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| **EXEMPT CATEGORIES** | | | | | |
| **Check all categories that the research meets. *NOTE:*** **The entire study and all activities must be covered under one or more of the exempt categories**. If not, stop and complete the IRB New Study Expedited Review Worksheet. Pregnant women, neonates, and fetus as participants are okay in exempt categories. Children are okay, unless otherwise noted in the category. | | | | | |
|  | 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. | | | | |
|  | 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:** | | | | |
|  |  | 1. 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; ***AND***   If children are participants, the procedures are limited to the use of educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. | | | |
|  |  | | Yes  No – *Exemption not granted; use Expedited Review Worksheet* | |  |
|  |  | | **OR** | |  |
|  |  | 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 ***AND***  If children are participants, the procedures are limited to the use of educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. | | | |
|  |  | | Yes  No – *Exemption not granted; use Expedited Review Worksheet* | |  |
|  |  | **OR** | |  | |
|  |  | 1. **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. ***AND*** No children are participants. | | | |
|  | | | Yes  No – *Exemption not granted; use Expedited Review Worksheet* | | |
|  | Research involving **benign behavioral interventions\*** in conjunction with the collection of information from an adult participant through verbal or written responses (including data entry) or audiovisual recording if the participant prospectively agrees to the intervention and information collection and at **least ONE of the following criteria are met (a, b or c) and answer follow-up question:** | | | | |
|  |  | 1. The information obtained is recorded by the investigator in such a manner that the identity of the human participants cannot readily be ascertained, directly or through identifiers linked to the participants; **OR** | | | |
|  |  | 1. Any disclosure of the human participants’ responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants’ financial standing, employability, educational advancement, reputation; **OR** | | | |
|  |  | 1. The information obtained is recorded by the investigator in such a manner that the identity of the human participants can readily be ascertained, directly or through identifiers linked to the subjects | | | |
|  | **AND**  Does the research involve deceiving the participants regarding the nature or purposes of the research?  **No**  **Yes -** Will participants authorize the deception through a prospective agreement to be in research in circumstances in which the participant is informed that he or she will be unaware of or misled regarding the nature or purposes of the research?  **Yes**  **No – STOP**- use the Expedited reviewer sheet, instead  **\*Benign Behavioral Interventions** *are*   * *Brief in duration* * *Harmless* * *Painless* * *Not physically invasive* * *Not likely to have a significant adverse lasting impact on the participants, and* * *The investigator has no reason to think the participants will find the interventions offensive or embarrassing*   *Provided all such criteria are met, examples include having the participants play an online game, solve puzzles under various noise conditions, or decide how to allocate a nominal amount of received cash between themselves and someone else.* | | | | |
|  | **Secondary research\* for which consent is not required. \***Research based on generated data or specimens collected from primary activity or research. Re-using identifiable information and identifiable biospecimens that were collected for the initial or primary activity. Does *not* include current investigator wanting to collect information or biospecimens directly from participants in addition to the data collected for primary activity. **Secondary research uses of identifiable private information or identifiable biospecimens, if at least ONE of the following criteria are met:** | | | | |
|  |  | 1. The identifiable private information or identifiable biospecimens are publicly available; **OR** | | | |
|  |  | 1. Information, which may include *information about* biospecimens *(but not include the biospecimens themselves),* is recorded by the investigator in such a manner that the identity of the human subjects **cannot** be readily ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; **OR** | | | |
|  |  | 1. **The research involves *only information* (no biospecimens) collection and analysis involving the investigators use of identifiable health information** **OR** | | | |
|  |  | 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 that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, [44 U.S.C. 3501](https://www.govinfo.gov/content/pkg/USCODE-2018-title44/html/USCODE-2018-title44-chap35-subchapI-sec3501.htm) note if all of the identifiable health 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](https://www.govinfo.gov/content/pkg/USCODE-2018-title5/html/USCODE-2018-title5-partI-chap5-subchapII-sec552.htm), and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, [44 U.S.C. 3501](https://www.govinfo.gov/content/pkg/USCODE-2018-title44/html/USCODE-2018-title44-chap35-subchapI-sec3501.htm) *et seq*.] | | | |
|  | **Demonstration projects and research 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 head 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, ***AND*** the research or demonstration project must be included on the list of research and demonstration projects published on the conducting or supporting Federal department or agency publicly accessible website prior to commencing the research involving human subjects. | | | | |
|  | **Taste and food quality evaluation** and consumer acceptance studies: | | | | |
|  |  | 1. If wholesome foods without additives are consumed; **OR** | | | |
|  |  | 1. 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. | | | |

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| Categories 7 and 8 involve Broad Consent, which Mercy Health does not support. |
| **If ALL research activities *do not fit* under one or more of the above categories, use the IRB New Study Expedited Review Worksheet.** |