|  |  |  |  |
| --- | --- | --- | --- |
| Study ID |  | PI |  |

To be classified as exempt, the research (1) must involve only procedures or be a type of research study listed in one or more of the exempt categories, and (2) cannot involve any of the exceptions for the exempt categories for research that involves children. Prisoners may ONLY be involved in the study if the research is aimed at involving a broader subject population that only incidentally includes prisoners.

|  |
| --- |
| **Section Completed by IRB Administrator** |
| **Common Rule Requirements** |
| 1. **Is this project conducted, supported, or required to comply with U.S. Department of Justice requirements or otherwise required to comply with the pre-2018 Common Rule requirements?**   No 🡪 Continue  Yes 🡪 *Do NOT use this form; use the HRP-312 - Worksheet – Exemption Determination Pre-2018.* |
| **Exempt Review Category(ies)** |

|  |  |  |
| --- | --- | --- |
| **(2) Select the appropriate exempt review category(ies) below to confirm that the research involves only procedures listed in one or more of the exempt review categories and explain why it meets that category(ies).** | | |
| 1 | Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. | |
| Explanation |  |
| 2(i) | Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:  (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.\*  *\*CANNOT involve children unless research only involves educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed.* | |
| Explanation |  |
| 2(ii) | Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:  (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.\*  *\*CANNOT involve children unless research only involves educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed.* | |
| Explanation |  |
| 2(iii) | **LIMITED IRB REVIEW REQUIRED.** Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:  (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).\*  \**CANNOT INVOLVE CHILDREN.* | |
| Explanation |  |
| 3(i)(A) | (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:  (A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;  (ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.  (iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.\*  \**CANNOT INVOLVE CHILDREN.* | |
| Explanation |  |
| 3(i)(B) | (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:  (B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or  (ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.  (iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.\*  \**CANNOT INVOLVE CHILDREN.* | |
| Explanation |  |
| 3(i)(C) | **LIMITED IRB REVIEW REQUIRED.** (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:  (C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).  (ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.  (iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.\*  \**CANNOT INVOLVE CHILDREN.* | |
| Explanation |  |
| 4(i) | Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:  (i) The identifiable private information or identifiable biospecimens are publicly available; | |
| Explanation |  |
| 4(ii) | Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:  (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; | |
| Explanation |  |
| 4(iii) | Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:  (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or | |
| Explanation |  |
| 4(iv) | Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:  (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq. | |
| Explanation |  |
| 5 | Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including 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. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.  (i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects. | |
| Explanation |  |
| 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. | |
| Explanation |  |
| 97 | Research involving the study of previously collected identifiable data. The data may include documents or records (but not identifiable biospecimens), unless disclosure of the data 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. This exemption allows the information to be recorded by the investigator in such a manner that subjects can be identified, directly or through identifiers linked to the subjects. | |
| Explanation | Confirm that the research does not involve:  Federal funding or federal training grants  FDA regulated  Sponsor or other contractual restrictions  Clinical interventions (including clinical behavioral interventions)  Receipt of an NIH certificate of confidentiality to protect identifiable research data  Be a project for which MSU serves as the IRB of record  Explanation: |
| 98 | (i) Research involving benign interventions in conjunction with the collection of data from an adult subject through verbal or written responses (including data entry) or video recording if the subject prospectively agrees to the intervention and data collection and at least one of the following criteria is met:  (A) The information obtained is recorded in such a manner that human subjects cannot be identified directly or through identifiers linked to the subjects; or  (B) Any disclosure of the human subjects’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation.  (ii) For the purpose of this provision, benign interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. If these criteria are met, such benign interventions might include research activities in which a subject is asked to read materials, review pictures or videos, play online games, solve puzzles, or perform cognitive tasks.  (iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception as described in (iv).  (iv) For the purpose of this provision, authorized deception is prospective agreement by the subject to participate in research where the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research. | |
| Explanation | Confirm that the research does not involve:  Federal funding or federal training grants  FDA regulated  Sponsor or other contractual restrictions  Clinical interventions (including clinical behavioral interventions)  Receipt of an NIH issued certificate of confidentiality to protect identifiable research data  Be a study for which MSU serves as the IRB of record  Children as research subjects  Explanation: |

Research is eligible for exempt review, limited IRB review is NOT Required

Research MAY be eligible for exempt review; LIMITED IRB REVIEW REQUIRED [2(iii); 3(i)(C)]

Research is NOT eligible for exempt review; proceed with review by the IRB.

Comments:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Determination made by: | | | | |
| Name: |  | Date: |  |  |
|  | | | | |
|  | | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **Section Completed by IRB Member ONLY when Limited IRB Review is REQUIRED** | | | |
| **NOTE: Any comments for the study team are submitted through Private Comment in Click.** | | | |
| **Limited IRB Review Determination**  To qualify for the limited IRB review exemption selected, the IRB must conduct a limited IRB review to make the determination required by §46.111(a)(7). 45 CFR 46.111(7) states that “[w]hen appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.”  I have determined that the criteria in 45 CFR 46.111(a)(7) have been met  I have determined that the criteria in 45 CFR 46.111(a)(7) have NOT been met  **Exemption Category(ies) Determination**  The study qualifies for all of the exemption category(ies) selected by the IRB Administrator  The study qualifies for different exemption category(ies) than what was selected by the IRB Administrator. Post Private Comment to IRB Administrator to request change to the 503; do not Submit Designated Review until the revised 503 is received.  Identify exempt category(ies) study is eligible for:  1  2(i)  2(ii)  2(iii)  3(i)(A)  3(i)(B)  3(i)(C)  4(i)  4(ii)  4(iii)  4(iv)  5  6  97  98  The study does NOT qualify for an exemption determination  **Comments for Study Team 🡪 Send Private Comment**  **Determination**  Study determined exempt  Non-exempt review required 🡪 Notify IRB Administrator through Private Comment  **Click Instructions when Submit Designated Review is Performed**   * DO NOT SUBMIT if there is a change in exempt category that needs to be made by PI * Select all appropriate exemption category(ies) * *REMOVE the expiration date* * Upload this completed worksheet to Item 7, Supporting Document | | | |
| IRB Member Name |  | Date Completed |  |
|  | | | |