



HSRB POLICY AND PROCEDURE STATEMENT

Policy/Procedure: Review of Conditionally Approved Projects

Policy/Procedure ID: 02-08-001 **Effective:** August 7, 2002

Frequently the initial review of HSRB projects, addenda, and annual renewals identifies conditions that the researcher must address in order to obtain final approval.

The Chair of the Board may designate responses to certain conditions to be approved in an administrative manner by the Administrator of the Board. These conditions are as follows:

- Inclusion of/change to contact information (investigator and HSRB)
- Inclusion of/change to specifically identified information or text (e.g., change “I understand...” to “I have been informed that...” addition of project title to consent document)
- Corrections to typographical and spelling errors on consent documents
- Printing of consent documents on BGSU (or other appropriate) letterhead
- Verification of documentation of approval by external organizations such as school districts, other IRBs, business organizations

Responses to other conditions for final approval require review by the Chair or designated member(s). These conditions include but are not limited to:

- Revision of consent documents to reflect appropriate reading level
- Clarification or justifications requested by reviewers
- Inclusion of/change to elements of consent for which assessment of appropriateness of wording or presentation to participants is required

When responses to conditions for approval are received in the Office of Research Compliance, the Administrator will review the responses and note on the review checklist those that can be approved administratively, and those requiring Board member review. The Administrator will review any responses for which administrative approval is appropriate and note the outcome on the review sheet. If there are responses that require Board member approval, the project file will be placed into the Responses to Conditional Approval folder to await Board member review. The Board member(s) reviewing the responses will note the outcome of the review(s) on the review sheet. The Office of Research Compliance will notify the investigator regarding the results of the review.