OBJECTIVE

To describe the policies and procedures for the exempt review process.

GENERAL DESCRIPTION

Research procedures that meet the categories set forth by the federal regulations [45 CFR 46.101(b)] may qualify for exemption. The Office of Research Integrity (ORI) reviews and approves all exemptions claimed for research conducted at the James Madison University (JMU). Research activities are exempt from the human research protection regulations when the only involvement of human subjects falls within one or more categories. The categories are as follows:

1. Research conducted in established or commonly accepted educational settings, involving normal education practices, such as:
   - Research on regular or special educational instructional strategies, **or**
   - Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
   - Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; **and**
   - Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability; **or**
   - Be damaging to the subjects' financial standing, employability, or reputation.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under category 2 of this section, if:
   - The human subjects are elected or appointed public officials or candidates for public office; **or**
   - Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
   - Public benefit or service programs;
   - Procedures for obtaining benefits or services under those programs;
   - Possible changes in or alternatives to those programs or procedures; or
   - Possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies:
   - If wholesome foods without additives are consumed; **or**
   - If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

The ORI reviews research in categories that are exempt from the federal human research requirements to determine whether an exemption is appropriate.

RESPONSIBILITY

Execution of SOP: IRB Members, ORI Staff, and Principal Investigator (PI)/Study Personnel

PROCEDURES

Submission and Screening

1. The PI submits a completed Review Application Form to the ORI. Instructions for preparing the application are available on the ORI website. The investigator may call or email the ORI with questions.

2. Upon receipt of the application, designated ORI staff screen the protocol including the informed consent process and documentation for completeness and accuracy. If it is clear to the designated ORI staff the application does not meet the criteria for exempt review, the designated ORI staff will inform the PI and advisor, if applicable, their application will be processed for either expedited or full review. The ORI makes the final determination regarding whether a protocol is eligible for exemption.

3. Based on the screening, ORI staff will contact the PI and advisor, if applicable, for any additional information needed for a thorough review.

4. ORI staff will enter the application into the ORI spreadsheet for tracking purposes, assign a number, and, for reporting purposes, place it on the next full board meeting convened meeting agenda.

5. After screening the application, ORI staff retain the original application in the ORI file and posts it electronically to the secure website accessible only to the IRB and other authorized users.

IRB Exempt Review

1. ORI staff receives the following:
    - Completed review application;
    - Verification of IRB training "Social/Behavioral Research Course, Basic Course" through CITI Program;
    - Data collection instruments (if applicable);
    - Consent form or requests for waiver of informed consent or a waiver of documentation of informed consent;
    - Any additional information ORI staff may have requested from the PI.

2. ORI staff is responsible for reviewing the application upon receipt to determine that all of the research procedures fit one or more of the exemption categories specified in the federal regulations. The ORI staff ensures that the research meets ethical principles and standards for protecting research subjects.

3. During review, ORI staff ensures that the research does not include any of the following:
    - Prisoners;
    - Survey or interview techniques which include children as subjects (this applies to exemption category #2 only); or
    - The observation of children where the investigator participates in the activities being observed (this applies to exemption category #2 only).

4. ORI staff contacts the PI and advisor, if applicable, for any clarification needed.

Review Outcome(s)

1. ORI staff makes one of the following recommendations:
    - Additional information needed to determine exempt status;
    - Required revisions needed to qualify study for exemption;
    - Disapproved of exempt status with rationale for disapproval and recommendations for submission of expedited or full review application;
    - Approved (general comments or suggestions may be included but not required for approval).

2. ORI staff can also recommend that the activities do not fall under IRB purview. In these cases the IRB handles the review using procedures outlined in SOP # 1: Determination of Activities That Need IRB Review.

3. ORI staff will forward the recommendation in writing via email to the PI and the advisor, if applicable.

4. The PI is responsible for submitting any requested revisions to the ORI. The ORI staff determines whether the revisions are sufficient for approval of exempt status, and, if so, will send an approval email and exempt notice memo to the PI and advisor, if applicable.

5. If ORI staff determines the revisions are inappropriate or insufficient, they may request that the PI make further revisions or process for an expedited review.

6. IRB records for all exempt determinations include the citation of the specific category justifying the exemption.

7. When the IRB has certified a research study as exempt, the IRB does not require continuation reviews.

8. If the PI and advisor, if applicable, have concerns regarding the IRB decision/ recommendations for changes in the study, they may submit the concerns to the IRB in writing, including a justification for changing the IRB decision. The PI may send the request to ORI and/or the IRB Chair for final resolution. If the investigator is still dissatisfied with IRB decision, they may send the study to the full IRB for review.

REVISION HISTORY

Version No.	Brief Description of Changes	Created on Date
00	Creation of SOP	7/20/2015
01	Addition of requiring IRB training	9/28/2022
02	Removed “Research being published or publicly presented outside of the classroom” as exclusion criteria in order to be in line with policy # 1104.	10/18/2022

SIGNATURE HISTORY

Name and Title	Signature	Date

REFERENCES

45 CFR 46.101(b)