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|  |  | **FORM: Exempt[[1]](#footnote-1)** |

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| **Date:** |       |
| **FHIRB #:** |       |
| **RG #:** |       | **Protocol #:** |       |
| **Principal Investigator:** |       |
| **Study Title:**  |       |

**PLEASE NOTE:**

* This worksheet supports the IRB in making an Exempt determination. The formal determination, including the appropriate regulatory Exempt category, will be communicated to the investigator in an Exemption letter.
* Studies involving pregnant women, fetuses, and neonates are eligible for exemption under all Exempt Categories.
* Research involving prisoners does not qualify for an exemption except “for research aimed at involving a broader subject population that only incidentally includes prisoners” [[2]](#footnote-2).
* Children are allowed in Exempt Categories 1, 4, 5, and 6. There are limitations or exclusions of children in Exempt Categories 2 and 3.
* If your research involves accessing Washington state agency records: This activity is not eligible for an Exempt determination[[3]](#footnote-3).
1. **REGULATORY CONSIDERATIONS:**
	1. Is this study regulated by the FDA, or will data be used in supporting the commercialization of an FDA‑regulated product?

[ ]  Yes → Please note only Exempt Category 6 is applicable.

[ ]  No

1.2 Does this research involve prisoners as a target population?

[ ]  Yes, please explain:

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[ ]  No

1.3 Does this research involve children?

[ ]  Yes → There are limitations or exclusions of children in Exempt Categories 2 and 3.

[ ]  No

1. **ETHICAL CONSIDERATIONS:**
	1. How are participants/records selected? Please explain:

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* 1. Will the study involve the access to or use of identifiable information and/or biospecimens about participants?

[ ]  Yes → Please explain your plan to protect the confidentiality of information and/or biospecimens (including restrictions on further access and use by others).

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[ ]  No

* 1. Will you be interacting with research participants?

[ ]  Yes → The consent materials and any recruitment materials are attached in Hutch IRB.
NOTE: The consent process includes the disclosure to participants of information about the study, including, but not limited to, the following:

* Description of the research and research procedures
* Statement that informs them that participation is voluntary
* Name and contact information for the study investigator
* Description of what measures will be followed to protect the privacy of participants and the confidentiality of their information and/or biospecimens

[ ]  No

1. **EXEMPT CATEGORIES:**

**Check the EXEMPT CATEGORY under which this research study qualifies for an exemption.**

[ ]  1) **EDUCATION:** Research conducted in established or commonly accepted education settings, that specifically involves normal education practices that are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction, 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.

[ ]  2) **TESTS, SURVEYS, INTERVIEWS, PUBLIC 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:

[ ]  2.i 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

[ ]  2.ii 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, or reputation; or

[ ]  2.iii 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 participants. **Note**: An IRB Chair (or designee) will conduct a “limited IRB review” to make a determination required by 45 CFR 46.111(a)(7).

**PLEASE NOTE**: Criteria 2.i and 2.ii, for research involving **survey or interview procedures** or **observation of public behavior**, do not apply to research with children, except for:

* + Research involving observation of public behavior when the investigator(s) do not participate in the activities being observed
	+ Research involving the use of educational tests.

**PLEASE NOTE:** Criterion 2.iii does not apply to research with children.

[ ]  3) **BENIGN BEHAVIORAL INTERVENTIONS:** 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 subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

[ ]  3.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 through identifiers linked to the subjects; or

[ ]  3.ii 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

[ ]  3.iii 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.

**Note**: An IRB Chair (or designee) will conduct a “limited IRB review” to make a determination required by .111(a)(7).

3.a Are the benign behavioral interventions 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 subjects will find the interventions offensive or embarrassing?

*Examples may 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.*

[ ]  Yes → Continue to 3.b

[ ]  No → Not eligible for Exempt Category 3.

3.b If the research involves deceiving the subjects regarding the nature or purposes of the research, will the participant authorize the deception through a prospective agreement to participate in the research?

[ ]  Yes → Please explain how agreement will be obtained and/or submit a copy of the agreement/consent to be used.

[ ]  No → Not eligible for Exempt Category 3.

[ ]  N/A → No deception is involved.

**PLEASE NOTE:** Exempt Category 3 does not apply to research involving children.

[ ]  4) **SECONDARY RESEARCH:** Secondary research uses of identifiable private information or identifiable biospecimens. Please respond to items 4.a and b:

4.a Type(s) of information or biospecimens (check all that apply):

[ ]  information [ ]  documents [ ]  records [ ]  pathological biospecimens

[ ]  diagnostic biospecimens

4.b Indicate which criteria are met:

[ ]  4.b.i. The information or biospecimens are publicly available.

[ ]  4.b.ii. The information, which may include information about biospecimens, is recorded (or received) by the investigator in such a manner that the identity of the participants cannot readily be ascertained directly or through identifiers linked to the participants; the investigator does not contact the participants; and the investigator will not re-identify subjects.
**NOTE:** For this option, you must submit either **a list of the specific data points** available in this research (e.g., age, diagnosis status, biomarker data, etc.) **or a copy of the data collection instrument** that will be used to record the de-identified information (unless the specific data points are listed in the protocol).

[ ]  4.b.iii. 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 federal law (i.e., the Paperwork Reduction Act of 1995 or the Privacy Act of 1974).

[ ]  5) **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 have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, 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.

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.

Please note: 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) **FOOD:** Taste and food quality evaluation and consumer acceptance studies:

[ ]  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.

Note: For FDA-regulated research, consent must be obtained in accordance with 21 CFR §50.20 and §50.25, and the consent must either be documented in writing in accordance with 21 CFR§50.27 or waived in accordance with 21 CFR §56.109(c)(1).

**Note:** Exempt categories 7 and 8 are applicable only when Broad Consent is obtained. **Fred Hutch does not allow the use of Broad Consent.**

**Please contact the Institutional Review Office at 206.667.5900 with exemption or IRB application questions.**

1. This document satisfies AAHRPP elements I-9, II.2.A, II.2.B, II.2.C, II.3.F, II.4.A, II.5.A [↑](#footnote-ref-1)
2. AAHRPP Tip Sheet 18: Review of Research involving Prisoners and the Role of the Prisoner Representative. [↑](#footnote-ref-2)
3. RCW Chapter 42.48: Washington "state agency" records means records from: (a) The department of social and health services; (b) the department of corrections; (c) the department of health; or (d) the department of children, youth, and families. [↑](#footnote-ref-3)