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|  | Diagram  Description automatically generated | **FORM - Research Assessment** |

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| --- | --- | --- | --- |
| **Date:** |  | | |
| **FHIRB # (if submitting in Hutch IRB):** |  | | |
| **RG #:** |  | **Protocol #:** |  |
| **Fred Hutch Researcher:** |  | | |
| **Person completing this form:** |  | | |
| **Project Title:** |  | | |
| **Similar/Related studies or projects:** |  | | |

Have you consulted with anyone in the IRO about this research? Who and when?

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***Note:*** *This form is only used for individuals whose primary appointment is at Fred Hutch. If your primary appointment is at UW or Seattle Children’s, or any other institution, please contact your institution’s IRB for assistance.*

*The intent of this form is to help the person most familiar with the planning and development of a project to decide whether or not the project is research under federal regulations and Washington state law. You may keep this form for your records if you determine your project does not meet the regulatory definition of research.* ***If you are unsure whether your project meets the regulatory definition of research, you may submit this form to the IRO for our opinion.***

***Human research protection regulations and the Fred Hutch Human Research Protection Program (HRPP) do not require that non‑research activities receive IRB approval or determination.*** *However, you may need confirmation from the Institutional Review Office (IRO) that the project is not research for other reasons, for example: a.) the Fred Hutch Finance Department needs verification in order to release funds if you are compensating individuals for their involvement in non-research activities, or b.) for submission to a journal for publication. To obtain a formal determination from the IRO that your activity is not research, please complete this form and attach it to your submission in the Hutch IRB electronic system. This form can be submitted as the “protocol” in Hutch IRB.*

**If you have filled out this form, and the conclusion is that the project qualifies as research, you MUST submit the research to the appropriate IRB and receive a final written determination before research activities may begin. (The only exception is a Not Human Research project using only sources on the IRB’s** [Pre-Reviewed Sources of De-identified Human Specimens and/or Data](https://extranet.fredhutch.org/u/irb/submissions-to-the-irb/research-not-involving-human-subjects.html#prereviewed) **list.) For help in determining whether Fred Hutch is the right IRB, see the** [**Selecting the Right IRB**](https://extranet.fredhutch.org/u/irb/selecting-the-right-irb.html) **webpage. If you need assistance in selecting the appropriate IRB application form at Fred Hutch, please contact** [**iro@fredhutch.org**](mailto:iro@fredhutch.org)**.**

THE FEDERAL POLICY FOR THE PROTECTION OF HUMAN SUBJECTS - COMMON RULE - 45 CFR 46 Subpart A

Please complete the following questions to assess whether the proposed activity involves research under the federal Common Rule. Fred Hutch generally applies the Common Rule to all research activities. There are other scenarios that may not be research. For guidance, see the IRB [Is It Research?](https://extranet.fredhutch.org/u/irb/submissions-to-the-irb/is-it-research.html) webpage.

1. Is this activity limited to scholarly or journalistic activity, such as oral history, journalism, biography, literary criticism, legal research, or historical scholarship, including the collection and use of information, that focuses directly on the specific individuals about whom the information is collected? [45 CFR 46.102(l)(1)]

Yes ® **Stop.** This activity is not research as defined by the Common Rule. Proceed to Question 7.

No ® Continue to Question 2.

1. Is this a public health surveillance activity, including the collection and testing of information or biospecimens that meets both the following criteria?

* Is conducted, supported, requested, ordered, required, or authorized by a public health authority, AND
* Is limited to activity necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters). [45 CFR 46.102(l)(2)]

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| A [*public health authority*](https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/is-recipient-public-health-authority/index.html) means an agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate. |

Yes ® **Stop.** This activity is not research as defined by the Common Rule. Proceed to Question 7.

No ® Continue to Question 3.

1. Is this activity limited to collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes? [45 CFR 46.102(l)(3)]

Yes ® **Stop.** This activity is not research as defined by the Common Rule. Proceed to Question 7.

No ® Continue to Question 4.

1. Is this activity limited to authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions? [45 CFR 46.102(l)(4)]

Yes ® **Stop.** This activity is not research as defined by the Common Rule. Proceed to Question 7.

No ® Continue to Question 5.

When answering Question 5 and Question 6, consider the following:

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| Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. [45 CFR 46.102(l)] |

1. Is this activity a “systematic investigation”?

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| A *systematic investigation* is an activity that involves a prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a question. |

Yes ® Continue to Question 6.

No ® This activity is not considered research as defined by the Common Rule. Proceed to Question 7.

1. Is this activity designed to develop or contribute to “generalizable knowledge”?

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| *Generalizable knowledge* means the information is expected to expand the knowledge base of a scientific discipline or other scholarly field or study and yield one or both of the following:   * Results that are applicable to a larger population beyond the site of data collection or the specific subjects studied (e.g., beyond Fred Hutch and Fred Hutch patients). * Results that are intended to be used to develop, test, or support theories, principles, and statements of relationships, or to inform policy beyond the study. |

Yes ® This activity is research as defined by the Common Rule. Proceed to Question 7 if you also want to assess whether the research may be an FDA-regulated clinical trial.

No ® This activity is not considered research as defined by the Common Rule. Proceed to Question 7.

FOOD AND DRUG ADMINISTRATION REGULATIONS - 21 CFR 50, 21 CFR 56, 21 CFR 312, and 21 CFR 812

Please complete the following questions to assess whether the proposed activity may be a clinical investigation under FDA regulations. For assistance with FDA regulatory requirements, it is highly recommended you contact the Cancer Consortium’s Clinical Research Support [Regulatory Affairs](https://www.cancerconsortium.org/research-support/clinical-research-support/regulatory-affairs.html).

1. Does this activity involve a “test article”?

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| A *test article* is any drug for human use, biological product for human use, medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the Federal Food Drug and Cosmetic Act or under Sections 351 and 354-360F of the Public Health Service Act (42 U.S.C. 262 and 263b-263n). [21 CFR 50.3(j), 56.102(l)] |

Yes ® Continue to Question 8.

No ® Continue to Question 8.

Not sure 🡪 If you are uncertain whether a test article is involved in an activity, please contact Clinical Research Support at [regulatoryaffairs@fredhutch.org](mailto:regulatoryaffairs@fredhutch.org). Proceed to Question 8.

1. Is this activity a “clinical investigation” involving a “drug” or “biologic product”?

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| A clinical investigation means any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. For the purposes of this part, an experiment is any use of a drug **except for the use of a marketed drug in the course of medical practice. [21 CFR 312.3(b)]**  A drug means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement. [21 USC 321(g)(1)]  A biologic product means any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention, treatment or cure of diseases or injuries of man |

Yes ® Continue to Question 9.

No ® Continue to Question 9.

Not sure ® If you are uncertain whether a drug is involved or whether the activity meets the definition of a clinical investigation, please contact Clinical Research Support at [regulatoryaffairs@fredhutch.org](mailto:regulatoryaffairs@fredhutch.org). Proceed to Question 9.

1. Is this activity an “investigation” involving a “device” or “biologic product” regulated as a medical device?

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| An investigation means a clinical investigation or research involving one or more subjects to determine the safety or effectiveness of a device. [21 CFR 812.3(h)]  Device (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:  (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,  (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or  (3) intended to affect the structure or any function of the body of man or other animals, and  which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 360j(o) of this title. [21 USC 321(h)] |

Yes ® Continue to Question 10.

No ® Continue to Question 10.

Not sure ® If you are uncertain whether a device is involved or whether the activity meets the definition of an investigation, please contact Clinical Research Support at [regulatoryaffairs@fredhutch.org](mailto:regulatoryaffairs@fredhutch.org). Proceed to Question 10.

1. Does the activity involve one or more “human subjects”?

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| A *human subject* under FDA regulations means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient. [21 CFR 50.3(g), 56.102(e)] |

Yes ® This activity is likely research as defined by the FDA. Proceed to Question 11 if you also want to assess whether the activity is research under Washington State law.

No ® This activity is likely not considered research as defined by the FDA. For confirmation that a project that involves FDA-regulated products is not a clinical investigation, please contact Clinical Research Support at [regulatoryaffairs@fredhutch.org](mailto:regulatoryaffairs@fredhutch.org). Proceed to Question 11.

WASHINGTON STATE LAW – RCW 42.48

Please complete the following questions to assess whether the proposed activity is research under Washington State law. The definition of research at RCW 42.48 applies only to certain records. Consider the following:

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| Research means the activity is a planned and systematic sociological, psychological, epidemiological, biomedical or other scientific investigation carried out by a state agency, by a scientific research professional associated with a bona fide scientific research organization, or by a graduate student currently enrolled in an advanced academic degree curriculum, with an objective to contribute to scientific knowledge, the solution of social and health problems, or the evaluation of public benefit and service programs. This definition excludes methods of record analysis and data collection that are subjective, do not permit replication, and are not designed to yield reliable and valid results. [RCW 42.48.010(4)] |

1. Does the activity involve individually identifiable personal records maintained by a state agency (e.g., electronic medical records maintained by UW Medicine)?

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| *Individually identifiable* means that a record contains information which reveals or can likely be associated with the identity of the person or persons to whom the record pertains. [RCW 42.48.010(1)]  *Personal record* means any information obtained or maintained by a state agency which refers to a person and which is declared exempt from public disclosure, confidential, or privileged under state or federal law. [RCW 42.48.010(3)]  *State agency* means any of the following:   * Washington State Department of Social and Health Services * Washington State Department of Corrections * Washington State Department of Health * Washington State Department of Children, Youth, and Families (formerly the Department of Early Learning) * Public institution of higher education, including:   + University of Washington   + Washington State University   + Western Washington University   + Central Washington University   + Eastern Washington University   + The Evergreen State College   + Public community colleges and technical colleges [RCW 42.48.010(6) and RCW 28B.10.016] |

Yes ® Continue to Question 12.

No ® **Stop.** This activity is not considered research as defined by Washington State law.

1. Does the activity use methods of records analysis and data collection that are subjective, do not permit replication, and are not designed to yield reliable and valid results?

Yes ® **Stop.** This activity is not considered research as defined by Washington State law.

No ® Continue to Question 13.

1. Is the activity a planned and systematic sociological, psychological, epidemiological, biomedical or other scientific investigation with an objective to contribute to scientific knowledge, the solution of social and health problems, or the evaluation of public benefit and service programs?

Yes ® This activity is research as defined by the Washington State law.

No ® **Stop.** This activity is not considered research as defined by Washington State law. Proceed to section **Activity Information** below if you plan to submit this form to the IRO.

ACTIVITY INFORMATION

Fill out this section if you plan to submit this form to the IRO. You may also fill out this section and keep the form for your records.

1. **Please attach a memo** describing your project briefly and providing rationale for your decision that this does not involve research.
2. Objectives. Describe the purpose, specific aims, or objectives that will be met by this specific project. If hypotheses are being tested, describe them:

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1. Please provide a one-sentence description of this activity:

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1. Inclusion. Who will be involved in the project? How are they selected and recruited?

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1. Will individuals be paid or otherwise compensated? For example, reimbursement of travel expenses or time required to be involved in the activity.

Yes ® Respond to Questions 18.a. – 18.d.

No

18.a. What is the amount and type of compensation (e.g., cash, services, etc.)?

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18.b. Will this amount be prorated?

Yes → Describe the payment schedule below:

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No

18.c. What is the reason for compensation?

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18.d. What is the expiration (last day the program can provide the incentive to participants)?

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