Exempt Categories Checklist

The purpose of this worksheet is to provide support for Designated Reviewers granting exemption determinations. This worksheet is to be used. It does not need to be completed or retained.

1	**GENERAL EXCLUSIONS FROM EXEMPTIONS** (Check if **"Yes"**. If any are checked, the research is not exempt.)
☐	The research is FDA-regulated.[i]
☐	The research involves Prisoners, conducted or funded by DHHS, Dept. of Defense (DOD), or Veterans Administration (VA), and is NOT aimed at involving a broader subject population that only incidentally includes prisoners.
☐	The research involves interactions with Prisoners.[ii]
☐	The research is classified and conducted or funded by the Department of Energy (DOE) (may be reviewed by convened IRB only).[1]

2	**Criteria for approval of exempt research (Check if "Yes")**	
☐	The research involves no more than Minimal Risk to subjects. **(Must be checked.)**	
☐	Selection of subjects is equitable. (That is, the research is appropriate for the population being studied.) **(Must be checked.)**	
☐	There are interactions with subjects: **(If checked, all of the following must also be checked.)**	
	☐	There will be a consent process
	☐	The consent process will disclose that the activities involve research.
	☐	The consent process will disclose the procedures to be performed.
	☐	The consent process will disclose that participation is voluntary.
	☐	The consent process will disclose the name and contact information for the investigator.
	☐	There are adequate provisions to maintain the privacy interests of subjects.

3	**The research falls into one or more of the following categories** (One or more categories must be checked)
☐	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.
☐	2. 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 be readily ascertained, directly or indirectly through identifiers linked to the subjects; OR ☐ (ii) Any disclosure of 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 ☐ (iii) The information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects can be readily ascertained, directly or indirectly through identifiers linked to the subjects, AND an IRB conducts limited IRB review.
	☐ If the research involves children and is conducted, funded, or subject to regulation by DHHS, Dept. of Defense (DOD), Dept. of Education (ED), Environmental Protection Agency (EPA), or Veterans Administration (VA), the procedures are limited to (1) the observation of public behavior when the investigator(s) do not participate in the activities being observed or (2) the use of educational tests and 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 indirectly through identifiers linked to the subjects; OR ☐ (ii) Any disclosure of 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 achievement, or reputation.

☐	3(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 indirectly, 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; OR ☐ (C) The information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects can be readily ascertained, directly or indirectly through identifiers linked to the subjects, AND an IRB conducts limited IRB review[iii]. (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.
☐	4. 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; OR ☐ (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; OR ☐ (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 (HIPAA), 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 ☐ (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.
☐	5. Research and demonstration projects which 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 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[iv] ☐ (i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal website 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.[v] 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 Dept. of Agriculture.
☐	7. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts limited IRB review
☐	Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use[vi].