UC San Diego INSTITUTIONAL REVIEW BOARD ADMINISTRATION	**OIA-312 WORKSHEET:** Exemption Determination		
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The purpose of this worksheet is to provide support for trained Office of IRB Administration (OIA) staff members and designated reviewers granting exemption determinations. This worksheet, or equivalent, is to be used. It does not need to be completed or retained.

Research cannot be exempt if any of the following are true:

- The research involves prisoners and is conducted or funded by Department of Health and Human Services (DHHS), Department of Defense (DOD), Veterans Administration (VA), National Science Foundation (NSF), or Department of Education (ED).
- The research involves interactions with prisoners.
- The research involves greater than minimal risk to subjects.

Studies involving pregnant subjects and children can qualify for exempt determination so long as the study meets all the requirements of the exempt category.

1 ETHICAL STANDARDS FOR EXEMPT RESEARCH:
(Check if "YES." Select all that apply.)

☐	Participants will be enrolled and subject selection is equitable.
☐	Identifiable information will be recorded and there are adequate provisions to maintain the confidentiality of the data.
☐	There will be interactions with subjects and there are adequate provisions to maintain the privacy interests of subjects.
☐	There will be interactions with subjects and the consent process discloses: ☐ That the activities involve research. ☐ The procedures to be performed. ☐ That participation is voluntary. ☐ The name and contact information for the investigator. ☐ For National Institutes of Health-funded research, the certificate of confidentiality information is included. ☐ For research conducted outside the United States, disclosure of risks due to local context is included.

2 REVISED COMMON RULE EXEMPTION CATEGORIES: THE RESEARCH FALLS INTO ONE OR MORE OF THE FOLLOWING CATEGORIES: (Select all that apply. One or more categories must be checked.)

☐		**1. Educational Research** Research, conducted in established or commonly accepted educational settings that specifically involves normal educational practices. This exemption 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. ***Both of the following must be checked:***
	☐	The research is not likely to adversely impact students' opportunity to learn required educational content.
	☐	The research is not likely to adversely impact the assessment of educators who provide instruction.
☐		**2. Educational Tests, Surveys, Interviews, 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). ***Subsection a must be checked. One of b, c, or d must be checked.***
	☐	a. ***At least one of the following must be checked:*** ☐ This research does not include children as defined by 45 CFR 46.402(a). ☐ ***FLEX:*** This research does include children and is not subject to regulation by DHHS, DOD, ED, Environmental Protection Agency (EPA), VA, or US Department of Agriculture (USDA). ☐ The procedures are limited to (1) the observation of public behavior when the investigator(s) do not participate in the activities being observed and/or (2) the use of educational tests.
	☐	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. ***If checked, STOP, section is complete. If not checked, proceed to subsection c.***
	☐	c. 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 subject. ***If checked, STOP, section is complete. If not checked, proceed to subsection d.***
	☐	d. 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. Limited review is complete and the following determination has been made: when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

☐ **3. Research Involving Benign Behavioral Interventions with Adult Subjects**
Research involving benign behavioral interventions[1] in conjunction with the collection of information from a subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and ***subsection a is checked and one of subsections b, c, or d is checked. If the project involves deception, e must also be checked or the project is not exempt.***

☐ a. ***At least one of the following must be checked to qualify for this exemption.***

☐ This research does not include children as defined by 45 CFR 46.402(a)☐ ***FLEX:*** This research does include children and is not subject to regulation by DHHS, DOD, ED, EPA, VA, or USDA.

☐ 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; ***If checked, proceed to subsection e. If not checked, proceed to subsection c.***

☐ c. 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; ***If checked, proceed to subsection e. If not checked, proceed to subsection d.***

☐ d. 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. Limited review is complete and the following determination has been made: when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. ***Proceed to subsection e.***

☐ e. If the research involves deceiving the subjects regarding the nature or purposes of the research, the subject authorizes deception through a prospective agreement to participate in research in circumstances in which the subject is informed that they will be unaware of or misled regarding the nature or purposes of the research. When appropriate, there is an adequate plan to debrief the subject about the true nature or purposes of the study after they have completed all study activities.

☐ **4. Secondary research for which consent is not required**
Secondary research uses of identifiable private information or identifiable biospecimens. ***At least one of the following must be checked to qualify for this exemption***

☐ (i) One of the below must be checked:
☐ The identifiable private information/biospecimens are publicly available.
☐ ***FLEX:*** The research is not federally funded by an agency that has adopted the Common Rule, the identifiable private information is not publicly available, and an IRB conducts a limited IRB review if any disclosure of the human subjects' responses outside the research would reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation. If limited review is complete, the following determination has been made: when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

☐ (ii) Information is recorded by the investigator in such a manner that:
- The identity of the 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.

☐ (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when at least one of the following is true:
☐ That use is regulated under 45 CFR part 160 and 45 CFR Part 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) (i.e. the protected health information (PHI) does not leave the covered entity).
NOTE: This category cannot be used for the review of UCSD studies.
☐ ***FLEX:*** The research is not federally funded by an agency that has adopted the Common Rule and an IRB conducts a limited IRB review. Limited review is complete and the following determination has been made: when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

[1] 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.

☐ **5. Research and demonstration projects conducted or supported by a federal department or agency**
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 designee 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. The research or demonstration project is published on the department or agency's list of research and demonstration projects that the department or agency conducts or supports under this provision.

☐ **6. Taste and food quality evaluation and consumer acceptance studies**
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 FDA or approved by the EPA or the Food Safety and Inspection Service of the Department of Agriculture. ***At least one of the following must be checked to qualify for this exemption:***

- ☐ The food contains only food ingredients at or below the level and for a use found to be safe.
- ☐ The food contains agricultural chemical or environmental contaminants at or below the level found to be safe by the FDA or approved by the EPA or the Food Safety and Inspection Service of the Department of Agriculture.

3 OLD COMMON RULE EXEMPTION CATEGORIES: THE RESEARCH FALLS INTO ONE OR MORE OF THE FOLLOWING CATEGORIES: (Select all that apply. One or more categories must be checked.)

☐ 1. Research conducted in established or commonly accepted educational settings, involving normal educational practices. (Both the procedures and objectives of the research involve normal education practices.)

☐ 2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses 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.

- ☐ If the research involves children and is conducted, funded, or subject to regulation by DHHS, DOD, ED, EPA, VA, or USDA the procedures are limited to (1) the observation of public behavior when the investigator(s) do not participate in the activities being observed and (2) the use of educational tests. **("N/A" if the research does not involve children or is not conducted, funded, or otherwise subject to regulation by these agencies.)**

☐ 3. Research involving the use of educational tests[2], survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section[3], if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

☐ 4.[4] Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. **(For research conducted, funded, or otherwise subject to regulation by any federal agency "existing" means "existing at the time the application is submitted to the IRB." Otherwise, it means "existing at the time the research is proposed or will exist in the future for non-research purposes.")**

☐ 5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs. In addition: (Check if **"Yes."** All must be checked.)

- ☐ The program under study delivers a public benefit[5] or service[6].
- ☐ The research or demonstration project is conducted pursuant to specific federal statutory authority.
- ☐ There is no statutory requirement that the project be reviewed by an IRB.

[2] Includes cognitive, diagnostic, aptitude, and achievement tests
[3] Pre-2018 45 CFR 46.101
[4] "If these sources are publicly available" was removed because public data cannot be private, and if there is no collection of identifiable private information, there can be no human subjects.
[5] For example, financial or medical benefits as provided under the Social Security Act
[6] For example, social, supportive, or nutrition services as provided under the Older Americans Act

	☐	The project does not involve significant physical invasions or intrusions upon the privacy of subjects.
	☐	The funding agency concurs with the exemption.
☐	6.[7] 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 FDA or approved by the EPA or the Food Safety and Inspection Service of the Department of Agriculture.	

[7] Note that for FDA-regulated research exemption (6) is an exemption from IRB review in 21 CFR Part 56, but unlike DHHS regulations is not an exemption from FDA requirements for consent in 21 CFR Part 50. If an organization's policy is to grant exemptions to FDA-regulated research in category (6), then additional criteria for such exemptions would be that consent will be obtained in accordance with 21 CFR 50.20 and 21 CFR 50.25, and the consent will be either be documented in writing in accordance with 21 CFR 50.27 or waived in accordance with 21 CFR 56.109(c)(1).