Exempt Review

I. Purpose

To define policies and procedures for review of human research that is exempt from the requirements set forth in 45 CFR 46 and 21 CFR 56.

II. Revisions from Previous Version

None.

III. Definitions

Minimal Risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or test.

IV. Policy

Research projects that meet the categories set forth by the federal regulations (45 CFR 46.104(d)and 21 CFR 56.104(d)) may qualify for exemption. The determination that human research is exempt must be made by the Institutional Review Board (IRB), not by an individual investigator or any other party or office. Research activities determined to be exempt are exempt from some of the requirements of the human research protection regulations when the only involvement of the participants falls within one or more of the exempt categories, the research is not regulated by the Food and Drug Administration (FDA) and does not include incarcerated individuals, unless the research is aimed at involving a broader participant population that only incidentally includes prisoners. For FDA regulated research, the only research that can be exempt is taste and food quality evaluations and consumer acceptance studies that meet the criteria at 21 CFR 56.104(d).

The research must also meet the following ethical criteria, even if it falls into one or more exemption categories:

1. The research presents no more than minimal risk to participants.
2. The risks to participants are minimized and reasonable in relation to anticipated benefits.
3. The selection of participants is equitable.
4. If the research involves interaction with participants:
    a. If appropriate, informed consent will be sought from the participants and documented;
    b. The circumstances of informed consent minimize coercion and undue influence;
    c. The participants will be informed that the activity involves research, a description of procedures, that participation is voluntary, and whom to call with questions; and
    d. The provisions for protecting the privacy interests of participants are adequate.
5. If private identifiable data are recorded, the provisions for maintaining the confidentiality of data are adequate.

Changes to exempt research (amendments) that may alter the exemption status, increase participant risk, or trigger additional IRB policy requirements (for example, requirements related to participant recruitment or informed consent) require review prior to implementation.

V. Procedure

Submission and Screening

1. After having completed the Intake in WRG, the Principal Investigator (PI) will submit a complete submission (initial application and other project documents) to the IRB via WRG-HS. Instructions for preparing the application are available on the IRB website. The researcher may contact the IRB office with questions.
2. The IRB staff will make an initial assessment to determine whether the project is minimal risk and direct the submission to the appropriate review process.
3. Upon receipt of the submission, the IRB staff will conduct pre-review activities as described in the Staff Processing of Submissions SOP. The IRB staff will make a preliminary determination regarding whether the project meets the criteria for exempt or limited IRB review, including minimal risk, and identify the exempt category(ies). If the application does not meet the criteria for exempt, limited IRB, or expedited review, the IRB staff will assign the project for full board review according to the Initial Full Review SOP.
4. Limited reviews will be conducted using the Expedited review process (See the Initial Expedited Review SOP).

Assigning Reviewers

1. All reviewers undergo initial training prior to conducting exempt reviews.
2. Experienced IRB staff conduct exempt reviews. If the staff reviewer determines that a non-staff IRB member reviewer is needed, the submission will be assigned to a non-staff member for review. The reviewer will notify IRB staff if they are unavailable to conduct a review during the assigned time period or has a conflict of interest.
3. The IRB staff will document who served as reviewer in WRG-HS. Reviewer assignments will not be made known to the PI or research team.

IRB Exempt Review

1. Reviewers have access to all documents submitted by the researcher.
2. The reviewer will document protocol specific findings (e.g. exemption category, requirement for informed consent) by completing the Reviewer Checklist(s).
3. The reviewer is responsible for reviewing the application in enough depth to confirm the research is minimal risk and determine that all of the research procedures fit one or more of the exemption categories as specified in the regulations. The reviewer will ensure that the research meets ethical principles and standards for protecting research participants.
4. During review, the reviewer will ensure that the research does not include any of the following:
    - Prisoners, unless the research is aimed at involving a broader participant population that only incidentally includes prisoners;
    - Survey or interview techniques which include children as participants (except for educational tests as described in 45 CFR 46.104(d)(1));
    - The observation of children where the researcher participates in the activities being observed (exemption category 2(i) and (ii) only);
    - FDA-regulated research other than activities described in 56.104(d).
5. If a non-staff reviewer is unable to respond within a week, the IRB staff may forward the protocol to another reviewer.

Review Outcome(s)

1. The reviewer will make one of the following recommendations by completing the Reviewer Checklist, if possible, no later than 5 business days from receipt:
    - Required modifications are needed to qualify the project for exempt status;
    - Recommend that the project qualifies for expedited review or requires review by the fully convened IRB (if the latter, the reviewer must provide a rationale for this determination);
    - Exempt (general comments or suggestions may be included but not required for approval).
2. When conducting limited IRB review, the reviewer cannot disapprove the project; instead, the reviewer will defer the project for review by the fully convened IRB.
3. The reviewer may also recommend that the activities do not fall under IRB purview (i.e. not human subjects research as defined by federal regulations). In these cases, the reviewer will indicate this on the Reviewer

Checklist and the IRB staff will send a determination letter to the PI outlining that IRB approval is not required.

4. Continuing review is not required for any project that receives an exempt determination.
5. The PI is responsible for submitting any requested modifications to the IRB. The reviewer will determine whether the modifications are sufficient to maintain determination of exempt status, and, if so, the IRB staff will send a determination letter to the PI.
6. If the reviewer determines the modifications are inappropriate or insufficient, they may request that the PI make further modifications. This review and modification process continues until there is a resolution. The reviewer may also determine the project no longer meets the criteria for an exempt determination as a result of the requested modification(s), and recommends expedited or convened board review.
7. IRB records and letters for all exempt determinations will include the citation of the specific category for the exemption.

VI. References

21 CFR 56.104(d)
45 CFR 46.104
45 CFR 46.102(j)
45 CFR 160 and 164, subparts A and E