



December 20, 2007

By Overnight Delivery

EXPEDITED REVIEW
Office for Human Research Protections
The Tower Building
1101 Wootton Parkway
Suite 200
Rockville, MD 20852

**Re: Comments on Proposed Amendments to Protection of Human Subjects:
Categories of Research That May Be Reviewed by the Institutional Review
Board Through an Expedited Review Procedure**

Dear Sir or Madam:

The Consortium of Independent Review Boards ("CIRB[®]") commends the Office for Human Research Protection ("OHRP") on the Agency's proposed amendments to the categories of research that may be reviewed by an institutional review board ("IRB") through an expedited review procedure, published in the Federal Register on October 26, 2007, 72 Fed. Reg. 60,848. As OHRP knows, CIRB is a consortium of independent institutional review boards ("IRBs") located in the United States and Canada. The membership has a central mission of promoting the protection and rights of human research subjects, while providing an understanding of how independent IRBs support this goal. Approximately 75% of clinical research in the United States is conducted in non-academic settings, and independent IRBs review a majority of this research. Thus, as an organization of independent IRBs, CIRB has a significant interest in proposed modifications to the expedited review categories.

CIRB has reviewed the proposed amendment to category 5 and believes that the clarification will assist IRBs in its understanding of the standards for expedited review under this category. The language of the proposed amendment makes clear that category 5 includes research involving materials (a) previously collected for nonresearch purposes, (b) previously collected for research purposes, provided that the materials were not collected for the currently proposed research, or (c) that will be collected for nonresearch purposes. This amendment will also be helpful to other members of the research community, such as

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investigators and sponsors, in that it will help in eliminating any confusion surrounding the types of research requests that can be submitted for expedited review under category 5.

In addition, CIRB supports the Secretary's Advisory Committee on Human Research Protections' ("SACHRP") recommended revisions to expedited review category 7. SACHRP's proposed revisions bring further clarify to category 7 in describing the type of behavioral research and research methods that may be reviewed using an expedited procedure. Finally, CIRB reviewed the entire expedited review list as requested by OHRP and the Consortium has no recommendations regarding the need for additional changes at this time.

CIRB thanks OHRP for the opportunity to comment on the proposed amendments to the expedited review list.

Sincerely,

A handwritten signature in cursive script that reads "Cami Gearhart". The signature is written in black ink and includes a small circular flourish at the end of the name.

Cami Gearhart
Chair

cc: CIRB Membership