Community Healthcare System

The Review

Community Healthcare System Central IRB (CHS CIRB)
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So Many Reviews, Which One Do I Choose?

A question frequently asked by the Principal Investigator or research staff is; "How do I determine what type of "review" procedure to request when submitting a form to the CHS CIRB office?"

First, be aware that the PI may *request* any type of review he may think is appropriate; however, the final determination will be made by the CHS CIRB office according to the federal regulations.

Exempt Review

The Code of Federal Regulations, CFR 45 §46 identifies several different categories of minimal risk research as being exempt from Federal regulations but not exempt from initial review and the ethical conduct of the study. A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in the daily lives of the general population or during the performance of routine physical or psychological examinations or tests.

The review may be carried out by the CHS CIRB Chair or a designee. The person(s) conducting the exempt review may either approve, require modifications to secure approval or refer the research to the Chair or the convened CHS CIRB for review in accordance with the non-exempt review procedures. The reviewer has no authority to disapprove the request.

Studies involving procedures, devices, or drugs subject to FDA oversight do not qualify for exempt review.

The CHS CIRB will request an annual update for all exempt research to be able to track all projects conducted within the system.

Expedited Review

The Code of Federal Regulation, CFR 21 §56, allows an IRB to use an expedited review procedure for research studies that represent no more than minimal risk to subjects to ongoing previously approved research. Included may be minor updates, administrative changes and the addition of investigators.

Continuing review can be expedited unless there have been substantive changes to the protocol that affect the risk/benefit ratio.

Facilitated Review

In this type of review, the initial review of the research was conducted by a "non-local" IRB. It was then presented by a local principal investigator to the CHS CIRB to be reviewed as being appropriate to conduct within the Community Healthcare System. An Chair or an Independent Reviewer is assigned to review the submission. He then has two options; 1) accept the non-local IRB review of the study. The non-local IRB then becomes the IRB of record; or 2) do not accept the non-local IRB review and refer the study for full CHS CIRB review. The CHS CIRB then becomes the IRB of record as in any other study. As with the exempt or expedited review,

the independent reviewer does not have the authority to disapprove the research.

Full Board Review

When the request for review does not fit into one of these categories, it is added to the agenda of the next convened meeting of the CHS CIRB for review by the full board. The agenda and all documents submitted for review are sent to the members two weeks prior to a meeting to allow for their complete review. In order for these documents to be approved, they must receive the approval of a majority of the members present (quorum), including at least one member whose primary concerns are in a nonscientific area.

Continuing Review

The CHS CIRB is responsible for conducting continuing review of ongoing research to ensure that the rights and welfare of human subjects are protected and to review the progress of the study. All research approved by the CHS CIRB must be reviewed *at least* annually or once every 364 days. The CHS CIRB determines the frequency and extent of continuing review for each study. It may require studies to undergo review more frequently as warranted by such factors as the nature of the study; the degree of risk involved; and the vulnerability of the subject population.

Continuing review may be conducted by expedited or full board review procedures.

Related Policies and Forms

IRB 7: Submission of a Research Study: Initial Review
IRB 7.1: Continuing Review of a CHS CIRB Approved Protocol; Lapse of Approval
IRB 7.2 Review of QA/QI Projects
IRB 7.3 Exempt Review
IRB 7.4 Expedited Review

CHS CIRB Contact Information
Jana L. Lacera, RN, MSA, CDM
Director, IRB/Bio-Ethics
901 MacArthur Blvd.
Munster, IN 46321
Phone: 219-703-1546
E-mail: jlacera@comhs.org

Add limited review