Scientific Review Policy

Scope

This policy outlines the procedures all departments and divisions must observe when conducting required scientific review on New Research Application submissions. Reliance On another IRB, that involves gene or cellular therapy, or fetal interventions will also require scientific review. It also defines the criteria to be considered.

Policy Statements

All New Research Applications as well as Reliance On another IRB only involving gene or cellular therapy or fetal interventions that are submitted to the Institutional Review Board (IRB) must undergo scientific review at the department or division level, or by specialty review committee prior to IRB review.

Responsibility for scientific review rests with each department or division for all submissions or the specialty review committee, if the protocol is related to gene, cellular therapy or fetal interventions. Departments and divisions are responsible for developing their own mechanism for educating reviewers to assure appropriate scientific review and to follow the formal process that assesses and evaluates the scientific merit, complexity, and potential risks of each research protocol, before that protocol is submitted to the IRB for review. This review is carried out within the CHeRP (Children's Hospital Electronic Research Portal) system using the standardized workflow and forms provided. Scientific review is required for all New Research Application submissions and will be routed to the Principal Investigator's (PI) home department. If the PI is a nurse the scientific review will be routed to the Nursing Review Committee. Reliance on another IRB only requires scientific review by the Gene and Cellular Therapy Committee or Fetal Therapy Board if applicable and will be routed accordingly.

All IRB SmartForms must be completed and corresponding documents such as study protocol, Investigator's Brochure and patient-facing materials, must be uploaded in CHeRP before requesting scientific review.

Studies that are collaboration/jointly designed, sponsored designed/Initiated, or investigator designed/Initiated and peer-reviewed will undergo a limited scientific review with a focus on the overall appropriateness of study design and risk to participants. Studies that are investigator-designed/Initiated and not peer-reviewed will undergo a more comprehensive review with an additional focus on statistical considerations (see items marked with * below).

Version: 1
Date: September 12, 2024

All correspondence takes place within CHeRP using the functionality provided in the system. Documents requiring revision should be uploaded and checked prior to the scientific review approval.

The scientific review process provides the IRB with the information it needs to determine whether the criteria for approval of research are met. To ensure that scientific review occurs before the IRB submission the IRB protocol application cannot be submitted until scientific review and approval is documented as complete in CHeRP. The IRB reserves the right to review and comment on the scientific review process as it relates to human subjects' protection and the criteria for IRB approval. If the IRB identifies areas of significant scientific concern, these issues are referred to the Department Chair or Division Chief for reconsideration at the scientific review level.

Procedures

Documentation of Scientific Review Process

1. Each Department Chair/Division Chief designates a scientific review coordinator(s) and scientific reviewers and provides this information in writing to Clinical Research Operations (CRO) to make sure this is captured appropriately in CHeRP. Names of Department scientific review coordinators are then made available to investigators.
2. Department Chairs and Division Chiefs are required to update their scientific review coordinator(s) and reviewers annually, or ad hoc if changes need to be made.

Criteria for Scientific Review

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

1. Is the question sufficiently important to warrant doing the study?
2. Does the protocol summarize the published literature relevant to the primary aims of the study? *
3. Are there adequate preliminary data to support the study? *
4. Are inclusion and exclusion criteria clear and safe?
5. Is the study designed around a coherent hypothesis:
6. Is the study designed to provide results in the stated time frame?*
7. Is the study design appropriate and well-described?
8. Does the protocol design (inclusion/exclusion, data analysis plans) reflect the demographics (age, sex, race, ethnicity, SES) and epidemiology of the condition/disease under study? *
9. Are the research questions and outcomes relevant and meaningful to target populations considering diversity, inclusion and equity of the research subject population?
10. Does this study involve placebos?

11. Is the use of placebo (duration and type) appropriate for the study populations?
12. Was a statistician involved in the design or review of this study?*
13. Are the endpoints important and clear?*
14. Is the sample size calculation clear and appropriate?*
15. Is the data analysis plan adequate and appropriate for testing the main hypothesis (hypotheses)?*
16. If the study is an interventional clinical trial, are there specific and appropriate stopping rules articulated?*
17. Are the facilities available at BCH adequate to carry out the study as proposed?
18. Are the proposed consent/assent forms appropriate?

Elimination of Multiple Scientific Reviews

1. Scientific review is only required from one department or division. Studies that involve gene and cellular therapy or fetal interventions will require review by a specialized interdisciplinary committee. To avoid multiple scientific review processes, these studies will be removed from the departmental queue and only go through specialty review. If this occurs, it is to be indicated in the appropriate section of the protocol application.