CONSORTIUM OF
INDEPENDENT REVIEW BOARDS

CIRB Press Release

Subject: March 26, 2009 Congressional Hearing on Institutional Review Boards

The House Energy and Commerce Committee's Subcommittee on Investigations and Oversight ("Subcommittee") is holding a hearing today entitled "Institutional Review Boards that Oversee Experimental Human Testing for Profit" to inquire about the review processes of Institutional Review Boards ("IRBs") that are corporately independent from the research institutions they oversee. While it is unclear what evidence will be presented at today's Subcommittee hearing concerning individual parties, the Consortium of Independent Review Boards ("CIRB®") wants to stress the significant role that independent IRBs play in fostering excellence in research and in raising the bar with regard to the enhanced protection of human subjects.

CIRB is concerned that the term "for Profit" in the title of today's Subcommittee hearing may be misunderstood. All IRBs, including institutional IRBs and independent IRBs, abide by the same federal and state regulatory and ethical requirements with regard to the protection of human subjects.[1] IRBs, whether independent or not, must fund their activities. No matter how an IRB is organized, there is a cost associated with the ethical review function. That cost must be accounted for within the overall budget of the clinical research, whether it is as a direct payment, or as an overhead cost that is included in an overall grant or contract awarded to a research institution. Thus, CIRB cautions that legislators should not focus on the method of payment, but on the integrity of the review process.

The role of the IRB is to review research proposals from an ethical perspective to ensure that human subjects' rights and welfare are adequately protected. Before a study begins, IRBs review the research protocol to evaluate whether participant risks are minimized, that the patient risk/benefit ratio is acceptable, that the informed consent document is accurate and complete, and that the study is to be conducted in an ethical manner. Once the research has begun, the IRB reviews periodic reports from the Investigator, reports of unanticipated problems involving risks to subjects or others, Investigator or Sponsor requests to modify the protocol, and other pertinent information to evaluate whether the rights and welfare of the participants continue to be protected under the protocol and the manner in which the protocol is being conducted.

[1] *See* 21 C.F.R. § 50; 21 C.F.R. § 56; 45 C.F.R. § 46 (2008).

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While the IRB's activities are critical to promoting human subject protection, the activity of minimizing risks to human subjects is a partnership obligation shared by IRBs, Sponsors such as pharmaceutical, biotechnology, or medical device companies, Principal Investigators, the Food and Drug Administration ("FDA"), and the Office for Human Research Protections ("OHRP"). For example, Sponsors are responsible for choosing qualified Investigators and for closely monitoring the conduct of the study, and Investigators are responsible for identifying qualified subjects, obtaining informed consent and following the study protocol. The FDA and OHRP have crucial regulatory oversight responsibilities.

Independent IRBs began to emerge in the 1980s to fill the gap created by FDA's new drug testing requirements. Because most institutionally based IRBs had existed within research institutions (such as academic medical centers and hospitals) and provided review only to their affiliated Investigators, very few IRBs were available to provide review to nonaffiliated researchers in private practice and community clinics. Independent IRBs thus evolved to provide review services to the non-academic community of private practitioners and clinics. Further, because independent IRBs are not limited to single site reviews, they are particularly suited to provide centralized review in multicenter trials. CIRB believes that the regulatory agencies recognize the value of a centralized IRB review process as a measure to reduce costs and duplication of effort in the conduct of multicenter clinical trials without sacrificing human subject protections.[2] Moreover, unlike institutional IRBs, independent IRBs are not embedded within a research organization. Thus, independent IRBs do not face the same structural conflicts that institutional IRBs encounter, which provides them with the ability to exclusively focus on the protection of the human subjects involved in the research.

Many academic institutions and hospitals now delegate some or, in certain situations, all of their work to independent IRBs in recognition of the professional and efficient reviews that independent IRBs can provide. Today, approximately 75% of clinical research in the United States is conducted in non-academic settings. Without the protocol review services provided by independent IRBs, patient access to experimental treatments could be dramatically curtailed, and the conduct of research could be unduly protracted. In the race to find cures or better treatments for serious and life-threatening conditions affecting our nation's citizens and their families, this is unacceptable.

The Consortium of Independent Review Boards has been a strong and consistent voice for the independent IRB community for fifteen years and remains dedicated to improving human subject protection for all IRBs. Independent IRBs who join CIRB agree to a voluntary, self-imposed Code of Ethics, by which the member organizations agree to minimize conflicts of interest, provide training to board members, and respect the jurisdiction of other boards.[3] CIRB members are also strong proponents of IRB accreditation. Most members are now accredited by the

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[2] FDA Guidance for Industry – Using a Centralized IRB Review Process in Multicenter Clinical Trials (March 2006, Procedural), available at http://www.fda.gov/cder/guidance/OC2005201fnl.pdf; 2006 National Conference on Alternative IRB Models: Optimizing Human Subject Protection, 2006 Conference Summary Report, available at http://www.aamc.org/research/irbreview/irbconf06rpt.pdf.

[3] *See* http://www.consortiumofirb.org/ethics_code.htm.

Association for the Accreditation of Human Research Protection Programs, Inc. ("AAHRPP"), and the remaining members are in the process of seeking such accreditation.

"The accreditation process allows an IRB to develop a strong set of procedures and demonstrate compliance with those procedures to AAHRPP, our accrediting organization," says Cami Gearhart, Chair of CIRB.

Over the years, CIRB and its members have also supported many legislative and regulatory actions to enhance human subject protection. These include, among others, IRB registration requirements, measures to prevent IRB forum shopping, and measures to ensure IRB receipt of meaningful information concerning adverse events. As such, CIRB remains a significant supporter of Representative DeGette's proposed legislation entitled "Protection for Participants in Research Act of 2008."

"I am proud," says Gearhart, "of the personal and professional commitment to ethics and human protection demonstrated by my colleagues within the Consortium of Independent Review Boards."

As we look to the future, the viability of highly ethical IRBs, both independent and institutional, is critical to maintaining the expanded access to clinical protocols U.S. citizens have come to expect, and to the prevention of unnecessary delays in the testing of investigational treatments. To that end, CIRB and its individual members will continue to identify and support measures that further enhance human subject protections because that, after all, is the IRB mandate.

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