

## Chapter 22

# IRB CERTIFICATION FOR SPONSORED RESEARCH TO EXTERNAL FUNDING AGENCIES

The Institutional Review Board is not directly involved in the grants/contract mechanism; however, institutional approval of "sponsored" research is coordinated between the IRB and the Sponsored Projects Office (SPO) in a "checks and balance" system. The Board is responsible for reviewing all research activities involving human subjects irrespective of the source of funding. Therefore, it is critical that an investigator who plans to submit a proposal to an external funding agency be familiar with the agency's and the hospital/university policies regarding the certification of IRB review and approval.

### **A. Overview of Funding Agencies' Human Subject Certification Requirements**

Most funding agencies (e.g., The National Institutes of Health, Robert Wood Johnson Foundation, etc.) require that research projects involving human subjects be reviewed by an Institutional Review Board prior to the submission of a grant/contract proposal. Formal certification that a research proposal has received the appropriate IRB approval must be sent to the agency.

The certification requirements vary from agency to agency. For example, some agencies have a special form or "item" on the application which must be completed by the applicant and signed by the Authorized Institutional Official. Other agencies accept the Institutional Review Board (IRB) approval letter which is signed by the IRB chairperson.

Agencies also differ with respect to their flexibility in accepting certification notices after the proposal has been received. For example, when submitting an application to The National Institutes of Health (NIH), it is critical that certification of approval be transmitted to the agency as soon as possible after the submission of the grant application. The grant application will not be reviewed if the certification document is not submitted before the Study Sections are convened. Other agencies may not require that certification be sent until the final decision with respect to funding status has been made. On the other hand, some agencies will not accept an application unless IRB certification is included. Questions regarding agency IRB certification policies should be directed either to the individual agencies or to the Grants Administration staff.

### **B. Initial Certification of Review**

1. Whenever possible, the research project should be submitted to the IRB prior to submission of the grant/contract application to the agency. The investigator is responsible for submitting the proposal for IRB review in a timely fashion.
2. If, due to the time constraints of the investigator, the research proposal has not been submitted to or reviewed by the IRB at the date of submission of the grant application to the agency, then the investigator is responsible for submitting the proposal to the IRB as soon as possible.
3. After final IRB approval has been obtained, the IRB office will obtain the authorizing official's signature and submit the appropriate certification to the agency in a timely

fashion. Verification of submission will be forwarded to the PI by the Sponsored Projects Office

### **C. Resubmission of Previously Rejected Grant Applications to Funding Agencies**

1. In the event that a research project previously approved by the IRB is resubmitted to an external funding agency, the investigator is responsible for contacting the RESEARCH AND GRANTS ADMINISTRATION... Office to determine the current IRB status of the proposal before the grant application is submitted to the agency.
2. IF IRB approval has not been obtained within the 12-month period preceding the agency's submission deadline, submission of a new application to the IRB is necessary. A new certification document cannot be issued until the IRB has reviewed the study in accordance with the regular review procedures.
3. If IRB approval has been obtained in the 12 months preceding the agency submission deadline, a new IRB application need not be submitted to the IRB, **provided no changes have been made in the research activities which affect the human research subjects.** The investigator is responsible for submitting: a) a letter to the IRB indicating that the revised application does not include modifications regarding the human subjects' participation; b) a revised GENERAL INFORMATION SHEET, if appropriate. The investigator must request that the Research Subjects Office prepare the certification document, as specified by the funding agency.
4. If the revised grant application includes changes which affect the human subjects, submission of a new application to the IRB is not necessary provided the previously reviewed study had received IRB approval in the 12 months preceding the agency deadline. The investigator is required, however, to submit to the IRB the following: a) a revised GENERAL INFORMATION SHEET; b) a description of the proposed changes; c) revised consent and/or assent form; d) a revised copy of the grant application. Instructions for submitting a request for approval of modifications may be obtained from the Sponsored Projects Office.

After the proposed modifications have been approved by the IRB, the investigator should contact the Sponsored Projects Office, requesting that the certification document be prepared.

### **D. Rejected Grant Proposals: No Plans for Resubmission or Implementation of Research**

If the grant proposal is rejected and if the investigator does not intend to resubmit the research project, the investigator should notify the Office of Research and Grants Administration so that the file may be closed.

### **E. Externally Funded Projects: Annual Recertification Procedures**

Most funding agencies require that funded research projects involving human subjects receive a Continuation Review by the IRB at least once every 12 months. The agencies also require that an updated certification document be submitted at specified intervals. The Sponsored Projects Office cannot

provide an updated certification document unless the project has been reviewed and approved in accordance with the Institution's Continuation Review procedures.

The investigator is responsible for completing, at specified intervals, a Continuation Review report form. A complete description of the IRB's Continuation review procedures may be obtained from the Office of Research and Grants Administration.

Once IRB approval of the Continuation review report has been obtained, the investigator should contact the Office of Research and Grants Administration, requesting that their certification document be prepared. The IRB office will submit recertification to the agency and verify this notification to the PI. Copies of all certifications will be kept on file in the Office of Research and Grants Administration.