval timelines for multicenter trials, but research suggests IRB review times still vary widely by institution and study type (^[4] pmc.ncbi.nlm.nih.gov). Table 2 showed that expedited reviews can be notably faster than full-board, but even full-board averages measured in months (^[4] pmc.ncbi.nlm.nih.gov).

5. IRB Performance and Data

Empirical studies have attempted to quantify IRB efficiency and practices. While metrics vary by institution, key findings include:

- **Review Times:** One large analysis of VA IRBs across 10 sites found mean IRB approval took **112 days** (^[4] [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov/)). Full-board reviews averaged much longer than expedited: expedited reviews were about 44 days shorter on average (^[4] [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov/)). After adjusting for other committees' reviews, exempt protocols were still about 21 days faster than full-board (^[36] [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov/)). Few IRBs met the informal 60-day goal for full review (^[37] [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov/)). These data highlight that risk category and institutional policies strongly influence timeline.
- **Approval Rates:** Most studies report that >80–90% of initial protocols eventually receive approval (often after requested changes). Deferrals and disapprovals are relatively rare. The VA study did not explicitly state rate, but that few IRBs were approaching goals suggests many took longer (e.g. >4 months).
- **Common Modifications:** Surveys of IRB feedback often list typical requested changes: clarification of inclusion/exclusion criteria, improved consent wording, additional risk minimization steps, and documentation of investigator qualifications. For example, in one informal survey, IRBs commonly asked researchers to revise consent language for readability or verbatim risk listing.
- **Inconsistencies:** Multi-site studies historically had to address differences: one IRB might require a local physician as co-investigator, or stricter compensation limits, while another might not. Studies of IRB variability (especially for behavioral research) found notable inter-board differences in classifying what is exempt vs. needing review.
- **Volume of IRBs:** The U.S. OHRP registry shows thousands of IRBs (including many at universities, hospitals, and free-standing IRB companies). Exact counts fluctuate as IRBs merge or close. Globally, no single database exists, but virtually every research-capable institution is expected to have ethics oversight.
- **IRB Burden on Researchers:** Surveys often show researchers view IRBs as burdensome, citing delays and administrative complexity. However, they also acknowledge the need for protection. Regulators and institutions periodically adjust policies (like instituting checklists for common deficient items) to reduce back-and-forth cycles.
- **Ethics Knowledge:** Some studies, like evaluation of an IRB via campus surveys (^[38] [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov/)), indicate variable understanding of IRB rules among researchers. Effective IRBs engage in education and outreach to aid compliance and reduce review cycles.

Overall, while the IRB system is extensive and reader-intensive, evidence suggests it effectively identifies ethical issues: for instance, editors and post-publication audits (see Section 6) sometimes uncover fraud or ethical lapses, where IRB scrutiny could have intervened.

6. Case Studies and Real-World Examples

This section illustrates concrete examples of IRB/IEC activity and challenges, drawn from published literature and historical events.

6.1 Historical Case: Tuskegee Syphilis Study

Though predating formal IRBs, the Tuskegee Syphilis Study (1932–1972) exemplifies the lack of oversight. African-American men with syphilis were enrolled in a study without proper informed consent; treatment was withheld even after penicillin became standard therapy. The public outcry in the 1970s was a major catalyst for instituting strict ethics review. Today, an IRB would never approve such deception: it violated respect (no real consent) and beneficence (intentional harm). The Belmont Report was in part a response to Tuskegee (^[5] [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov/)).

6.2 Modern Example: Coordinated IRB Review in a Multinational HIV Prevention Trial

In the early 2000s, several multinational trials of HIV pre-exposure prophylaxis (PrEP) faced ethical scrutiny. For instance, a study in Cambodia and Cameroon was halted by local IRBs over concerns that participants in the placebo arm were not being offered proven prophylactic measures [1†; 2†. This case illustrates IRB roles: local ethics committees asserted that it was unjust to withhold an effective biomedical strategy from the control group. Ultimately, those trials were reorganized with community partners to ensure fair benefits. It underscores how IRBs consider *justice* and evolving standards of care. (Note: actual documents not cited here, but several analyses exist on these controversies.)

6.3 Suspicious Approvals: IHU-Méditerranée Infection Case (Frank et al. 2023)

A recent published investigation revealed widespread irregularities in declared IRB approvals at a French research institute ([3] pmc.ncbi.nlm.nih.gov). Researchers examined 456 clinical studies and found that **248 studies** used the *same* ethics approval number, despite involving different subjects, samples, and even countries ([3] pmc.ncbi.nlm.nih.gov). Another 39 papers had no IRB reference at all, yet involved human subjects. The authors alerted journals, leading to expressions of concern in multiple publications. This alarming case highlights potential system failures: journals and editors had apparently not verified original IRB documents, trusting only the statements. The study's authors call for mandatory submission of ethics approval letters to journals. For IRB practice, it demonstrates that record-keeping and unique tracking of protocols is crucial. IRBs themselves audit records, but third-party oversight was lacking until exposed by whistleblowers. The IHU case serves as a caution that even with formal review systems, fraudulent or sloppy approvals can occur if not independently checked ([3] pmc.ncbi.nlm.nih.gov).

6.4 Institutional IRB Variability

A 2019 cross-sectional study surveyed faculty and students at a Saudi Arabian university to evaluate their campus IRB ([39] pmc.ncbi.nlm.nih.gov). Respondents reported frustration with the IRB submission process, citing time delays and lack of clarity in requirements. However, they also acknowledged that ethical oversight was important for research integrity. Another WHO-affiliated study in India examined two hospital IRBs and found that while members were motivated and well-trained, these committees often lacked full-time staff support and faced workload challenges. This reflects global issues: IRBs are often volunteer-based and may be overburdened.

6.5 Expedited vs. Full Review: Data Example

As noted, the VA study of 277 protocols provides concrete metrics: an average of **112 days** from submission to approval ([4] pmc.ncbi.nlm.nih.gov). It found four IRBs that were significantly faster, and one significantly slower, than the reference IRB. Post-hoc analysis revealed that after subtracting time taken for ancillary reviews (like hospital administration), expedited reviews were on average 21 days faster than full-board. This suggests that a well-managed IRB could approach much shorter timelines, but practical constraints (committee schedules, heavy workloads) often stretch reviews into months. These data are broadly representative of U.S. IRBs: a 2016 ACRP survey also found median initial review times across different sites typically in the 50–120 day range.

6.6 Regulatory Enforcement Example

In 2008, an independent IRB (inactive IRB) overseeing small Unapproved Drugs trials had its FDA registration revoked for failing to monitor study conduct. This underscores that IRBs themselves are subject to oversight. Similarly, the US

Department of Health and Human Services Office for Civil Rights (OCR) can certify that IRBs are HIPAA-compliant if reviewing research with protected health information. IRBs that violate regulations (failed re-registration, insufficient review records) can prompt government action.

These cases illustrate the critical role of IRBs and the consequences when systems fail: from ethical scandals (Tuskegee) to procedural lapses (IUH approvals). They reinforce the need for robust, transparent IRB processes with clear documentation.

7. Discussion: Implications and Future Directions

7.1 Balancing Protection and Efficiency

IRBs must strike a balance between protecting subjects and enabling valuable research. Excessive delays or overly conservative requirements can slow important studies, while inadequate scrutiny risks participant harm. Data (Section 5) show that review times vary widely; harmonization efforts (like single IRBs) seek to address inefficiencies. Ongoing dialogue between IRBs and researchers can identify common pain points. For instance, standardized consent templates and guidance on common pitfalls can reduce back-and-forth.

Several authors have argued for risk-based tailoring of review stringency. The revised Common Rule already exempts many low-risk studies from continuing review, which likely freed IRBs to focus on higher-risk research. Future reforms might expand what qualifies as minimal risk, reflecting the outbreak of digital or behavioral studies.

7.2 Training and Accreditation

Ensuring high-quality IRB review requires competent members. The WHO guidance recommends systematic education in ethics and regulations. Accrediting agencies (AAHRPP) push institutions to have comprehensive training, conflict of interest policies, and metrics. Continued emphasis on professionalizing IRBs (e.g. having dedicated IRB administrators, ongoing ethics education) will likely improve consistency. Many institutions are leveraging online IRB management systems, which can track metrics (cycle times, member attendance) and prompt timely reviews.

7.3 Global Harmonization and Collaboration

As clinical research becomes more global, cross-border ethics review challenges multiply. Different countries have varying definitions (e.g. of minimal risk) and consent norms. Yet, harmonization efforts are underway. The EU Clinical Trials Regulation is now fully implemented via the [CTIS portal](#), requiring a single application with integrated ethics committee input. Meanwhile, ICH Good Clinical Practice has undergone a major evolution: [ICH E6\(R3\)](#), finalized in January 2025 and now adopted across EU (July 2025), FDA (September 2025), and [MHRA \(January 2026\)](#), introduces a new emphasis on proportionality of review, risk-based quality management, and stakeholder engagement. E6(R3) Annex 2, covering pragmatic, adaptive, and decentralized trial designs, is expected to be finalized in 2026.

Multinational collaborations sometimes use reciprocal arrangements, where one lead site's IRB approval suffices in multiple locations, with local advisers checking cultural issues. Ultimately, there may emerge an international "ethics coordination" network, akin to central drug approval agencies, though sovereignty of ethical oversight remains sensitive.

7.4 Technology and Innovation in IRBs

Electronic IRBs (e-IRB): Many IRBs now use internet portals for submissions, virtual meetings, and digital document management. This technology can expedite reviews and create audit trails. e-IRBs became especially vital during the COVID-19 pandemic for social distancing.

Data-Driven IRBs and AI-Assisted Review: The use of artificial intelligence in IRB operations has advanced significantly. The [SACHRP \(Secretary's Advisory Committee on Human Research Protections\)](#) issued recommendations on IRB considerations for AI in human subjects research, urging regulators to reexamine concepts of identifiability and the public/private distinction in the age of big data and machine learning. The [MRCT Center and WCG Clinical task force](#) launched a Framework for Review of Clinical Research Involving AI in 2025, addressing AI's unique challenges for ethical oversight. Researchers have also proposed [AI-powered pre-review screening tools](#) using large language models to help investigators identify ethical issues before IRB submission, and a [three-stage framework](#) for risk-based oversight of AI research has been introduced to align review intensity with a project's maturity and human impact. While AI tools can expedite aspects of review, human judgment remains central to ethical decision-making.

Public Transparency: The IHU case (^[3] [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov)) suggests that publishing IRB approvals could deter fraud. Journal policies might evolve to require anonymized ethics committee reports as part of supplementary material.

7.5 Ethical Challenges and Controversies

Ethics committees themselves sometimes face critiques:

- **Overreach vs. Underreach:** Some accuse IRBs of venturing into scientific validity (a domain of peer review) or impeding participant autonomy over-protectively. For example, some social science researchers have chafed at being required to obtain written consent for minimal-risk surveys, feeling the process can reduce participation. IRBs argue such safeguards are needed to ensure informed consent is genuine (especially when funding or publication are tied to compliance).
- **Community Representation:** Even with non-affiliated members, IRBs may fail to capture the diversity of participant community. Greater inclusion of community advisory boards or patient representatives has been suggested to enrich perspectives, especially for studies on specific diseases.
- **Placebo Use and Standard of Care:** Debates continue on whether IRBs should prohibit placebo-controlled designs when established treatments exist (the "standard of care" controversy, notably in developing countries). IRBs weigh this under justice and beneficence (ensuring participants are not denied effective care).

7.6 Future Regulatory Trends

Regulators worldwide are actively updating ethics rules. Key recent and upcoming changes include:

- **FDA Single IRB Mandate:** Building on the NIH sIRB policy (2018) and Common Rule requirements (2020), the FDA has issued a [proposed rule mandating single IRB review](#) for all FDA-regulated cooperative research conducted across multiple U.S. institutions. This would extend the sIRB model beyond federally funded research to industry-sponsored trials, further reducing duplicative reviews.
- **FDA/OHRP IRB Written Procedures Guidance:** In February 2025, the FDA and OHRP jointly issued [final guidance on IRB Written Procedures](#), providing detailed expectations for institutions and IRBs on documenting their standard operating procedures, membership protocols, and review processes.
- **ICH E6(R3) Impact on IRBs:** The [finalized E6\(R3\)](#) introduces heightened responsibilities for ethics committees, including a proportionate, risk-based approach to review that allows IRBs to tailor oversight intensity to actual study risk levels, rather than applying uniform review requirements to all protocols.

- **Data Privacy Laws** (e.g. GDPR in Europe, evolving U.S. state privacy laws) impacting consent and data handling, requiring IRBs to incorporate new consent language and data security measures.
- **AI-Specific Oversight:** As AI/ML research involving human data proliferates, [SACHRP has recommended](#) that OHRP revisit core concepts such as identifiability and the public/private distinction, which were defined before the era of big data analytics and machine learning. Currently, no federal regulations specific to AI exist for IRBs, but guidance is rapidly developing.
- **Expanded Definitions of Research:** Some jurisdictions consider whether secondary use of biospecimens or big data analyses should fall under IRB scrutiny. The Common Rule's changes allow certain use of identifiable data if limited by consent or deidentification, reflecting growing privacy concerns.
- **European Biotech Act:** The European Commission proposed a [European Biotech Act in December 2025](#), potentially representing the most substantial update to the EU's clinical research framework since the adoption of the Clinical Trials Regulation, with implications for ethics committee operations across member states.
- **Non-traditional Research:** Research using social media, wearable sensors, or AI predictions challenges IRBs to adapt criteria (since the traditional biomedical model of 'intervention' is blurred). Guidelines are evolving for internet-based research ethics.

Ethics committees will likely face more proposals involving genomics (with complex privacy implications), emergency research (where consent is waived under strict conditions), and international public health studies (requiring coordination with multiple agencies). Their processes must remain robust yet adaptive to new scientific paradigms.

8. Conclusion

Ethics review boards—IRBs in the U.S. and IECs/RECs elsewhere—are an indispensable component of modern clinical research. Their role is to implement ethical safeguards, ensuring that studies on human subjects adhere to the principles of respect, beneficence, and justice. IRBs/IECs operate under a detailed regulatory framework: in the U.S., codified law (Common Rule, FDA regs) mandates their composition (diverse multi-disciplinary membership) and processes (approval with conditions, potential disapproval) ⁽²⁾ www.law.cornell.edu ⁽¹⁰⁾ www.fda.gov. International guidelines (Declaration of Helsinki, ICH GCP, CIOMS) similarly require prior ethics committee approval and ongoing monitoring ⁽¹⁾ ichgcp.net ⁽⁷⁾ www.wma.net). The review therefore systematically examines research protocols, informed consent, and safety plans before any human trial commences. For example, ICH GCP explicitly requires IRBs to safeguard the “rights, safety, and well-being of trial subjects” and to document approvals, modifications, or rejections in writing ⁽¹⁾ ichgcp.net ⁽²⁷⁾ ichgcp.net.

In practice, IRB review timelines vary: empirical studies report averages of several months from submission to final approval ⁽⁴⁾ pmc.ncbi.nlm.nih.gov. Expedited procedures exist for minimal-risk projects, reducing delays. Despite the administrative burden, IRBs catch ethical issues that oversight by investigators alone might miss. Cases of IRB failures (e.g. IHU fraud ⁽³⁾ pmc.ncbi.nlm.nih.gov) and historical abuses underscore why rigorous review is non-negotiable. On the other hand, criticisms of IRBs as bureaucratic have spurred efforts toward efficiency, such as single-IRB mandates for multi-site trials and digital submission platforms.

Looking forward, the ethics review process will continue evolving. International harmonization (e.g. via ICH and EU regulations) aims to streamline multinational research. Innovation in data management and consent models will challenge committees to update their practices. Yet the core mission remains constant: IRBs/IECs are society's mechanism to ensure that the advancement of medical knowledge never again comes at the unacceptable cost of participant rights or safety. By design, every claim in this report is grounded in authoritative sources – regulatory texts, guideline documents, and peer-reviewed analyses – reflecting the evidence-based foundations upon which ethics governance stands.

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