

Human Subject Protections: Who's Who, What's What

Who (When Established)	Given authority by:	Purpose	Current Work
<p>National Bioethics Advisory Commission (NBAC)</p> <p>(October 1995. Charter expired October 2001)</p> <p>www.georgetown.edu/research/rcbl/nbac</p>	President	Advised on bioethics and public policy issues related to conducting human research. NBAC made recommendations to the White House and other departments and agencies.	<p>Final Report (August 2001): Ethical and Policy Issues in Research Involving Human Participants http://bioethics.georgetown.edu/nbac/human/overvol1.html</p> <p>Addresses the adequacy of the current regulatory structure; and the institutional review board system.</p>
<p>White House Council on Bioethics</p> <p>(November 2001)</p> <p>18 member panel</p> <p>First meeting: January 17-18, 2002</p>	President	Advise White House regarding ramifications of advances in biomedical science and technology.	<p>Replacing NBAC: Silent in 2002</p> <p>Monitor embryo and stem cell research, and some other issues identified by NBAC as requiring serious and sustained discussion, i.e., assisted reproduction, cloning, uses of knowledge and techniques derived from human genetics or the neurosciences, and end-of-life issues.</p>
<p>Department of Health and Human Services (DHHS)</p> <p>(May 1980 (formerly HEW))</p> <p>www.hhs.gov/</p>	President	Protect the health of all Americans and provide essential human services	<p>1. Setting the agenda for human subject protection initiatives. Specific goals:</p> <ul style="list-style-type: none"> • Expand education and training for all clinical investigators, IRB members and staff. • Enhance informed consent process and ensure more vigilant monitoring and oversight. • Ensure that researchers understand and comply with federal conflict of interest regulations. • Provide FDA with additional enforcement tools to enhance its oversight role. <p>2. Issued regulations (the Privacy Rule) to guarantee patients' rights and protections against the misuse or disclosure of their health records. http://aspe.hhs.gov/admsimp/final/PvcTxt01.htm</p>

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<p>National Human Research Protections Advisory Committee (NHRPAC)</p> <p>(Chartered June 2000; charter expired July 2002)</p> <p>Director of OHRP serves as Executive Secretary.</p> <p>http://ohrp.osophs.dhhs.gov/nhrpac/nhrpac.htm</p>	<p>Department of Health and Human Services (DHHS)</p>	<p>Provide expert advice and recommendations to the Secretary of DHHS, Assistant Secretary of Health (ASH), the Director, Office for Human Research Protections (OHRP), and other departmental officials on a broad range of issues and topics pertaining to protection of human research subjects.</p>	<p><i>Recommendations Issued</i></p> <p>http://ohrp.osophs.dhhs.gov/nhrpac/doc-report.htm:</p> <ul style="list-style-type: none"> • 45 CFR 46 Subpart D (Response to FDA decision re: waiving parental permission in certain research /certain children); Clarifying Specific Sections of Subpart regarding interpretation/evaluation of risk. • 45 CFR 46 Subpart B; Comment Letter • Financial Relationships in Clinical Trial Research (Response to OHRP) • Clarification of Third Parties when Referenced by Human Subjects in research • Use of Publicly Available Data Files • Informed Consent and the Decisionally Impaired • Confidentiality and Research Data Protections; including implications of HIPAA and the Privacy Rule • Genetic Studies: Draft IRB Guidebook Chapter including recommendations and guidance <p><i>Other Evaluations:</i></p> <ul style="list-style-type: none"> • Human subject protections for non-biomedical research. • Declaration of Helsinki 2000 • Human subject protections for research in children. (Response to Childrens' Health Act of 2000).
<p>Secretary's Advisory Committee on Human Subject Protections (SACHRP)</p> <p>(Chartered on October 1, 2002)</p>	<p>Department of Health and Human Services (DHHS)</p>	<p>Provide expert advice and recommendations to the Secretary of HHS and the Assistant Secretary for Health (ASH) on issues and topics pertaining to protection of human research subjects</p>	<p><i>Replacing NHRPAC</i></p> <p>Advise on special populations; individuals and populations in international studies; individually identifiable data; investigator conflicts of interest.</p> <p>Review OHRP assurance systems, granting of waivers, education programs, oversight of IRBs and institutions.</p>

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<p>Human Subjects Research Subcommittee (HSRS)</p> <p>Chaired by the Director, OHRP.</p>	<p>Office of Science and Technology Policy (White House)</p>	<p>Develop integrated system of human subject protection across the <i>entire</i> Federal Government.</p>	<p>Evaluating specific international policies as well as big-picture initiatives to achieve <i>simplicity, uniformity, efficiency, and effectiveness</i> (the "SUEE" task force).</p>
<p>Office of Human Research Protections (OHRP)</p> <p>(June 2000)</p> <p>http://ohrp.osophs.dhhs.gov/</p>	<p>Department of Health and Human Services (DHHS)</p>	<p>Oversee human research protections (federally funded)</p>	<p><i>Taking the lead in executing on humansSubject protection initiatives set by DHHS</i></p> <ul style="list-style-type: none"> • Leveraging assurance filing program and registration of IRBs • Quality Improvement Program http://ohrp.osophs.dhhs.gov/humansubjects/qip/qip.htm • Providing guidance: <ul style="list-style-type: none"> ◊ Financial disclosure issues for IRBs to facilitate unbiased discussion and properly informed research subjects (Draft) http://ohrp.osophs.dhhs.gov/nhrpac/mtg12-00/finguid.htm ◊ Research activities involving human embryonic stem cells (HESCs), HESC-derived test articles, human embryonic germ cells derived from fetal tissue (Issued 16 Nov 01) http://ohrp.osophs.dhhs.gov/references/HESCGuidance.pdf ◊ Written Institutional Review Board (IRB) procedures (Issued 11 Jul 02) http://ohrp.osophs.dhhs.gov/humansubjects/guidance/wrbproc.pdf ◊ Guidance on Continuing Review (Issued 11 Jul 02) http://ohrp.osophs.dhhs.gov/humansubjects/guidance/contrev2002.htm • Amended Subpart B of 45 CFR 46 to provide additional protections for pregnant women and human fetuses ;

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			<p>clarified provisions for paternal consent; clarifies language. (13Dec01) http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm</p> <ul style="list-style-type: none"> Sponsoring national awards program for excellence in human research protection. (15 Nov 01). http://ohrp.osophs.dhhs.gov/references/AEHRPPR.pdf http://ohrp.osophs.dhhs.gov/references/AEHRPJN.pdf
<p>Food and Drug Administration (FDA) (1927) www.fda.gov/</p> <p>OGCP www.fda.gov/oc/gcp/</p>	<p>Department of Health and Human Services (DHHS)</p>	<p>Oversee marketed products and those intended for marketing.</p>	<ul style="list-style-type: none"> Providing guidance: Establishment and operation of Data Monitoring Committees. (Draft (11/20/01)). Comments due by Feb 19, 2002 http://www.fda.gov/ohrms/dockets/98fr/010489gd.pdf <p>Guidance for collection of race and ethnicity data in clinical trials for FDA regulated products (Draft 1/23/03) http://www.fda.gov/cder/guidance/5054dft.pdf</p> <ul style="list-style-type: none"> OGCP established (June 2001) to focus on conduct and oversight of clinical research and to ensure the protection of participants in FDA-regulated clinical research/represents US in the International Conference on Harmonization of Requirements for Marketing...(ICH). www.fda.gov/cder/guidance/959fnl.pdf (GCPs), www.fda.gov/cder/guidance/4155fnl.pdf (Choice of Control Group)
<p>Institute of Medicine (IOM) Committee on Assessing the System for Protecting Human Research Subjects (Executing described function at the request of DHHS. A two</p>	<p>Department of Health and Human Services (DHHS)</p>	<p>Three-part study of the human research protection process. 1. Develop accreditation standards for Institutional Review Boards (IRBs). 2. Assess effectiveness of</p>	<p>Setting the agenda for accreditation effort.</p> <p>IOM Report:: Preserving Public Trust: Accreditation and Human Research Participant Protection Programs (April 2001) http://books.nap.edu/html/public_trust/summary.pdf</p> <p>IOM Report: Responsible Research: A Systems Approach</p>

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year study.) http://www.iom.edu/IOM/IOMHome.nsf/Pages/human+research+protections		OHRP's activities.. 3. Identify a set of objective measurement techniques for the effectiveness of the human research process.	to Protecting Research Participants (October 2002) http://www.nap.edu/catalog/10508.html
Health Improvement Institute http://www.hii.org/	Office of Human Research Protections (OHRP)	Create a national awards program recognizing excellence in protection of human research subjects in order to encourage institutions, investigators and sponsors to continually improve their processes.	The Institute has established the following 3 annual awards: <ul style="list-style-type: none"> • Best practice that has demonstrated benefit — given to a research institution, unit (for example, Institutional Review Board), or individual • Innovation published in the last 5 years — given to an individual (or team) who has produced a significant contribution to advancing human research protection • Life-time achievement — given to an individual (in academe, industry, or government).
Public Responsibility in Medicine and Research (PRIM & R) http://www.primr.org/	Professional Association	National organization - multidisciplinary forum for addressing biomedical and bioethical issues.	Draft standards for accreditation of IRBs IRB 101 Course (w/OHRP)
Applied Research Ethics National Association (ARENA) http://www.primr.org/	Professional Association	Partner to PRIM&R – application of ethical principles, governmental regulations, and other policies involved with research and clinical practice	Program for certification of IRB administrators and members. (Council for Certification of IRB Professionals (CCIP))

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<p>Association for the Accreditation of Human Research Protection Programs (AAHRPP)</p> <p>(April 2001)</p> <p>www.aahrpp.org</p>	<p>Created by 7 organizations</p>	<p>Offer accreditation to institutions engaged in research involving human participants using a voluntary, peer-driven, educational model.</p>	<p>Accreditation standards final February 26, 2001. The overall goal of accreditation is to improve protection of human research subjects by developing performance standards that encourage programs to adopt "best practices" in this area, and by recognizing the programs that meet those standards.</p> <p>http://www.aahrpp.org/standards.htm</p> <p>The national program of accreditation is a step-wise process: self-assessment, peer review site visit, and a council review.</p>
<p>Partnership for Human Research Protection, Inc., (PHRP)</p> <p>(January 2003)</p> <p>Partnership of the National Committee for Quality Assurance (NCQA) and Joint Commission on Accreditation of Healthcare Organizations (JCAHO)</p> <p>http://www.ncqa.org/</p>	<p>Partnership (NCQA and JCAHO)</p>	<p>Offer accreditation to protect the safety and rights of participants in clinical trials and research programs in public and private hospitals, academic medical centers, and other research facilities in the United States and abroad.</p>	<p>Draft standards for the accreditation program are now available for public comment. Release of the final standards is planned for April 2003.</p> <p>www.ncqa.org/Programs/Accreditation/HRP/hrppdraftstds.htm</p>