Modifications to Exempt Research

The purpose of this document is to provide guidance on when researchers must seek IRB staff review prior to implementing proposed modifications to research granted "exempt" status. Exempt status is granted for research that is very low risk and where all the procedures are in specific exemption categories defined by federal regulations. Changes in research procedures, participant characteristics, the content or scope of information to be collected, confidentiality plans, etc. may result in loss of exempt status. Accordingly, IRB staff review of modifications focuses on verifying that the project continues to be eligible for exempt status.

Exempt research is subject to fewer regulatory requirements than non-exempt research. To provide flexibility to ISU researchers, the ISU IRB allows some changes (i.e., those that clearly should not alter the exempt status of the research) to be implemented without prior IRB staff review.

For student-led projects: Student PI’s must consult with their supervising investigator (i.e., the individual who is formally named as supervisor on the IRB application) and obtain concurrence about whether or not prior IRB staff review is needed before implementing any changes to exempt research.

When is IRB review required for modifications to exempt research?

Researchers must request a determination by IRB staff regarding exempt status if the modifications include any of the following:

- New inclusion of participants from a vulnerable population (e.g., children, prisoners, pregnant women, cognitively impaired persons, persons who are institutionalized, etc.);
- A change in study procedures or methods of data collection, including but not limited to
  - substantive changes to the sensitivity level, nature, or scope of data to be collected; when assessing sensitivity level, researchers must consider factors such as:
    1. Whether the information collected could, if accidentally disclosed, reasonably present ANY risk of harm to participants’ reputation, employment situation, financial standing, student standing, familial relationships, or of criminal or civil liability; AND
    2. Whether the information may reasonably present any psychological or emotional discomfort for participants, be embarrassing, stigmatizing, etc.
  - changes in privacy, confidentiality, or data security protections, or how identifiers will be collected or recorded (e.g., using less secure data storage devices, adding plans to collect identifying information, moving interviews to less private locations, new plans to video record or photograph people, etc.);
  - the addition of any physical interventions;
  - the addition of usability testing procedures;
  - any changes that may reasonably increase the risk or discomfort to the participants.
- Any change such that the revised procedures are not all included in the exemption categories defined by federal regulations. Note: The specific category or categories for which the research was granted exemption can be found in the approval letter provided when the study was last reviewed.
The following are examples of modifications that will not alter the exempt status of the research and can be made without review by IRB staff:

- Removing or rearranging questions on surveys, interviews, focus group protocols, etc.
- Rereviewing of questions on surveys, interviews, or focus group protocols for clarity or readability, provided the substantive content or sensitivity level of the question does not change. For example, changing "How frequently do you consume bread?" to "How often do you eat bread?" does not change the content. Changing "How frequently do you consume bread?" to "How frequently do you consume alcohol?" is a revision that would require review because the substantive content and sensitivity level of the question has changed.
- Adding questions that are very similar in content, scope, nature, and sensitivity level to those described in the previously-exempted protocol. When assessing sensitivity level, researchers must consider factors such as:
  1. Whether the information collected could, if accidentally disclosed, reasonably present ANY risk of harm to participants’ reputation, employment situation, financial standing, student standing, familial relationships, or of criminal or civil liability; AND
  2. Whether the information or process of collecting the information may reasonably present any psychological or emotional discomfort for participants, be embarrassing, stigmatizing, etc.
- Changes in course assignments that are being collected for analysis for a research study, provided that the assignment is being administered for educational purposes and not solely as part of the research protocol.
- Changes in the format of compensation (i.e., from a gift card to cash), provided the amount of compensation remains the same. Or, minor changes in the amount of compensation, provided the change does not raise concerns with undue influence.

How to seek approval of modifications to exempt research.

Researchers who plan to modify the study and believe it may still be exempt, may amend the IRB application in IRBManager. IRB staff will review the proposed changes to determine whether exempt status is still appropriate. You will receive a response indicating either 1) that your study is still exempt and you may proceed without further review, or 2) that your study is no longer exempt and additional information is needed.

Approval for changes in personnel.

ISU policy requires that all personnel involved with a project be listed as key personnel on the corresponding IRB protocol and that completion of human subjects training is verified by IRB staff before those individuals are involved with any project-related human subjects research activities. **Therefore, researchers must seek prior approval of all personnel changes—even to exempt research.**

Approval for personnel changes may be sought by amending the IRB application in IRBManager.

What if project is no longer eligible for exempt review?

If the project will be modified such that it no longer qualifies for exempt review, additional information must be provided in the IRB Application in IRBManager. The form will prompt responses to relevant sections.

Document History

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