

## WORKSHEET: Exemption

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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<sup>i</sup>.
- The research is Dept. Of Justice-regulated. **[SKIP to and complete Sections #4 and #5]**
- The research involves Prisoners, conducted or funded by DHHS or Dept. of Defense (DOD), and is NOT aimed at involving a broader subject population that only incidentally includes prisoners.
- The research involves interactions with Prisoners.<sup>ii</sup>
- The research is classified and conducted or funded by the Department of Energy (DOE) (may be reviewed by convened IRB only).<sup>iii</sup>

### 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)

- Exempt Category 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.
- Exempt Category 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. **[See 3.213 (HRP-319) - WORKSHEET - IRB Review or Exempt Research Review when HIPAA Applies]**
  - If the research involves children and is conducted, funded, or subject to regulation by DHHS, Dept. of Defense (DOD), Dept. of Education (ED), or Environmental Protection Agency (EPA), 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.
- Exempt Category 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

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<input type="checkbox"/>	<input type="checkbox"/>	<p>(C) The information obtained is recorded by the investigator in such a manner that the identity of the <u>Human Subjects</u> can be readily ascertained, directly or indirectly through identifiers linked to the subjects, AND an IRB conducts limited IRB review<sup>vii</sup>. <b>[See 3.213 (HRP-319) - WORKSHEET - IRB Review or Exempt Research Review when HIPAA Applies]</b></p>
	<input type="checkbox"/>	<p>(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.</p>
	<input type="checkbox"/>	<p>(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.</p>
<input type="checkbox"/>		<p><b>Exempt Category 4:</b> Secondary research for which consent is not required: Secondary research uses of <u>identifiable private information</u> or <u>identifiable biospecimens</u>, if at least one of the following criteria is met:</p>
	<input type="checkbox"/>	<p>(i) The <u>identifiable private information</u> or <u>identifiable biospecimens</u> are publicly available; OR</p>
	<input type="checkbox"/>	<p>(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the <u>human subjects</u> 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</p>
	<input type="checkbox"/>	<p>(iii) For research that involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under HIPAA, AND an IRB conducts a HIPAA Privacy Review <b>[See 3.213 (HRP-319) - WORKSHEET - IRB Review or Exempt Research Review when HIPAA Applies]</b> OR</p>
	<input type="checkbox"/>	<p>(iv) 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 <u>identifiable private information</u> 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 <u>identifiable private information collected</u>, 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.</p>
<input type="checkbox"/>		<p><b>Exempt Category 5:</b> 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<sup>v</sup></p>
	<input type="checkbox"/>	<p>(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 <u>human subjects</u>.</p>
<input type="checkbox"/>		<p><b>Exempt Category 6:</b><sup>vi</sup> 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.</p>

#### 4 One Of The Following Is True:

<input type="checkbox"/>	The research is DOJ-regulated.
<input type="checkbox"/>	The review is related to research determined to be exempt prior to January 21, 2019, and the organization continues to apply Pre-2018 requirements to some or all research initiated prior to January 21, 2019.

#### 5 The Research Falls Into One Or More Of The Following Categories (One Or More Categories Must Be Checked)

**[Pre-2018 45 CFR 46 Requirements]**

<input type="checkbox"/>	<input type="checkbox"/>	<p><b>Exempt Category 1:</b> Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. (Both the procedures involve normal education practices and the objectives of the research involve normal educational practices.)</p>
	<input type="checkbox"/>	<p><b>Exempt Category 2:</b> 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 <u>Human</u></p>

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		<p><u>Subjects</u> can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the <u>Human Subjects'</u> 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. In addition:</p>
	<input type="checkbox"/>	<p>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 and (2) the use of educational tests. <b>("N/A" if the research does not involve children or is not conducted, funded, or otherwise subject to by these agencies.)</b></p>
	<input type="checkbox"/>	<p><b>Exempt Category 3:</b> Research involving the use of educational tests<sup>vii</sup>, survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the <u>Human Subjects</u> 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.</p>
	<input type="checkbox"/>	<p><b>Exempt Category 4:</b> <sup>viii</sup> 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. <b>(For research conducted, funded, or otherwise subject to regulation by any federal agency "existing" means "existing at the time the research is proposed." Otherwise, it means "existing at the time the research is proposed or will exist in the future for non-research purposes.")</b></p>
	<input type="checkbox"/>	<p><b>Exempt Category 5:</b> Research and demonstration projects which are conducted by or subject to the approval of Dept. 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 <b>"Yes"</b>. All must be checked)</p>
	<input type="checkbox"/>	The program under study delivers a public benefit <sup>ix</sup> or service <sup>x</sup> .
	<input type="checkbox"/>	The research or demonstration project is conducted pursuant to specific federal statutory authority.
	<input type="checkbox"/>	There is no statutory requirement that the project be reviewed by an IRB.
	<input type="checkbox"/>	The project does not involve significant physical invasions or intrusions upon the privacy of subjects.
	<input type="checkbox"/>	The funding agency concurs with the exemption.
	<input type="checkbox"/>	<p><b>Exempt Category 6:</b> <sup>xi</sup> 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.</p>

<sup>i</sup> The organization's policy is to not grant exemptions to FDA-regulated research in category (6).

<sup>ii</sup> AAHRPP Tip Sheet 18: Review of Research Involving Prisoners and the Role of the Prisoner Representative.

<sup>iii</sup> DOE N 443.1

<sup>iv</sup> For NOTE

<sup>v</sup> Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

<sup>vi</sup> Note that for FDA-regulated research exemption (6) is an exemption from IRB review in 21 CFR §56, but unlike DHHS regulations is not an exemption from FDA requirements for consent in 21 CFR §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 §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).

<sup>vii</sup> Includes cognitive, diagnostic, aptitude, and achievement tests

<sup>viii</sup> "If these sources are publicly available" was removed because public data cannot be private, and if there is no collection of private identifiable data, there can be no Human Subjects.

<sup>ix</sup> For example, financial or medical benefits as provided under the Social Security Act

<sup>x</sup> For example, social, supportive, or nutrition services as provided under the Older Americans Act

<sup>xi</sup> Note that for FDA-regulated research exemption (6) is an exemption from IRB review in 21 CFR §56, but unlike DHHS regulations is not an exemption from FDA requirements for consent in 21 CFR §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 §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).