

REB review of funded projects

Introduction

At the June 16, 2005 CRS meeting of research directors-the issue of REB review of funded (and non-funded) projects was discussed. Several attendees questioned why the REB is not reviewing projects without confirmed funding and it was agreed that the REB would review this issue, report back to Research Directors, and disseminate REB policy to the broader research community.

Background & rationale

The REB must be assured that studies have sufficient funds to complete the proposed research. To expose research subjects to potential harms and inconveniences of the research without secured funding and the prospect of project completion is unethical.

Beginning in January 2001, the NIH introduced a "just-in-time" procedure, i.e., the REB approval process does not have to take place until it is determined that funding is going to take place. NIH took this decision in response to the fact that fewer than half of all applications submitted to NIH are funded, and in order to reduce the burden on applicants and REBs. Further information on the NIH policy can be found at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-031.html>

Canadian granting agencies have similar procedures in place. CIHR, Heart & Stroke Foundation, CCF Foundation, Juvenile Diabetes Research Foundation, National Cancer Institute of Canada, and PSI all allow ethics approval to follow award announcements. Funds are released only following receipt of ethics approval from the REB.

REB review principles

A recent audit of the 184 clinical research grant applications submitted through SickKids in 2003 revealed that less than half were funded. (111 of them were rejected or withdrawn, 69 were approved, 4 were pending). The overall success rate was 37.5% including pending.

Consistent with the current requirements of major granting agencies, the REB has also adopted a "just-in-time" review process and only reviews those applications with confirmed funding. Due to present workloads, if the REB did not limit its review to successful grants and projects that are otherwise funded, a second REB (or second REB monthly meeting) would have to be established to review all submissions. Investigators would also have the additional responsibility for completing REB applications and preparing consent forms for projects without assurances of funding.

REB review & exceptions

In the event that applications are submitted to the REB for which funding has not been confirmed, office staff will followup with investigators to confirm whether alternate funding sources are available, should their grant be unsuccessful. Other circumstances eg., a pilot study is planned, unique requirements of granting agency, will also be explored with the investigator and a decision reached regarding whether REB review should go forward.