



Department/Division Scientific Review of Human Subjects Research

Policy

- All research that is to be submitted to the Committee on Clinical Investigation (CCI) must undergo scientific review at the department or division level prior to submission to the Committee.
- Responsibility for scientific review rests with each department or division, and each is to develop its own mechanism for assuring appropriate scientific review. Departments and divisions are responsible for establishing an explicit and formal process of scientific review that assesses and evaluates the scientific merit, complexity, and potential risks of each research protocol, before that protocol is submitted to the CCI for review.

Purpose

To outline the procedures that all departments and divisions are required to observe in performing scientific reviews. The policy also defines the criteria to be considered during the review process.

Procedures

Documentation of Scientific Review Process

1. Prior to protocol submission to the CCI, each Chair and Division Chief is to submit to the CCI, in writing, his or her department/division's process for conducting scientific review. A copy of this document is to be maintained in the CCI administrative office and placed on the CCI website.
2. Chairs and Division Chiefs are to be required to update their department/division's scientific review process as necessary.
3. In order to assure that scientific review occurs prior to CCI submission, the CCI protocol application requires a scientific review signature. An individual other than the Chair or Division Chief may be assigned responsibility for the scientific review process.
4. The CCI requires that any scientific review correspondence (e.g., questions and responses, letters of final approval) be submitted as part of the protocol application. This information often facilitates CCI deliberations, and may expedite the review process.

5. The CCI reserves the right to review and comment on the scientific review process as it relates to human subjects protection. If the CCI identifies areas of significant scientific concern, these issues are referred to the Chair or Division Chief for reconsideration at the scientific review level.

Criteria for Scientific Review

The following basic criteria are to guide those assigned responsibility for scientific review:

- Are the specific aims and corresponding hypotheses clearly stated?
- Is the primary outcome (and secondary outcomes, as appropriate) stated and defined?
- Has an appropriate literature search been performed such that the rationale for the study is adequately presented? (When risks to the subject are high, an extensive search is required.)
- Does the question or hypothesis being tested provide important knowledge to the field?
- Are there adequate preliminary data in the literature (or from the investigator) to justify the research?
- Is it feasible or reasonable to achieve the results in the proposed time frame, including the time required to recruit, retain, or follow subjects?
- Are the proposed tests or measurements appropriate, and are they necessary, to answer the scientific question?
- Are the individuals conducting the trial properly qualified and trained to perform the protocol procedures?
- Does the research present risk to the subjects and, if so, is it acceptable?
- Are the research procedures consistent with sound research design and do not unnecessarily expose subjects to risk.
- How do the risks of the new treatment/therapy compare to standard treatment/therapies?
- Is any standard of care denied as part of this study?
- If the protocol includes a placebo that might present a risk (even if not great), is the placebo essential for the conduct of the trial? (Have/should other study designs been/be considered?)
- Does the research include an appropriate representation of gender, minorities, and children?

Elimination of Multiple Scientific Reviews

Scientific review is only required of one department or division. Certain locations within the Hospital require scientific review in addition to departmental review. In order to avoid multiple scientific review processes, Chairs and Division Chiefs may defer the scientific review to another division. If this occurs, it is to be indicated in the appropriate section of the protocol application. Protocols that involve use of Catalyst resources will be submitted through their central scientific review process.

Related Content

Document Attributes

Title	Department/Division Scientific Review of Human Subjects Research		
Author	Susan Kornetsky	Dates Reviewed/ Revised	04/01/05. 06/20/05 05/04/07 03/19/2010
Reviewed/ Revised by	Susan Kornetsky		
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Approved	Susan Kornetsky Director of Clinical Research Compliance Carleen Brunelli, MBA, PhD Vice President for Research Administration		