

Michigan State University Human Research Protection Program	
<i>Subject: Exemptions</i>	
<i>Section: 8-1</i>	<i>This policy and procedure supersedes those previously drafted.</i>
<i>Reviewed by: IRB, URC, UGC, Legal Counsel; Revision reviewed by HRP/IRB Administrative Committee</i>	<i>Approved by: Vice President of Research and Graduate Studies, 4-21-2005; Revision approved by the Vice President of Research and Graduate Studies on 11-2- 2005</i>
<i>Related Sections: 5-5, 6-9-B, 8-10, 9-2, Appendix 14-14</i>	

Summary

This policy and procedure is substantially revised. Institutional Review Board (IRB) staff will make a determination of Exempt status within 3-5 business days after evaluating the investigator's application against a detailed checklist. The investigator is responsible for knowing and adhering to the ethical principles of human subject research. The IRB chair or members are involved in the evaluation and determination in specific limited instances, e.g., if the staff denies Exempt status, when requested by staff. The investigator is responsible for informing the IRB immediately of any adverse or unexpected events that would alter the Exempt status, and when the research is completed.

I. Policy

Michigan State University (MSU) has a long history of requiring research involving human subjects conducted by MSU employees to be subject to review in order to protect subjects. This practice included projects that could be classified as Exempt from Institutional Review Board review under federal regulations (45 CFR 46.101(b) and 21 CFR 56.104). In the past, these Exempt projects underwent a review by the MSU Institutional Review Board similar to projects determined to fall within the Expedited category of review and were subject to the same continuing review requirements. At this time this policy is being revised to differentiate review requirements between Exempt and non-Exempt research.

This policy is now revised to reduce the initial and continuing review requirements, to identify who determines Exempt status, and to describe the criteria for Exempt status and protection of participants in Exempt research.

1.1. Continuing Review, Reporting Requirements, and Expiration of Exempt Status:

A research project that is determined by the IRB staff to meet the criteria for Exempt status is exempt from initial and annual continuing review by the IRB committee members. The investigator, however, is required to report to the IRB any expected revisions in the research activity that will cause the research to change from Exempt to Expedited or Full Review status. The investigator is also required to report to the IRB any unexpected or adverse events that occur or new information obtained that may

cause the research activity to change from Exempt to Expedited or Full Review status. When the research project is completed, the investigator is required to notify the IRB. The Exempt status expires when the research project is completed (closed) or when the review category changes as described above.

1.2. Determination of Exempt Status

The investigator may not make the determination of Exempt status. This is in compliance with the Terms of the Federal Wide Assurance that requires written procedures for “*Verifying, by a qualified person or persons other than the investigator or research team, whether proposed human subject research activities qualify for exemption from the requirements of the Common Rule.*” The investigator may submit an application to the IRB office requesting Exempt status. The application process follows the same procedures as for other Initial applications and must be submitted by the Responsible Investigator (MSU faculty member with the rank of assistant professor or higher, or researcher that has a formal written agreement with MSU). See Section 6-9-B “Graduate Student Research” of the HRP Manual for details regarding graduate student research.

The IRB staff will review the application and make the determination, consulting with the chair of the IRB, or the chair’s designate (IRB or Privacy Board member), as appropriate. The determination requires that the research activity meets the criteria for Exempt status and meets the criteria for protection of research participants in Exempt research.

The IRB staff will then issue a letter of Exempt designation to the investigator.

For projects approved prior to this policy’s effective date the IRB staff will determine the project’s Exempt status either at the time of annual renewal of the original research protocol, or by special request of the investigator before the annual renewal date.

1.3. Criteria for Exempt Status:

The criteria for Exempt status follow all applicable federal regulations including: 45 CFR 46.101(b)(1) through (6), 45 CFR 46.301(a), 45 CFR 46.306(a) and (b), 45 CFR 46.401(b) and 21 CFR 56.104. The criteria are applied to all research regardless of funding or funding source.

These regulations identify specific categories of Exempt research activities and also identify when there are exceptions. For research under this MSU policy, if a specific research activity meets the exemption criteria for one applicable regulation but not another, the research activity will not be given the Exempt status but will be processed under procedures for Expedited or Full Review.

To be classified as Exempt, the research:

1. Must involve only procedures or be a type of study listed in one or more of the Exempt Categories (sections 3.1 and 3.2);
2. Cannot involve any of the Exceptions for the Exempt Categories (section 4.1 - children being surveyed, interviewed or interactively publicly observed);
3. Cannot involve prisoners as research subjects (section 4.2); and
4. Cannot be greater than minimal risk.

“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 tests.” 45 CFR 46.102(i)

1.4. Criteria for Protection of Human Subjects in Exempt Research:

Research that is determined to be Exempt from IRB review is not Exempt from protection of the human subjects. The following criteria to protect human subjects must be met:

1. The investigator assures that all investigators and co-investigators are trained in the ethical principles, relevant Federal Regulations and institutional policies governing human subject research;
2. The investigator assures that human subjects will voluntarily consent to participate in the research when appropriate (e.g. surveys, interviews) and will provide subjects with pertinent information, e.g. risks and benefits, contact information for investigators and IRB chair, etc.;
3. The investigator assures that human subjects will be selected equitably, so that the risks and benefits of the research are justly distributed.
4. The investigator assures that the IRB will be immediately informed of any information, unexpected or adverse events that would increase the risk to the human subjects and cause the category of review to be upgraded to Expedited or Full Review;
5. The investigator assures that the IRB will be immediately informed of any complaints from participants regarding their risks and benefits; and
6. The investigator assures that confidentiality and privacy of the subjects and the research data will be maintained appropriately to ensure minimal risk to subjects.

These criteria are specified on the signature page of the application. The Responsible Investigator’s signature acknowledges that he/she understands and accepts these conditions. Investigators can refer to the MSU website, www.humanresearch.msu.edu , for specific information on training, voluntary informed consent, privacy, and how to notify the IRB of adverse or unexpected events.

1.5 Audit of Exempt Research

The IRB maintains the authority to audit research determined to be Exempt (see Section 8-10, “Project Audits”, in the HRP Manual for audit policies and procedures). If the audit reveals that the research activities differ from the application to the IRB for Exempt Status (e.g., conducting non-approved research that meets the criteria for

Expedited or Full Review status), if investigators are not fulfilling the agreed upon assurances for participant protection, the research will be considered in Noncompliance. See Section 9-2, “Noncompliance”, of the HRP Manual for policies and procedures. Investigators should retain records for audit following MSU guidelines, see Appendix 14-14, “Michigan State University Guidelines on Research Data: Management, Control and Access” of the HRP Manual.

2. Procedure

2.1 Initial Applications

The investigator must submit an Initial Application to the IRB including instruments, surveys, data abstraction sheet, etc. If the investigator selects the Exempt category on the application, he/she must also submit the signature page acknowledging they read and accepted the responsibility to protect research participants.

IRB staff will review the application and determine if the research meets the criteria for Exempt research and meets the criteria that participants are protected. The determinations are documented using an Exempt worksheet. If the staff cannot make the determination the IRB chair, or chair’s designee (IRB or Privacy Board member) will make the determination whether the research meets the criteria after evaluating the application and completing the Exempt worksheet. The completed worksheet will reference all categories under which the exemption is granted.

The completed worksheet is placed in the file and the protocol will be processed based on the category of review.

Determination - Exempt

If the project is determined to meet the criteria for Exempt Status and if the signature page has been received, the IRB staff will send an Exempt Designation Letter to the investigator. If the signature page has not been received, the investigator will be prompted.

Determination - Not Exempt (Expedited or Full)

If the IRB staff determines that the project does not to meet the criteria for Exempt Status, the IRB chair (or designate) reviews and signs the worksheet. The IRB staff will send an email to the investigator informing him/her of the determination. The email will include an explanation of why the project did not meet the Exempt criteria. The IRB staff will assign the appropriate category to the application, request additional information as needed and initiate the relevant IRB review process, e.g., assign the protocol to reviewers.

Timeframe

Processing of applications for Exempt Status is estimated to take 3 - 5 working days. Processing time may increase if the application is incomplete, unclear or lacks all necessary attachments (e.g. signed cover sheet, consent process information – forms or information sheets, surveys, etc).

2.2 Exempt Projects Approved Prior to Policy's Effective Date

Exempt projects with current approval have two options:

1. Investigator Request at any time prior to expiration of current approval, or
2. Annual Renewal

Investigator Request

The investigator should complete and submit a signed Exempt Assurance Form to the IRB office and request the extended expiration period for Exempt Status. The review process will be the same as that described in the Initial application section.

Renewals

At the expiration of the current annual approval the investigator should complete the renewal form and also submit a signed Exempt Assurance Form. The IRB staff will review projects to verify the Exempt status. The review process will be the same as that described in the Initial application section.

2.3 Revisions to the Project

Investigators are not required to submit Revisions to the IRB once a project is designated as Exempt **as long as** those changes do not affect the Exempt category or criteria for Exempt determination (changing from Exempt Status of the project to Expedited or Full Review, or changing criteria for requesting Exempt Status).

Revisions in procedures that would change the Exempt category include but are not limited to:

1. New knowledge that increases the risk level;
2. Use of any methods described in the Expedited review categories that do not meet the Exempt criteria (e.g. audio or video taping, blood draws);
3. Surveying or interviewing children (under 18) or observing public behavior of children and participating in the activities being observed;
4. Change in the way identifiers are recorded (directly or indirectly) from existing data, documents, records, pathological specimens, or diagnostic specimens so that subjects can be identified;
5. Addition of an instrument, survey questions, etc. that would pose more than minimal risk to subjects;
6. Addition of an instrument, survey, etc. from which information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) 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;
7. Addition of prisoners as research subjects; and / or
8. Addition of other vulnerable populations that may pose more than minimal risk.

If there are plans to make any of the above changes, a Revision Form with all appropriate attachments (new or revised instruments, consent forms, etc.) must be

submitted to the IRB for review and approval by the IRB prior to initiation of such changes.

2.4 Additional Investigators – Graduate Students

If an additional co-investigator is added to the project after determination of the Exempt Status the investigator is responsible for their training on human subjects research and all protections for research subjects included in their Exempt Assurance Form. The IRB should be notified of the addition of a graduate student as a co-investigator **if** the research is part of the student's graduate thesis. The investigator submits a Revision form to the IRB to make this change.

Reason

The Graduate School requires an IRB approval letter if the graduate student used human subjects in their research. If a graduate student investigator is added to the project without notification to the IRB, the IRB will have no record of the graduate student being on the project when requested for input from the Graduate School.

2.5 Closure

The investigator must notify the IRB when the research project is closed. This will remove the project from the group of projects subject to audit, and the IRB file will be moved to archives for document retention as required by 45 CFR 46.115(b).

An investigator should close the research project when:

- The project no longer meets the definition of “human subject”, e.g., data are deidentified and the researcher does not have the ability to personally identify any data; or
- Data collection and analysis are complete; or
- The investigator is no longer an MSU employee and an alternate MSU researcher has not been designated as the responsible investigator.

3. Exempt Categories

3.1. Exempt Categories for Research Subject to FDA Regulations (Clinical Investigations):

21 CFR 56.104 Exemptions from IRB requirement. “The following categories of clinical investigations are exempt from the requirements of this part for IRB review:

- “(a) Any investigation which commenced before July 27, 1981 and was subject to requirements for IRB review under FDA regulations before that date, provided that the investigation remains subject to review of an IRB which meets the FDA requirements in effect before July 27, 1981.”

- “(b) Any investigation commenced before July 27, 1981 and was not otherwise subject to requirements for IRB review under Food and Drug Administration regulations before that date.”
- “(c) Emergency use of a test article, provided that such emergency use is reported to the IRB within 5 working days. Any subsequent use of the test article at the institution is subject to IRB review.”
- “(d) Taste and food quality evaluations 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 Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.”

3.2. Exempt Categories for Research Subject to DHHS Regulations:

45 CFR 46.101(b). “Unless otherwise required by Department or Agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:”

- “(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) 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: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) 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 paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) 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: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to

those programs or procedures; or (iv) 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, (i) if wholesome foods without additives are consumed or (ii) 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 Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.”

4.0 Exceptions for the Exempt Categories

4.1 Children

The regulations require additional protections for research involving children. All Exempt Categories above apply to children as research subjects with the exception of Exempt Category (2). This category applies to research involving children as subjects only under specific conditions as specified in 45 CFR 46.401(b):

“Exemptions at [§46.101\(b\)\(1\)](#) and (b)(3) through (b)(6) are applicable to this subpart. The exemption at [§46.101\(b\)\(2\)](#) regarding educational tests is also applicable to this subpart. However, the exemption at [§46.101\(b\)\(2\)](#) for research involving survey or interview procedures or observations of public behavior does not apply to research covered by this subpart, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.” 45 CFR 46.401(b)

In other words: Research involving children **cannot** be classified as Exempt if the research involves:

1. Survey
2. Interview procedures
3. Observations of public behavior when the investigator participates in the activities being observed

Research involving children **can** be classified as Exempt if the research involves only educational tests and observation of public behavior where the investigator does not participate in the activities being observed and meets the other conditions of 45 CFR 46.101(b)(2).

4.2 Prisoners

The federal regulations on exemptions listed above do not apply to research involving prisoners. Research involving prisoners as subjects is **never** Exempt from the regulations.

“The regulations in this subpart are applicable to all biomedical and behavioral research conducted or supported by the Department of Health and Human Services involving prisoners as subjects.” 45 CFR 46.301(a)

“Except as provided in paragraph (a) of this section, biomedical or behavioral research conducted or supported by DHHS shall not involve prisoners as subjects.” 45 CFR 46.306(b)