

The Children's Hospital of Philadelphia
Institutional Review Board Policy on Expansion of Expedited Review Procedure
Category 5

Policy Number: 11.0
Effective Date: 12/31/2003
Revision Date:

Background:

Title 45 of the Code of Federal Regulation, § 46.110 policy guidance states the Secretary, HHS, has established, and published as a Notice in the **Federal Register**, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. Category 5 pertains to research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

Policy:

The Children's Hospital of Philadelphia Institutional Review Board (IRB) has established a policy to expand the use of Category 5 of the expedited review criteria, in order to capture research proposed using data, documents, records or specimens, previously collected under an IRB approved protocol for research purposes. This will permit the research to be reviewed via an expedited review, thus alleviating the need for full Committee review.

Procedure:

1. When a research protocol is submitted to the IRB, the Research Regulatory Affairs staff will review the proposed research to determine eligibility for expedited review, as per SOP.
2. In addition to applying the definition of Category 5 [when the research proposed is intended to utilize materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes, (such as medical treatment or diagnosis)], if the research proposed is utilizing materials collected for research purposes (i.e.: an approved IRB protocol), category 5 will also apply to this research.
3. This policy will apply when a modification is proposed for review as well.