|  |
| --- |
| **REVIEWER CHECKLIST – EXEMPT** |
| **PRO #:** Click or tap here to enter text. | **Principal Investigator:** Click or tap here to enter text. |
|  | **Department:** Click or tap here to enter text. |
| Determination |
| [ ]  This project qualifies as **Exempt** under:  |
|  | [ ]  45 CFR 46.104 (HHS) | [ ]  21 CFR 56.104 (FDA) [Approval under Category 6 only] |
| [ ]  Principles of respect for persons, beneficence, and justice are appropriately addressed. |
| [ ]  The study involves interaction with subjects, and subjects are consented prior to the initiation of research activities (e.g. via an informational letter). |
| Exemption Categories. Check all that apply.\* |
| \* If any research activity does not qualify under an Exemption category, the project cannot be considered or reviewed as Exempt. |
| [ ]  (1) **Education Evaluation**: 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. |
| [ ]  (2) **Surveys, Interviews, Focus Groups, Educational tests, Observation**: 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. Check all that apply:* * [ ]  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
* [ ]  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
* [ ]  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 45 CFR 46.111(a)(7).
	+ [ ]  When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
	+ [ ]  For federally funded projects, the NIH Data sharing and Management plan is uploaded
 |
| [ ]  (3) **Benign Behavioral Interventions**: 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. Check all that apply:* * [ ]  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;
* [ ]  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
* [ ]  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 45 CFR 46.111(a)(7).
	+ [ ]  When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
* 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.
* 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.
 |
| [ ]  (4) **Secondary Review of Records, Specimens, etc.:** Secondary research uses of identifiable private information or identifiable biospecimens for which consent is not required,*if at least one of the following criteria is met. Check all that apply:* * [ ]  The identifiable private information or identifiable biospecimens are publicly available;
* [ ]  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;
* [ ]  The research involves only information collection and analysis involving the investigator’s use of identifiable health information for the purposes of ‘‘health care operations’’ or ‘‘research’’ or for ‘‘public health activities and purposes’’; or
* [ ]  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.
 |
| [ ]  (5) **Federally-Supported research / demonstration projects:** 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 havebeen 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.* 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.
 |
| [ ]  (6) **Taste and food quality evaluation:** Taste and food quality evaluation and consumer acceptance studies. *Check all that apply:** [ ]  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.
 |
| (7) **Storage or maintenance for secondary research requiring broad consent:** Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review. |
| (8) **Secondary Research for which broad consent is required**: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, *if the following criteria are met. Check all that apply:** Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained;
* Documentation of informed consent or waiver of documentation of consent was obtained;
* An IRB conducts a limited IRB review
 |
| NOTE: Because the use of broad consent has not been adopted, the MCW/FH IRB does not utilize Exemption categories 7 and 8. |
| **HIPAA** |
| The IRB also functions as the privacy board for research projects. While HIPAA determinations will likely mirror consent determinations, they are separate in order to address this dual IRB function. |
| [ ]  Project utilizes MCW ICF templates which contain HIPAA Authorization (Section E).* [ ]  Consent/HIPAA recruitment waiver is granted to scan records and identify subjects prior to consent.
 |
| [ ]  Waiver of HIPAA Authorization granted. |
| [ ]  All subjects are deceased and access to this data is granted.  |
| [ ]  Limited Data Set would be utilized, and any necessary data agreements are provided. |
| [ ]  Only de-identified data is utilized. |
| [ ]  HIPAA process has already been determined and no new determinations are needed (e.g. material received from an IRB-approved bank, from another institution, etc.). |
| [ ]  Project does not access or create Personal Health Information. |
| Reviewer Comments / Signature |
| **Reviewer Comments:** Click or tap here to enter text. |
| IRB Reviewer Name: Click or tap here to enter text. | Date: Click here to enter a date. |