

EXEMPT CHECKLIST BYU HRPP

EXEMPTION 1: Research conducted in established or commonly accepted educational settings, involving normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content and does not adversely impact the assessment of educators who provide instruction, such as:	YES	NO	N/A
1. All the research is conducted in established or commonly accepted educational settings (e.g., public school, higher education)	☐	☐	☐
2. Study involves normal educational practices.	☐	☐	☐
3. Study is unlikely to adversely impact students' opportunity to learn required educational content.	☐	☐	☐
4. Will not likely adversely impact the assessment of educators who provide instruction.	☐	☐	☐
5. Includes research on regular and special education instructional strategies.	☐	☐	☐
6. Includes research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.	☐	☐	☐
EXEMPTION 2 (SUBSECTION I): Research involving the use of educational tests, survey procedures, interview procedures or observation of public behavior and information is obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained.	YES	NO	N/A
1. 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.	☐	☐	☐
2. Involve educational tests	☐	☐	☐
3. Survey, interview procedures AND NO CHILDREN.	☐	☐	☐
4. Observations of public behavior. IF children are observed, the investigator CANNOT participate in the activities being observed	☐	☐	☐
EXEMPTION 2 (SUBSECTION II): Research involving the use of educational tests, survey procedures, interview procedures or observation of public behavior and disclosure of subjects' responses outside research would not reasonably place the subjects at risk.	YES	NO	N/A
1. 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.	☐	☐	☐
2. Survey and interview procedures do NOT involve children.	☐	☐	☐
3. Observations of public behavior. IF children are observed, the investigator CANNOT participate in the activities being observed.	☐	☐	☐
4. Educational tests; can involve children.	☐	☐	☐
EXEMPTION 2 (SUBSECTION III): Limited IRB review required. research involving the use of educational tests, survey procedures, interview procedures or observation of public behavior and information can readily be ascertained and disclosure of subjects' responses outside research could reasonably place the subjects at risk.	YES	NO	N/A
1. The identity of the human subjects can readily be ascertained, directly or indirectly through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the required determination.	☐	☐	☐
2. Limited IRB Review Criteria: The IRB makes the determination that when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.	☐	☐	☐
3. No minors.	☐	☐	☐
EXEMPTION 3 (SUBSECTION I, A): Research involving benign behavioral interventions in conjunction with the collection of information from adult subjects and information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained.	YES	NO	N/A
1. 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.	☐	☐	☐
2. Benign Behavioral Interventions (e.g. play an online game, solve puzzles under various noise conditions, how to allocate a nominal amount of cash received between themselves and someone else)	☐	☐	☐
3. Behavioral Interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects. No reason for PI to think the subjects will find the interventions offensive or embarrassing.	☐	☐	☐
4. Deception is not applicable unless: subject authorizes the deception through an agreement BEFORE participation, where subject is informed that they will be unaware or misled regarding the nature or the purposes of the research.	☐	☐	☐
5. No minors.	☐	☐	☐

EXEMPTION 3 (SUBSECTION I, B): Research involving benign behavioral interventions in conjunction with the collection of information from adult subjects and the disclosure of subjects' responses outside research would not reasonably place the subjects at risk.	YES	NO	N/A
1. Any disclosure of the subjects' responses outside 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.	☐	☐	☐
2. Benign Behavioral Interventions (e.g. play an online game, solve puzzles under various noise conditions, how to allocate a nominal amount of cash received between themselves and someone else)	☐	☐	☐
3. Behavioral Interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects. No reason for PI to think the subjects will find the interventions offensive or embarrassing.	☐	☐	☐
4. Deception is not applicable unless: subject authorizes the deception through an agreement BEFORE participation, where subject is informed that they will be unaware or misled regarding the nature or the purposes of the research.	☐	☐	☐
5. No minors.	☐	☐	☐
EXEMPTION 3 (SUBSECTION I, C): Limited IRB review required. research involving benign behavioral interventions in conjunction with the collection of information from adult subjects and information obtained is recorded by the investigator in such a manner that the identity of the human subjects can be readily ascertained and disclosure of subjects' responses outside research <u>could</u> reasonably place the subjects at risk.	YES	NO	N/A
1. The identity of the human subjects can readily be ascertained, directly or indirectly through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the required determination.	☐	☐	☐
2. Benign Behavioral Interventions (e.g. play an online game, solve puzzles under various noise conditions, how to allocate a nominal amount of cash received between themselves and someone else)	☐	☐	☐
3. Behavioral Interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects. No reason for PI to think the subjects will find the interventions offensive or embarrassing.	☐	☐	☐
4. Deception is not applicable unless: subject authorizes the deception through an agreement BEFORE participation, where subject is informed that they will be unaware or misled regarding the nature or the purposes of the research.	☐	☐	☐
5. Limited IRB Review Criteria: The IRB makes the determination that when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. 45 CFR 46.111(a)(7)	☐	☐	☐
6. No minors.	☐	☐	☐
EXEMPTION 4 (SUBSECTION I): Secondary research uses of identifiable private information or identifiable biospecimen – publicly available.	YES	NO	N/A
1. Publicly available private information or identifiable biospecimens.	☐	☐	☐
EXEMPTION 4 (SUBSECTION II): Secondary research uses of identifiable private information or identifiable biospecimens – information recorded by investigator in a manner that identity of subjects cannot readily be ascertained.	YES	NO	N/A
1. Information 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.	☐	☐	☐
EXEMPTION 4 (SUBSECTION III): Secondary research uses of identifiable private information or identifiable biospecimens – use of identifiable health information regulated under HIPAA.	YES	NO	N/A
1. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under HIPAA (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).	☐	☐	☐
EXEMPTION 4 (SUBSECTION IV): Secondary research uses of identifiable private information or identifiable biospecimens – research conducted by or on behalf of a federal department or agency using government-generated or government collected information obtained for non-research purposes that will be maintained according to certain federal privacy standards.	YES	NO	N/A
1. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology.	☐	☐	☐
EXEMPTION 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.	YES	NO	N/A
1. Studies under contracts or consulting arrangements, cooperative agreements, or grants.	☐	☐	☐
EXEMPTION 6: Taste and food quality evaluation and consumer acceptance studies	YES	NO	N/A

1. If wholesome foods without additives are consumed.	☐	☐	☐
2. 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.	☐	☐	☐
RESOURCES			
1. https://hrpp.msu.edu/help/required/exempt-categories.html			
2. https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/exempt-research-determination/index.html			