

# The Purpose, Composition, and Function of an Institutional Review Board: Balancing Priorities

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The institutional review board (IRB) is one part of the research enterprise designated to protect human subjects. At times the IRB can feel like an oppressive oversight body bound by regulations and designed to inhibit research. However, in reality the IRB was an attempt by the federal government to streamline a variety of processes to ensure the protection of human subjects. Growing out of a history of unethical scientific research, the principle goal of the IRB is to protect human subjects. At some institutions the IRB has an additional role, to take a second look at proposed scientific methods to ensure the highest quality research. The legal basis, purpose, composition, and function of an IRB, and potential challenges in human-subjects research are reviewed here. *Key words: institutional review board, IRB, Common Rule, federal law, research ethics.* [Respir Care 2008; 53(10):1330–1336. © 2008 Daedalus Enterprises]

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## Introduction

Patients who participate in clinical research generally place an extraordinary degree of trust in the investigators, the institutions in which research is conducted, and the research enterprise as a whole, that the patients' best interests will be served in the context of research.<sup>1</sup>

The institutional review board (IRB) is one part of the research enterprise designated to protect that trust. At times the IRB can feel like an oppressive oversight body bound by regulations and designed to inhibit research. However, in reality the IRB was an attempt by the federal government to streamline a variety of processes to ensure the protection of human subjects. Growing out of a history of unethical scientific research, the principle goal of the IRB is to protect human subjects. At some institutions, the IRB has an additional role, to take a second look at proposed scientific methods to ensure the highest quality research.<sup>2</sup> The legal basis, purpose, composition, and function of an IRB, and potential challenges in human-subjects research are reviewed here.

## Historical and Ethical Perspectives on the IRB

Unfortunately, medical research has not always been grounded in the core ethical standards we now believe central to our endeavors. Our modern ethical standards have their basis in the Nuremberg Code, which were developed in response to the atrocities revealed in the Nuremberg military tribunal. The first provision of the Nuremberg Code states that "the voluntary consent of the human subject is absolutely essential." The Nuremberg Code goes on to state several of the principles on which our modern IRBs base decisions, including capacity to consent, freedom from coercion, and comprehension of the research's risks and benefits. Other provisions of the Nuremberg Code require the minimization of risk and harm (ie, a favorable risk/benefit ratio).<sup>3</sup> These statements were echoed in many documents that followed, including the "Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects," first adopted in 1964.<sup>4</sup>

The first United States protections came into being in May of 1974,<sup>4</sup> in part as a response to the "Tuskegee Study of Untreated Syphilis in the Negro Male," conducted between 1939 and 1972. During the study, 399 African-American males were not treated for syphilis, did not give informed consent, and were not informed of their diagnosis; instead they were told they had "bad blood" and could receive free medical treatment, rides to the clinic, meals, and burial insurance in case of death in return for participating.<sup>5</sup> Investigations into the conduct of this experiment

led to protections described in the "Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research," released in 1978, which outlined 3 ethical principles that form the basis of IRB oversight: respect for persons, beneficence, and justice.<sup>6</sup> These protections raised the status of the previously released National Institutes of Health Policies for the Protection of Human Subjects and created the IRB as one of the mechanisms to protect human subjects.

Codification of these recommendations began in the Department of Health and Human Services and the Food and Drug Administration in 1981. Until 1991, federal departments and agencies had various policies regarding how they funded, conducted, and supported clinical research. Code of Federal Regulations Title 45, Part 46 (widely known as the Common Rule) unified these policies for all agencies except the Food and Drug Administration. Thus, human-subjects research is governed by 2 federal agencies: Health and Human Services and the Food and Drug Administration. The Office for Human Research Protections implements the regulations and assures that institutions comply with the Common Rule. Losing the Office for Human Research Protections' approval effectively shuts down an institution's human research programs.<sup>7</sup> Many federal agencies, however, such as Veterans Affairs, have additional policies and procedures. Therefore, individual institutions must adapt their systems for protecting human subjects, based on the mix of their research portfolios.<sup>1</sup>

## Establishment of the IRB and Institutional Responsibilities

All institutions that conduct federally sponsored research must provide the federal government an "assurance" that states the institution's principles for protecting the rights and welfare of human subjects. The most common approach is a multiple-project assurance, whereby the institution takes responsibility for multiple projects without the need to renegotiate an assurance for each individual project.<sup>1</sup> The Common Rule governs how the assurance is executed through the designation of one or more IRBs. The assurance document includes:

1. A statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects in research conducted at or sponsored by the institution, regardless of whether the research is subject to federal regulation.
2. Designation of one or more IRBs established in accordance with the requirements of this policy, and for which provisions are made for meeting space and sufficient staff to support the IRB's review and record-keeping duties.
3. A list of IRB member names, earned degrees, representative capacity, experience (eg, board certifications, licenses) sufficient to describe each member's chief antic-

ipated contributions to IRB deliberations, and any employment or other relationship between the IRB member and the institution.

4. Written procedures the IRB follows for: conducting its initial and continuing review of research; reporting its findings and actions to the investigator and the institution; determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since the previous IRB review; and ensuring prompt reporting to the IRB of proposed changes in a research activity, and that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

5. Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of: any unanticipated problems involving risks to subjects or others, or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and any suspension or termination of IRB approval.<sup>7</sup>

The assurance serves as a contract, and through it the institution assumes a weighty set of legal, ethical, and fiscal responsibilities. The assurance commits the institution to holding all research to the same standards and procedures, regardless of the sponsor, and the institution assumes fiscal responsibility for IRB operation. Finally, local oversight is a principal means of protecting human subjects.<sup>1</sup>

Under the Common Rule, an institution can also establish more than one IRB or designate another institution's IRB to review its research, based on the institution's needs and the kinds of research it is involved with. If the research is supported by the Department of Health and Human Services, such designations must have prior approval from the National Institutes of Health's Office for Protection From Research Risks.

In addition to the IRB, each institution should have a single individual responsible for the oversight of research and IRB functioning: the Authorized Institutional Official. This individual can be the institution's CEO or a delegate of sufficient authority to speak or act for the institution, such as the director of research and development, a dean or assistant dean, or the hospital administrator.<sup>7</sup>

### Composition of the IRB

The federal policy requires that an IRB have at least 5 members: a chairperson, a scientific member, a nonscientific member, a lay person not affiliated with the institution, and a practitioner. The IRB must be sufficiently qualified through the experience and expertise of its members

and the diversity of their backgrounds, including considerations of their racial and cultural heritage and their sensitivity to issues such as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The composition of the board must provide the professional competence necessary to review research activities and be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. No IRB may consist entirely of members of one profession.

The board is not limited to 5 members, and should be large enough to ensure adequate protection for vulnerable subjects.<sup>7</sup> There are specific protections outlined by the Department of Education regarding handicapped children and mentally disabled persons.<sup>8</sup> The IRB may invite individuals who have competence in special topics to assist with review of projects outside the IRB members' expertise, but those invited individuals do not get to vote in IRB decisions. No IRB member may participate in the review of any project in which they have a conflicting interest, except to provide information.

The membership of the IRB must be submitted to the Office for Protection From Research Risks and kept in the IRB's records. The membership list must include name, earned degrees, capacity, experience sufficient to describe the member's contribution to IRB deliberations, and employment or other relationship with the institution or possible conflicts of interest.<sup>7</sup>

### Purpose

The primary purpose of the IRB, as stated by the National Commission for Protection of Human Subjects of Biomedical and Behavioral Research in its report on IRBs, is to provide independent review of research proposals to determine whether they fulfill ethical standards. This protects investigators from potential conflicts that can arise between the investigators' concern about the pursuit of knowledge and the welfare of human subjects. In this context, "research" is a systematic investigation designed to develop or contribute to generalizable knowledge and "human subjects" are individuals about whom an investigator obtains data through intervention or interaction with the individual, or identifiable private information.<sup>9</sup> The Common Rule requires IRBs to determine the acceptability of a research project in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. IRBs also assume responsibility for suspension or termination of research projects not being conducted in accordance with federal and IRB requirements.<sup>7</sup>

## Function

The primary function or role of the IRB is to safeguard human subjects by training researchers in research ethics and best practices and reviewing research proposals. In reviewing a research protocol the IRB must balance the research's risk to the human subjects with the benefits to society. Confusion can arise from the definitions of risk and benefit. "Risk" is used to express probabilities, whereas "benefit" is used to express a fact. The IRB requires both in expressing a risk/benefit ratio. When weighing the risks and benefits, the IRB must focus on the conditions that make a situation dangerous per se, as opposed to those chances that specific individuals are willing to undertake. It is in this context that research that proposes benefits must be judged.

In addition to protecting human research subjects, the IRB provides certain administrative assurances through internal audits and record-keeping. Audits ensure that the institution's policies and procedures are upheld and allow early identification and correction of problems. Federal law also stipulates that the institution or IRB maintain adequate documentation of IRB activities, including IRB procedures, membership, all research proposals reviewed, minutes of IRB meetings, records of continuing review activities, all correspondence between the IRB and investigators, and statements of important new findings provided to subjects.<sup>7</sup>

## Review Process

Federal law establishes 3 types of IRB review: exempt, expedited, and full. Regardless of the review type, the submission requirements remain the same (Table 1).

### Exemption From Full Review

Federal law allows for human-subject research of minimal risk to be exempt from IRB review (eg, taste preference for certain foods; study uses existing data that is publicly available or subjects cannot be identified; cognitive testing of political candidates or elected officials; and a study in which the data are de-identified). It is always appropriate to discuss the proposal with a member of the IRB staff to determine if the study is appropriate for exempt status.<sup>7</sup>

### Expedited Review

Approval of a research proposal that qualifies for expedited review is in the purview of the IRB chair and does not require full committee review. Such a study involves either slightly more than minimal risk and therefore is not exempt, or has been previously accepted by full committee

Table 1. IRB Review Levels and Examples

Type of Review	Examples
Exemption from full review	Epidemiologic study of COPD with NHANES data Study of changes in days on mechanical ventilation, using de-identified institutional data
Expedited review	Case-control study of patients with COPD admitted to the intensive care unit on the relationship between evidence of right-heart strain and patient outcomes Cross-sectional study of a new biomarker for ventilated patients, requiring a single blood draw from the patient
Full board review	Randomized controlled trial of a new drug or device for COPD treatment Cross-sectional study requiring bronchoscopy following administration of methacholine

IRB = institutional review board  
COPD = chronic obstructive pulmonary disease  
NHANES = National Health and Nutrition Examination Survey

review and is being resubmitted with minor revisions. Federal law codifies this process. A "minimal risk" study is one in which the probability of harm or discomfort is not greater, in and of itself, than that ordinarily experienced in daily life or during the performance of routine psychological or physical examinations or tests. An expedited review procedure can be carried out by the IRB chairperson or by more experienced IRB members designated by the chairperson. In reviewing the research proposal, the reviewer may exercise all of the authorities of the IRB except that the reviewer may not disapprove the research.<sup>6</sup> Categories of research that may be appropriate for expedited review are listed at <http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm>.

### Full IRB Review

All other proposals require full IRB review. The IRB meets on an established schedule to review these proposals, and a majority of the IRB members present must approve the proposal. Notification of the IRB decision must be given to the investigator in writing. If the IRB disapproves the proposal, the notification must include the reasons for that decision.<sup>7</sup>

### Criteria for IRB Approval of Research

For a research proposal to be approved, it must meet certain minimum requirements. First, the risk to the subjects must be minimized by using sound research principles and, when appropriate, leverage procedures already

being performed on the subjects for diagnostic or treatment purposes. The proposal must establish that the risks to the subjects are reasonable in relation to anticipated benefits to the subjects. When weighing risks and benefits, the IRB does not consider the possible long-range effects of applying knowledge gained in the research. Second, the selection of subjects should be equitable and should avoid undue emphasis, if possible, on vulnerable populations. If a vulnerable population is to be approached and there is any possibility of coercion, the protocol should establish how human-subject protections will be maintained.

Contacting potential subjects to obtain further information is a sensitive phase of the research. The IRB considers how the investigator proposes to initially contact potential subjects (eg, through the patient's employer, physician, institution that has the records, or directly) and what information will be conveyed in the initial contact. The proposal must describe the study's procedures for and documentation of data monitoring, maintaining patient confidentiality, and obtaining informed consent, unless the informed-consent requirement is waived.

Informed consent is one of the primary ethical requirements in human-subjects research; it reflects the basic principle of respect for persons. It is too often forgotten that informed consent is an ongoing process, not a piece of paper or a discrete moment in time. The goal of informed consent is to assure that prospective subjects understand the nature of the research and that they knowledgeably and voluntarily decide whether to participate. This assurance protects all parties: IRB; subject, whose autonomy is respected; and investigator, who otherwise faces legal hazards. The "proxy consent" of someone other than the subject is not the same as the subject's own consent, although it may be an acceptable substitute if a subject is unable to give informed consent.<sup>7,10,11</sup>

The informed-consent requirement may be waived entirely if the research meets certain conditions.<sup>7</sup> Modification or waiver of the informed-consent requirement is not allowed under the Food and Drug Administration regulations.<sup>11</sup> Situations in which modification or waiver of the informed-consent requirement may be indicated call for careful consideration by the IRB. The decision to waive informed consent or documentation of informed consent should be clearly documented in the IRB's minutes. The IRB may approve a waiver of some or all of the consent requirements if: the research involves no more than minimal risk to subjects; the waiver or alteration will not adversely affect the subjects' rights and welfare; the research could not be carried out without the waiver or alteration; and, if appropriate, the subjects will be provided with additional pertinent information after they have participated in the study. Epidemiologic studies based on chart review may be considered exempt from informed consent if the data can be de-identified or the subjects' identities

can be adequately protected. The IRB must determine whether the knowledge being sought is important enough to justify the invasion of privacy required to obtain the information about the nonconsenting (or unaware) subjects. Furthermore, the IRB must be sure that subjects are not involved in research under false pretenses.<sup>7</sup>

### Oversight

IRB approval of a proposal is not a one-time event, but an ongoing process that involves continual IRB oversight. The IRB can suspend or terminate previously approved research (eg, a study that is found to cause unexpected serious harm to the subjects or that is not being conducted per IRB requirements). The IRB reevaluates ongoing research at an interval appropriate to the degree of risk, but not less than once per year.<sup>7</sup> The institution can also exercise oversight by preventing or terminating an IRB-approved study. However, an institution cannot override an IRB's decision to disapprove a submitted protocol.

### The IRB and the Health Insurance Portability and Accountability Act

The Health Insurance Portability and Accountability Act of 1996 led the Department of Health and Human Services to create the privacy rule (Code of Federal Regulations Title 45, Sections 160 and 164), which created a new wrinkle in health research by creating "protected health information," which can only be transferred or disclosed under specific circumstances without the written permission of the individual. The IRB can waive or alter the privacy rule under federal law for the purposes of research. Depending on the kind of research, the waiver may be attached to the informed consent or waived all together when it would be impractical for the researcher to obtain the subject's consent and there is no risk to the subject if protected health information is disclosed to the researcher.<sup>12</sup>

### Dilemmas

It is believed that the informed-consent process empowers patients to protect their own self interest; however, many patients place a great deal of trust in their physicians. Patients often look to their physician to guide them through research participation. To maintain patient trust and our ethical standards, researchers and IRBs must ensure that the patient's trust is not misplaced.<sup>1</sup> The IRB has a principle role in maintaining that trust. The complexity of this process can lead to challenges, and breaches of this process can be detrimental to the entire scope of human subjects research.<sup>13-15</sup> Challenges that IRBs and the IRB process face include changes in insti-

tutional preferences in study design and methods, and the large number of studies the IRB members must review annually.

Despite the weighty federal regulations, there are substantial differences between IRBs, which can lead to dilemmas for investigators. A survey of IRB responses to a proposal for a multicenter cystic fibrosis study found that, despite the same genetic risk, the risk evaluations from 31 independent IRBs ranged from minimal to high. The study proposal underwent expedited review in 7 IRBs, and full review in 24 IRBs. The number of consents required by the IRBs ranged from 1 to 4; 15 IRBs required  $\geq 2$  consents, whereas 10 IRBs did not require assent from children. Fifty-two percent of the IRBs' concerns focused on the genetic aspects of the study.<sup>16</sup> This variability among IRB responses to proposals is not confined to genetic studies.

Marked variation was also found among 6 IRBs that evaluated the same multi-institution education-research proposal for a study on medical students' quality of life. Four IRBs found the study appropriate for expedited review, and the remaining 2 required full review. Five of the IRBs required revisions. One IRB approved the study as written. And there were substantial differences in the amount of time required to review the study (range 1–101 d among the IRB administrators and IRB members, and range 6–115 d by the IRB committees), and the delay prevented one school from participating.<sup>17</sup> These findings reflect differences in IRB size, composition, and "personality."

The IRB's size and composition are deliberately unspecified beyond the above-mentioned 5 required members, so the IRB can reflect the institution's needs and to provide flexibility in the membership so that all interested groups have a voice.<sup>7</sup> This was reflected in a survey of 129 IRBs,<sup>18</sup> which showed considerable differences in the size, composition, and training of IRBs. The survey raised the question of racial and gender diversity: 66% of the respondent IRBs' members were male and 90% were white. Differences in IRB decisions may reflect the composition and atmosphere of the committee. Two studies found that the lay, nonaffiliated members felt "intimidated" by scientific members, and that minority members felt dismissed by other members.<sup>19,20</sup> This raises challenges to the IRB's ability to adequately protect the interests of human subjects. At the same time, this homogeneity may be appropriate, depending on the typical research population of an individual institution.

An additional challenge to clinicians, researchers, IRBs and the Department of Health and Human Services recently surfaced with regard to quality-improvement research. The Office for Human Research Protections halted a quality-improvement study in which clinicians used a checklist to implement evidence-based practices in inten-

sive care units in Michigan.<sup>21</sup> We need to establish the difference between quality-improvement, quality-improvement research, and human-subject research, and to better understand minimal risk and the Common Rule.

## Summary

Despite the challenges, the IRB successfully works with researchers to establish sound ethical research for the improvement of health care. Though researchers may find the IRB process overwhelming and overbearing, it is necessary to ensure that researchers are not left in the position of balancing the scientific benefits of new knowledge with the ethical dilemmas that seeking that knowledge might create.

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