



Human Subjects

Office of Research

UNIVERSITY OF GEORGIA

IRB Review of Modifications Required for Approval



Human Subjects

Office of Research

UNIVERSITY OF GEORGIA

Approval of Research with Conditions

IRBs often request that investigators (a) make specified changes to the research protocols or informed consent documents; or (b) submit clarifications or additional documents. When doing this, depending on the circumstances, the IRB is either:

- precluded from approving the research or
- permitted to approve the research with conditions

The IRB may require the following as conditions of approval of research:

- Confirmation of specific assumptions or understandings on the part of the IRB regarding how the research will be conducted (e.g., confirmation that the research excludes children);
- Submission of additional documentation (e.g., certificate of ethics training);
- Precise language changes to protocol or informed consent documents; or
- Substantive changes to protocol or informed consent documents along with clearly stated parameters that the changes must satisfy.

[Approval of Research with Conditions: OHRP Guidance \(2010\)](#)

Extra Changes?

How should the IRB handle changes to research that are proposed after the IRB has approved the research with conditions?

1. Administrative protocol changes like typo corrections do not need additional review
2. Minor changes can be reviewed via Expedited procedure AFTER final approval is granted (e.g., conditions are verified as satisfied.)
3. **Changes to the research that are more than minor would require further review by the IRB at a convened meeting.**

- Select reviewer of modifications/responses carefully
- Timeliness of responses compared to IRB meeting schedule may impact route of review
- State required modifications clearly and be as prescriptive as possible OR
- Describe parameters for acceptable responses