

In 2003, WIRB was the first independent IRB to be accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP). In 2006 and again in 2009, AAHRPP renewed WIRB's accreditation status. WIRB continues to be fully accredited.

WIRB strives to respond to the evolving needs of the global research community and has provided services internationally since 1986.

In 2001, in response to Canada's revised research review requirements, WIRB established a panel to review research conducted in Canada. The Panel, composed primarily of Canadian nationals, held its first review meeting in October 2001.

Today WIRB provides review services for more than 400 organizations (academic centers, hospitals, networks and in-house biotech research), as well as for individual investigators in all 50 states and internationally. WIRB has worked with all major pharmaceutical and device manufacturers, CROs, and the biotech industry. In 2007, WIRB started a panel devoted to dedicated clinical pharmacology units (such as phase 1 units).

In 2007, WIRB launched a web portal that allows WIRB's clients to track their submissions, view the review history and download regulatory documents. In 2009, WIRB began to offer "smart" online versions of many WIRB submission forms. Look for our expanded and improved portal and smart forms near the end of 2011.

3. Regulations Affecting Clinical Research, Including HIPAA

A. The Regulatory Framework Within Which WIRB Functions

WIRB is registered with FDA/OHRP. WIRB's IRB registration number is IRB00000533, and WIRB's parent organization number is IORG0000432.

WIRB reviews many types of human subject research, including clinical research, behavioral research, and epidemiological research, in the United States and internationally. WIRB reviews research in accordance with three primary standards, as well as other regulatory standards, when appropriate:

- the Food and Drug Administration (FDA) Regulations on research with human beings (21 CFR 50 and 56), and
- the Health and Human Services (HHS) Regulations on research with human beings (45 CFR 46 Subparts A, B, C, and D),
- the International Conference on Harmonization (ICH) "Guidance for Industry—E6 Good Clinical Practice: Consolidated Guideline."

The FDA regulations apply to clinical investigations conducted on medical products under FDA jurisdiction that will be marketed in the United States; principally drugs, devices and biologics.

The HHS regulations apply to research that is funded by HHS and other agencies that have adopted "the Common Rule," represented at 45 CFR 46, Subpart A. Institutions that receive federal funding for research must obtain an "assurance," a formal agreement with the government in which the institution promises to take prescribed steps for the protection of human subjects. Usually, the type of assurance will be a Federalwide Assurance (FWA) from the Office for Human Research Protections (OHRP). However, for some research, other types of assurances may be used or necessary. If you have questions about obtaining an assurance, see the section of this investigator handbook entitled "Special Considerations for Federally Funded Research," consult the OHRP web site, or contact WIRB's Client Services at 1-800-562-4789 or clientservices@wirb.com.

The International Conference on Harmonization (ICH) is an international standard for drug approval that has been adopted as either law or guidance in many countries (EU, Canada, Japan and the United States). In the United States, FDA has adopted it as guidance. ICH is similar to the FDA drug and IRB regulations, but has a few stricter standards.

WIRB has established written procedures that ensure that research approved by WIRB meets these three primary standards. However, WIRB may vary from the requirements of one of the three standards when it is not applicable. For instance, we will allow the investigator to vary from the ICH requirement that the subject receive a signed consent form for an HHS-regulated behavioral interview study conducted in a setting where a signed copy of the consent form represents an unacceptable risk of breach of confidentiality for the subject.

In addition, WIRB reviews research funded by the Department of Defense, the Department of Education and other federal agencies.

B. HIPAA

WIRB also provides services under the Privacy Rule (45 CFR Parts 160 and 164 of the Health Insurance Portability and Accountability Act of 1996). WIRB will review requests for waivers of authorization and partial waivers of authorization for covered entities upon request (WIRB forms for requesting review of partial and full waivers of authorization are available on the Download Forms page of www.wirb.com). WIRB will also review authorization language upon the request of a covered entity. If the authorization language is embedded in the research consent document, then the IRB must review it. If the authorization language is separate from the research consent document, then the covered entity may determine whether or not to submit the language for IRB review. WIRB will review separate authorization documents upon request.