CONSORTIUM OF
INDEPENDENT REVIEW BOARDS

January 22, 2013

Via http://www.regulations.gov

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20993

Re: Draft Guidance for IRBs, Clinical Investigators and Sponsors – IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is Needed, **Docket No. FDA-2012 D-0847**

Dear Sir or Madam:

The Consortium of Independent Review Boards ("CIRB®") appreciates the opportunity to comment on the Food and Drug Administration's ("FDA") draft guidance document titled *Draft Guidance for IRBs, Clinical Investigators and Sponsors – IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is Needed* ("Draft Guidance"). As FDA knows, CIRB is a consortium of independent institutional review boards ("IRBs") that provide services to institutions external to their individual member institutions. Independent IRBs have review responsibility for a majority of the FDA-regulated clinical research conducted in the United States. As a result, CIRB has a significant interest in this Draft Guidance.

CIRB commends the FDA for issuing this Draft Guidance because it provides clarification as to the IRB's role in connection with the review of clinical investigators and research sites, as well as the IRB's responsibilities as it relates to the assessment of whether an investigational new drug application ("IND") or an FDA-approved investigational new device application ("IDE") is necessary for a given clinical study.

In supporting the recommendations set forth in the Draft Guidance, CIRB notes that the Draft Guidance principles represent current practice for its members. Because the members of CIRB have always provided review of clinical investigators and clinical sites not affiliated with their institutions, the employment of procedures to review the qualifications of the investigator and the adequacy of the research site has been part of CIRB member practices from the very beginning. CIRB agrees that the employment of site questionnaires, medical license verification procedures,

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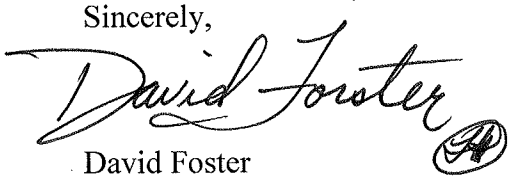
and other related practices are critical to the unaffiliated IRB's risk/benefit analysis during the review process. Moreover, CIRB agrees that IRBs should have procedures to review the sponsor's determination that an IND is not necessary in a drug study, and for reviewing the sponsor's significant risk/nonsignificant risk determination as it relates to a device study.

CIRB thanks the FDA for issuing this Draft Guidance and for the opportunity to submit comments. CIRB looks forward to additional opportunities to provide FDA with its collective experience in advancing the protection and welfare of human subjects involved in clinical research.

Sincerely,



David Foster
Chair

cc: Joanne Less – FDA