Issuing Department: Human Subjects Protection Program (HSPP)
Policy Number: 2011-016.0
Policy Title: Scientific Review

Purpose

The purpose of this policy is to set forth the requirements regarding the scientific review of protocols involving human subjects.

Definitions

See policy 2011-007.0 for definition of the following terms:

Human Subject | IRB Approval | Conflict of Interest

Policy

The Institutional Review Board (IRB) requires formal scientific review of studies that require review by the convened board. If scientific review has not already been conducted (e.g. NIH, FDA), the Scientific Review Committee (SRC) of the HSPP will conduct the review. The SRC is advisory to the IRB and as such the IRB may agree or disagree with the recommendations of the SRC. The IRB reserves the right to require additional review by the SRC even if another review has already been conducted.

Final IRB approval may only be granted after the scientific review is completed and the results of such have been provided to the IRB for consideration. While preference is for the convened board to see the review, contingent approval may be granted based upon receiving a recommendation for approval, or contingent approval from the SRC. If the SRC recommends deferral because substantive changes to the study are recommended, the study, along with the recommendations of the SRC, will be referred back to the convened board. The Chair always reserves the right to refer a study back to the convened board after receipt of the results from the SRC.

The HSPP's SRC will be comprised of at least 3 members appointed by the Director of the HSPP for an open ended term. One member will be designated as Chair. The SRC will strive to complete its review during the week prior to each convened IRB meeting, as necessary. In most cases the SRC Chair will obtain input from at least 2 primary reviewers. However, if necessitated by scheduling conflicts or other unforeseen circumstances, one member of the SRC may conduct the review. The SRC may call upon individuals with specific areas of expertise on an as needed basis for consultation. No member of the SRC or consultant may participate in the review of a study in which s/he has a conflict; including a financial interest in the sponsor, or a professional or personal interest in the study. If needed, the IRB may call upon an external scientific advisory committee to conduct the review (e.g. a scientific review committee within another dept. at UConn Health).

In evaluating a study the SRC will consider:

- clarity of the research question
- appropriateness and efficiency of design
- rigor and feasibility of methods
- qualifications and expertise of the research team
- scholarship and pertinence of background material and rationale
- adequacy of sample size and relevance of controls

- and the validity of the statistical analysis plan.

In addition, the SRC may desire to comment on the proposal's scientific relevance or compelling ethical or patient safety issues. The SRC may also provide additional information to be conveyed to the investigator for educational value.

For studies reviewed via the expedited or exempt process, the assigned reviewer will also give consideration to these factors and will only grant approval to those studies determined to have scientific merit.

Procedure

The Principal Investigator (PI) will be informed by the application instructions when scientific review by the SRC will be required and will indicate that such a request is being made within the application material provided to the IRB.

Upon receipt of the material the IRB Regulatory Specialist will forward the material to the Chair of the SRC. The Chair of the SRC will in turn assign the reviewers from among the SRC membership, noting a date by which their review is due.

The Chair of the SRC will then send a summary of the findings of the SRC for each study evaluated directly to the IRB Regulatory Specialist by e-mail, or through upload to an electronic system, prior to the convened meeting date.[+]

The IRB Regulatory Specialist will distribute the results of the SRC review to the IRB members by e-mail or by notification to log into the electronic system prior to the meeting.

Based on the results of the scientific review the IRB may approve the study, require the investigator to make changes prior to approval and/or exercise the right to disapprove a study.

- If there are concerns related to the scientific merit of the study, the PI will be informed of the findings by the standard letter (e.g.. approved contingent letter, deferral letter) prepared by the IRB.

The PI will be required to respond in writing to the IRB to address those concerns identified and further review will occur as necessitated by the approval decision (e.g. by the Chair for contingent approvals, by the board for deferrals).

+review by the IRB may continue if for some reason the summary from the SRC is not received in time – however only contingent approval based upon a positive report from the SRC may be granted. If the report from the SRC recommends deferral of approval, the study is referred back to the convened board.

Related Policies

2011-009.5 – Review by Convened Board

Basis

45 CFR 46.111
21 CFR 56.111

Document Attributes:

Date Revised: 8/17/2017

Replaced Version: 5/6/2013

Reviewed and Approved By:

Richard H. Simon *17 August 2017*

Richard Simon, MD **Date**
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