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| --- | --- | --- | --- |
| **Date:** |  | | |
| **FHIRB #:** |  | | |
| **RG #:** |  | **Protocol #:** |  |
| **Principal Investigator:**  *(Fred Hutch researchers only)* |  | | |
| **Study Title:** |  | | |

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|  | Diagram  Description automatically generated | **FORM - Not Human Research Determination** |

INSTRUCTIONS

* **Use this form ONLY if the research consists solely of obtaining and using data or specimens from some source other than the participants** (for example, it is a medical records review project or a study on leftover biospecimens).
  + Do not use this form if this is a collaborative research project and the overall project is non-exempt human subjects research. Instead, consider first whether Fred Hutch’s portion of the project would “engage” the institution in the research. See Section 3 of [*IRB Policy 1.14* *Determining when Activities are Research or Research Involving Human Research Participants*](https://extranet.fredhutch.org/en/u/irb/policies-and-procedures/_jcr_content/leftParsys/download_8/file.res/Determining-Human-Research.pdf)(015) and the OHRP guidance on [Engagement of Institutions in Human Subjects Reseach](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html). **Please consult with** [**IRO@fredhutch.org**](mailto:IRO@fredhutch.org) **in this context.**
  + If after completing this form, you determine this project does not meet the criteria for a Not Human Research determination, use [*HRP-251 - FORM - IRB Application (No Contact)*](https://extranet.fredhutch.org/en/f/irb/irb-application.html) instead.
  + If you will interact with subjects, use [*HRP-250 - FORM - IRB Application (Contact)*](https://extranet.fredhutch.org/en/f/irb/irb-application.html) instead, for example if this project involves consenting participants to collection of biospecimens, or if it involves overseeing sites that interact directly with participants.
* This form is used in conjunction with Hutch IRB to submit a new study to the Fred Hutchinson Cancer Center IRB.
* **Answer all questions. Use non-technical language as much as possible.**
* **NOTE: Do not convert this Word document to PDF.** The ability to use “tracked changes” is required in order to modify your study and respond to screening requests.

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[1. Not Human Research Criteria](#_Toc125624080)

[2. Research Design](#_Toc125624081)

1. Not Human Research Criteria

Please complete the following questions to help determine if the proposed research activity involves human subjects under DHHS/OHRP guidance:

* 1. Does this research **only** involve de-identified human information or biospecimens obtained from a provider on the list of IRO Pre-reviewed Sources (e.g., ATCC, dbGaP, CHTN)? *Complete list can be found at the following link:*  <https://extranet.fredhutch.org/en/u/irb/submissionstotheirb/research-not-involving-human-subjects.html>

Yes → **STOP**.

Research using **only** human information or biospecimens from IRO Pre-reviewed Source(s) source(s) is presumptively considered Not Human Subjects and does not need to be reviewed separately by the IRB.

No → Continue.

* 1. Is there any possibility that you could make a link to the identity of an individual even if you are using coded information?

Yes  No

* 1. Will any other investigator collaborating with you on this research be able to identify any human subject directly or indirectly through coding systems (this does not include the provider of the information or biospecimens if they are only providing data or specimens and they are prohibited by regulation, policy, agreement, or contract from releasing the identifiers to you)?

Yes  No

* 1. Will the activity involve the use of a drug other than the use of a marketed drug in the course of medical practice?

Yes  No

* 1. Will the activity involve determining the safety or effectiveness of a medical device (e.g., an *in vitro* diagnostic assay)?

Yes  No

* 1. Will the information or biospecimens support the marketing of an FDA regulateddrug/biologic/device?  
     *(Note: If the research is conducted under an IND or IDE, this answer would be “yes”)*

Yes  No

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| **Not Human Subject Determination - IRB Submission Instructions:**  **If you answered “Yes”** to any question 1.2 through 1.6 above, the proposed study is Research Involving Human Subjects.  Please submit the appropriate Application for Review. If you need assistance selecting the appropriate application, please contact [IRO@fredhutch.org](mailto:IRO@fredhutch.org).  **If you answered “No”** to questions 1.2 through 1.6, please complete the flow chart below to confirm the Not Human Research Criteria are met. |

**1.** Does the research study exclusively involve the use of human information, cells, or biospecimens obtained from IRO Pre-reviewed Source (e.g., ATCC, dbGaP, CHTN)?

**NO**  **YES**

**2.** Will you have interaction or intervention with living individuals involved in the past or future collection of the biospecimens/information?

2. Is interaction

**STOP – This activity is NOT Human Research and no IRO submission is required.**

**YES**

**STOP. This is Human Subjects Research.** Use the appropriate Application for Review instead.

**NO**

**3.** Can you or any member of your research team link the biospecimens/information directly, or through a coding system, to identifiable information about living or deceased individuals?

**YES**

**NO**

**This activity is NOT Human Research, but you must submit to IRO to confirm the determination.**

**NO**

**4.** Consider the provider of the biospecimens/information. Can the provider link, directly or indirectly, to identifiable information about living or deceased individuals?

**YES**

**5.** Is the provider involved in conducting the research? For example, will they collaborate with you on activities related to this research (other than just providing biospecimens or information)?

***NOTE: To check “No” overall for this box, you must be able to answer “No” to all of the following questions:***

1. Are you returning data to the provider?  **Yes**   **No**
2. Is the provider involved in study interpretation or analysis of the data resulting from the coded information/specimens?  **Yes**   **No**
3. Will the provider share authorship of presentations or manuscripts related to the research?  **Yes**  **No**

**YES**

**YES**  **NO**

**NO**

1. Can you confirm **and document** that the provider will never disclose to you the identities of the individuals to whom the biospecimens/information pertain? Examples include:
   * The key to decipher the code is destroyed before the research begins; or
   * The research team and the holder of the key to the code enter into an agreement preventing the release of the key to the team members under any circumstances (e.g., a data use and/or material transfer and use agreement); or
   * There are IRB-approved written policies in place preventing the provider from releasing the key to the team members under any circumstances; or
   * There are other legal requirements prohibiting the release of the key under any circumstances.

1. Research Design

2.1 Describe your research plan in detail. Use non-technical language. You may attach a separate scope-of-work document or protocol.

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2.2 What are the objectives that will be met? If this information is clearly described in a separate protocol or scope of work document, reference the specific page(s) where applicable:

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2.3 What are the study’s sources of biospecimens and/or participant information (e.g., medical records, other studies, a repository, etc.)? Provide name, address, institution/company, and a brief description of what information and/or biospecimens will be provided from each source.

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| --- | --- | --- | --- |
| **Name** | **Address** | **Institution/Company** | **Description** |
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For public or medical record sources, or from sources on the [IRB Pre-Reviewed Sources of De-identified Human Specimens and/or Data](https://centernet.fredhutch.org/cn/u/irb/submissionstotheirb/research-not-involving-human-subjects/_jcr_content/leftParsys/download_f2c7/file.res/Pre-Reviewed-Sources-De-identified-Human-Specimens.pdf): You do not need to attach any other documentation about these sources.

For all other sources: You must submit supporting documentation (e.g., a gatekeeper letter, material or data transfer agreement, contract, etc.) from the provider of the information and/or biospecimens. The documentation should acknowledge your use of the information and/or biospecimens for this specific project and should confirm consent was appropriately obtained or waived for future research use.

Important Notes:

1. Receiving information and/or biospecimens from outside your home institution may require a material transfer or data use agreement (MTA/DUA). Fred Hutch researchers, review <https://centernet.fredhutch.org/cn/u/business-dev/form-questionnaire.html> or contact Business Development at [MTA@fredhutch.org](mailto:MTA@fredhutch.org) for more information. UW researchers, contact the Agreements Group at [mta-group@uw.edu](mailto:mta-group@uw.edu).
2. If this project involves the use of information and/or biospecimens that are covered by a Certificate of Confidentiality (CoC), you should be aware the CoC protections extend to the information and/or biospecimens permanently. When you receive such biospecimens or data, you are obligated to uphold the disclosure restrictions. For example, data from an NIH repository such as dbGaP or biospecimens and/or data collected or generated by another research project covered by a Certificate of Confidentiality.

2.3.a Are there any restrictions on the research uses for the information and/or biospecimens (e.g., they may not be transferred from your institution to another researcher, or no genetic testing is allowed on the samples)?

Yes → Please explain:

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No

2.3.b Will the study’s biospecimens include human fetal tissue?

Yes → Provide information about where the tissue is obtained and attach an attestation (from the provider or third-party supplier) that informed consent was obtained at the time of tissue collection.

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No

2.3.c Does this study involve the use or destruction of embryonic stem cells?

Yes → Provide information about where the stem cells are obtained (e.g., NIH-approved cell line).

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No

2.4 Provide a list of all specific data points available in this research at Fred Hutch (e.g., age, diagnosis status, biomarker data, etc.). You can provide the list below, or indicate a page of the protocol where this is described, or attach a separate document or the data collection instrument that will be used to record the de-identified information.

As a reminder, if you can link the biospecimens or information in your proposed research directly or indirectly to identifiable data available at Fred Hutch, this would be considered Human Subjects Research.

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