CONSORTIUM OF
INDEPENDENT REVIEW BOARDS

From the Board of the Consortium of Independent Review Boards

Competing Interests – Members are IRBs not Affiliated with a Research Institution

Independent IRBs were created, and continue to operate, in response to the federal government's IRB review and oversight requirements as research started to shift from academic medical centers to out-patient clinics, private medical practitioner offices, and smaller hospitals. These research venues frequently did not have the staff, experience, or understanding to undertake the development of their own IRBs and, thus, independent IRBs were created to fill the void. The record of the independent IRBs is excellent. In the thirty-plus years since independent IRBs began to emerge, the FDA has rarely cited such entities in warning letters or site inspection reports. In the three years since accreditation has become available for IRBs, we estimate that about 10% of independent IRBs have become accredited in comparison to a considerably smaller percentage of the academic IRBs. It is no wonder that when the Department of Health and Human Services Office of the Inspector General reviewed the IRB process, one of the four reports prepared by the OIG in 1998, "Institutional Review Boards: The Emergence of Independent Boards", indicated that the independent IRBs were fulfilling their mission.

In light of this positive information, the Consortium of Independent Review Boards ("CIRB"), an organization made up of independent IRBs, is distressed to see the discussion of the IRB community divided into two separate and distinct categories with one category, those being "paid" for their services, identified as having a fundamental conflict of interest flaw that weakens its ability to appropriately serve the research participant. No matter how an IRB is organized, there is a cost associated with the ethical review function. That cost must be accounted for, whether it is a direct payment or as an overhead cost that is included in an overall grant or contract. Thus, the focus should not be on the method of payment but on the integrity of the process. IRBs, whether academic or independent, should have procedures to address conflicts of interest. Members of CIRB adhere to a Code of Ethics which, among other things, commits the members to guard against conflicts of interest.

Independent IRBs serve an essential function, and based on the information to date, have performed well. That being said, the clinical research process is fluid and the practices of today may not be adequate for tomorrow. Moving forward the first question should not be whether the IRB is paid a separate fee for its services; the more vital question should be how does the IRB, whether independent or institution based, serve and protect the research participant during clinical research. As an organization, CIRB, and its individual members, will strive to address and readdress the question of improving participant protection because, in the end, that is the

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IRB mandate. The method of funding the IRB is only one point of discussion and should not in and of itself drive or be a major focus of the debate.