Community Healthcare System

The Review

CIRB Website www.drcomhs.org
Central Institutional Review Board

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Demystifying the IRB Process

The IRB has a long-standing reputation of mystifying the research community. The tedious forms, requests for additional information, and time constraints have provoked a common feeling of frustration among investigators, their staff, and the IRB. The mission of the CHS CIRB is to protect the rights and welfare of human research subjects by assuring that anyone who conducts research within the System complies with the federal regulations.

The Focus of IRB Review

The fundamental responsibility of the CHS CIRB is to protect the rights and welfare of research subject. A thorough review by the CHS CIRB focuses on the risks, merits, built-in protections and ethics of proposed human subject research. The CHS CIRB also carries the responsibility of assessing the ability of the investigator to administer the approved research protocol.

Risks, Benefits, and Protections: A primary focus of the CHS CIRB review is to examine the risks and benefits of the proposed research. Once the level of risk has been established, the CHS CIRB seeks to determine that all of the necessary protections for participating human subjects are built into the research design. These "protections" include, but are not limited to, minimizing risk to research subjects, evaluating that the risk is fairly disturbed among subjects, ensuring the privacy and confidentiality of research subjects, and ensuring that legally effective informed consent is obtained.

Ethical considerations: The ethical review of proposed human subject research occurs throughout the review process. During CHS CIRB review, Board members refer to key guidance documents that spell out the ethical considerations investigators should use when designing their research plan. The Belmont Report, for example, is a highly regarded guidance document that advocates for the principals of ***respect for persons****;* recognizing the personal dignity and autonomy of individuals, ***beneficence****;* the obligation to protect individuals from harm by maximizing anticipated benefits and minimizing possible risks of harm and ***justice****;* requiring that the benefits and burdens of the research be distributed fairly.

Investigators: Yet another focus of CHS CIRB review is to determine if the investigator(s) is qualified to conduct the proposed research project. Board members must feel secure that investigators have the expertise to carry out the proposed research as written and approved, that they are knowledgeable about human subject protections as they apply to the proposed research project, and that they have the resources necessary to conduct the project in a safe and efficient manner. The CHS CIRB *Submission of a Protocol Form* guides the investigator and the research staff in preparing to answer these questions for the CHS CIRB.

Listed below are several recommendations that may improve your working relationship with the CHS CIRB.

Accuracy counts! Make sure that the information provided to the IRB is accurate. When inaccuracies are detected the Office will return the submission and request additional information and/or corrections. All forms should be down loaded for each submission to ensure that you are using the most recently approved version. Any inaccuracies may delay review of the submission.

Be consistent between all of the forms. Titles and version dates must be the same throughout. Study procedures must be consistent between the protocol and the consent form. Consents must be submitted in the correct format.

Adhere to the published deadlines. The deadlines are established to allow for sufficient review of the protocols prior to the scheduled m meeting. Adequate review is mandated in the federal regulations. All submissions received after the deadline will be prepared for the following meeting.

There is no substitute for completeness. Incomplete submissions slow the IRB process. A partial or incomplete submission will be returned to the investigator. This will delay review of the submission.

Contact the IRB Office. When you are unsure of which forms to complete or how to complete them, please ask the IRB staff. It is much easier to get it right the first time and avoid unnecessary delays that may interfere with your research plans.

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