

## **What is an IRB?**

An institutional review board (IRB) [also known as: Human Subjects Research Committee, HSR, or ethical review board, ERB] is designated to review and monitor biomedical and behavioral research involving human subjects.

In accordance with Department of Health and Human Services (HHS) regulations, an IRB has the authority to approve, require modifications in, or disapprove research. An IRB performs critical oversight functions for research conducted on human subjects that are scientific, ethical, and regulatory. Seventeen federal departments and agencies have signed on to the “Common Rule” – these agencies include health, education and science; NSF, NIH, NICHD, and Dept of Ed., as well as hundreds of other offices that participate in federal funding of research, adopt the Common Rule.

IRBs are mandated by the Research Act of 1974, which defines IRBs and requires them for all research that receives funding, directly or indirectly, from what was the Department of Health, Education, and Welfare at the time, and is now the Department of Health and Human Services (HHS). IRBs are themselves regulated by the Office for Human Research Protections (OHRP) within HHS. IRBs were developed in direct response to research abuses earlier in the twentieth century. Two of the most notorious of these abuses in the US were the Tuskegee Syphilis Study, which between 1932 and 1972 as sponsored by the U.S. Public Health Service allowed syphilis to remain untreated in hundreds of illiterate black men in rural Alabama, and the Willowbrook Hepatitis Study, which between 1963 and 1966 at the Willowbrook State School in NY deliberately infected retarded children with hepatitis through food or injection in order to study the natural history of hepatitis.

The principles that guide IRBs were first articulated in the Belmont Report, and were subsequently modified many times, most recently in 2005. The full name of the report is "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" created in April, 1979. In 1991, the Common Rule was adopted by seventeen federal departments, known as the HHS regulations 45 CFR part 46, subparts A-D. The final subpart D details additional safeguards for children and, thus, plays an important part in the deliberations of the Lesley IRB. Protections for other vulnerable populations are detailed elsewhere in the regulations.

IRB membership is strictly mandated by the Code of Federal Regulations (45 CFR 46):

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall 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. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

(b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.

(c) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

Membership is stipulated in this way (including both scientists with varying backgrounds and non-scientists) in order to promote thorough and unbiased scientific review of protocols by the IRB as well as to foster sensitivity to the special needs and concerns of the targeted subject pool.

The purpose of an IRB review is to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in a research study. To accomplish this purpose, IRBs review research protocols and related materials (e.g., informed consent documents and investigator brochures) to ensure protection of the rights and welfare of human subjects of research. The chief objectives of every IRB protocol review are to assess the scientific merit of the research and its methods, to promote fully informed and voluntary participation by prospective subjects who are themselves capable of making such choices (or, if that is not possible, informed permission given by a guardian or suitable proxy) and to maximize the safety of subjects once they are enrolled in the project.

According to both the Belmont Report (with later amendments) and the International Conference on Harmonization of Good Clinical Practice (European Union), the IRB should safeguard the rights, safety, and well-being of all trial subjects. Special attention should be paid to trials that may include vulnerable subjects, such as pregnant women, children, prisoners, the elderly, or persons with diminished comprehension. Furthermore, in adherence to **the ethical principles of beneficence, respect for persons, and justice, the IRB only approves research for which the risks to subjects are balanced by potential benefits to society, for which there is a bona fide informed consent process for participants, and for which selection of subjects affords opportunities to participate for all eligible populations.**

The IRB should conduct continuing review of each ongoing trial at intervals appropriate to the degree of risk to human subjects, but at least once per year.

There is an on-going debate concerning IRB review of social science and education research. The debates have been conducted in recent national conferences and a variety of revisions are being discussed at the time this summary was being prepared. To date, no major modifications have been enacted. The issues include: since the Common Rule regulations were written with biomedical and laboratory science methods in mind, the fit is problematical between IRB review and social science methodologies, especially ethnography. Federal agencies supporting social science have attempted to provide guidance in this area, especially the National Science Foundation. In general, the guidance assures IRBs that **the regulations have some flexibility and rely on the common sense of the IRB to focus on limiting harm, maximizing informed consent, and limiting pointless bureaucratic limitation of valid research.** See the NSF website: Frequently Asked Questions <<http://www.nsf.gov/bfa/dias/policy/hsfaqs.jsp>>.