



## Institutional Review Board Administrative Office Resources

### Policy

Boston Children's Hospital maintains an administrative office to oversee the Human Subject Protection Program, and to provide administrative support to the Institutional Review Board (IRB) and the Education and Quality Improvement Program for Human Subject Protection. The Director of Clinical Research Compliance reports to the Vice President of Research Administration. It is the responsibility of the Director of Clinical Research Compliance to identify the immediate and long-term resource requirements of the Human Research Protection Program, and to provide for them as appropriate.

### Purpose

The purpose of this policy is to describe the process for requesting and securing resources for the Institutional Review Board (IRB) Office.

### Procedure

The Director of Clinical Research Compliance is responsible for the preparation and maintenance of the IRB Administrative budget. In developing the budget, the Director is expected to comply with Hospital guidelines for budget preparation. Operational and capital budget requests are prepared on an annual basis for submission to the Vice President for Research Administration for review and approval. The budget is then processed through the appropriate institutional channels for review and approval.

### General and Capital Funds

The IRB Office maintains its own general funds budget.

The general funds budget is a component of the overall budget for Research Administration.

The Boston Children's Hospital budget year begins October 1.

Capital funding requests are a component of the capital fund allocation to Research Administration. On an annual basis, the Director of Clinical Research Compliance submits requests for capital funding to the Vice President of Research Administration.

On an annual basis, the Director of Clinical Research Compliance prepares and submits a proposed general fund budget to the Vice President of Research Administration.

In preparing both the general fund and capital budgets, the requirements of the IRB and the Education and Quality Improvement Program are considered. The IRB Chair and all staff are included in the budget planning process.

The proposed budgets are reviewed by the Vice President of Research Administration and submitted for approval. As necessary, requests for increases must be justified, and required

reductions are to be discussed prior to implementation. Funding for the IRB Administrative Budget is a component of the Hospital’s general and capital funds.

Should unanticipated funding requirements arise over the course of the budget year, the Director of Clinical Research Compliance prepares a request for additional funding for submission to the Vice President for Research Administration for consideration.

## Restricted Funds

Effective October 1999, corporate sponsors are charged an IRB administrative fee. The purpose of this fee is to assign financial responsibility to corporate sponsors for the IRB protocols they sponsor. These funds are used to develop and fund a human subject education and training program.

At the time a clinical trial agreement is negotiated and signed, this fee is included in the invoices sent to the sponsors. When received, these funds are placed in a separate restricted account for the sole use of the IRB Office. Fees for continuing approval may also be sent to sponsors.

## Related Content

None identified

## Document Attributes

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