# IRB Review of Federally Funded Grant Applications

Effective: October 5, 2005
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Contact: Office for Responsible Research

## Introduction

The purpose of this policy is to provide clarification regarding Institutional Review Board (IRB) review of federally funded research projects.

## Policy Statement

Health and Human Services (HHS) regulations at 45 CFR 46.103(f) require institutional certification-when research is supported by a federal department or agency-that the proposed research has been reviewed and approved by the IRB. In order to be in compliance with the regulations, investigators must submit copies of the federal grant proposal with the application for IRB approval.

IRB review of the two documents will consist of a side-by-side comparison of the application for IRB approval to the federal grant application. If discrepancies are found between the two documents, the investigator must provide clarification. This clarification may consist of:

- Reconciling the information in the application to match the grant;
- Confirmation of what the actual research plan involves (e.g., confirm the portions of the grant application that are correct, provide an explanation for additional items included in the IRB application, confirm that procedures listed in the grant application have been removed from the research plan or will be conducted at a later date, etc.).

This approach is based upon the guiding principal that the IRB is responsible for the protection of the human subjects and that by clarifying any discrepancies, the IRB will know what is being approved in both documents. This form of review also allows the flexibility necessary to accommodate changes 1) in the federal grant proposal due to budget reductions, 2) in the scope of the project, or 3) for which the investigator has obtained their program officer's approval, etc.

### Approval of Scope Changes

Any changes in scope may require funding agency approval. Principal Investigators (PIs) are responsible for requesting from the Office of Sponsored Programs Administration (OSPA) a determination as to whether such approval is required.

## Resources

### Links

- Institutional Review Board
- Institutional Review Board Information and Forms
- Office for Responsible Research
- 45 CFR 46 Protection of Human Subjects
- Office for Human Research Protections Common Compliance Oversight Findings