Modifications to Exempt Research

Background

The purpose of this document is to provide guidance on when researchers must seek IRB 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, privacy or confidentiality measures, etc. may result in loss of exempt status. Accordingly, IRB 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 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 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 from the IRB regarding exempt status if the modifications include any of the following:

- Any change such that the revised procedures are not **all** included in one or more of the exemption categories defined by federal regulations. Note: For reference, the specific category or categories for which a specific study was granted exemption can be found in the approval letter provided when the study was last reviewed.

- New inclusion of participants from a vulnerable population (e.g., children; prisoners; cognitively impaired persons; persons who are institutionalized; persons in a subordinate role to the researcher(s), such as students in courses they teach, research assistants, or employees; and/or other persons who are vulnerable to coercion or undue influence given the specific context of the study);

- **All changes in study 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 the IRB before those individuals are involved with any project-related human subjects research activities.

- 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 or its collection may reasonably present any psychological or emotional discomfort for participants, be embarrassing, stigmatizing, etc.;
    - substantive changes that may adversely affect:
        1. students' opportunity to learn required educational content; or
        2. the assessment of educators who provide instruction;
    - the addition of any physical interventions;
    - new addition of or substantive changes to behavioral interventions (e.g., duration, potential for discomfort or embarrassment, etc.);
    - the addition of or change in use of deception or incomplete disclosure (where information about the purpose or nature of the research is intentionally withheld from participants);
    - any changes that may reasonably increase the risk or discomfort to the participants;
    - any change in method of "recording" or "capturing" participant responses such that the method is no longer limited to verbal or written responses or audiovisual recording (e.g., adding physiological measures);
- Removing plans to inform potential participants about the study prior to their enrollment
    - For exempt research involving deception or incomplete disclosure, potential participants MUST be informed that they will be unaware of or misled about the nature or purpose of the research prior to their enrollment in the study. This is called "authorized deception." Any changes to these plans require prior IRB approval. Removing a process for authorized deception means the research will no longer be eligible for exemption.
- ANY direct or indirect changes in privacy, confidentiality, or data security protections, including but not limited to:
    - changes in how or whether direct or indirect identifiers will be collected or recorded;
    - moving data collection activities to less private locations;
    - changing from individual interviews to focus groups (focus groups are inherently less confidential);
    - the addition of plans to video record or photograph people, or collect biometric identifiers;
    - changes that result in deductive disclosure risk or otherwise compromise confidentiality (e.g., sharing individual responses or raw data with persons familiar with the participants or study setting, public data sharing, choosing to identify the specific research site when sharing results, etc.).

IMPORTANT: Seemingly unrelated changes can alter privacy, confidentiality, or data security protections, and thus require IRB review. For example:

- adding plans to collect data using Amazon Mechanical Turk (or a similar online venue) typically involves automatic recording of an identifier (e.g., WorkerID) resulting in a process that is no longer anonymous;[1]
- adding compensation plans often necessitates collection of some type of identifier to track participation;
- altering recruitment plans can raise privacy issues—for example,
    - recruitment via social media posts that allow tagging or sharing is much less private than recruitment via personal email or direct messaging;
    - indirect recruitment (via posted flyers or ads) typically provides greater privacy than direct contact methods;
- altering survey questions to collect more detailed demographic information can raise concerns about deductive disclosure;
- changing survey administration plans (e.g., from paper to online, from one online platform to another, etc.) can alter how identifiers are collected or raise other confidentiality issues;
- changing the source of participants can raise privacy or confidentiality concerns if the new source is a small or known group (e.g., a specific workplace or organization, a small school district, etc.).

The following are examples of modifications that will not alter the exempt status of the research and can be made without IRB review:

- Removing or rearranging questions on surveys, interviews, focus group protocols, etc.
- Rewording 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 survey or interview 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 to behavioral interventions where the resulting intervention is very similar in nature, duration, and potential for harm, embarrassment, or discomfort to the intervention(s) described in the previously-exempted protocol.

[1] See IRB Guidance Mechanical Turk (MTurk) for more information.

- 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.

What if a 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.

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