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|  | Diagram  Description automatically generated | **FORM - Repository or Registry Supplement** |

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

Use this form when establishing a local repository, registry, or data bank. For the definition of a repository, please see <https://extranet.fredhutch.org/en/u/irb/glossary.html#repository>.

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| **Gatekeeper Name:** |       |

*Above, you must list the name and role of the person(s) or group who will be the “gatekeeper” for the stored information and/or biospecimens. The gatekeeper is the person or group ultimately responsible for assessing all requests for information and/or biospecimens to ensure the requests meet the parameters of the IRB approval of this repository/registry. The gatekeeper must also verify that the research projects requesting access to the materials in this repository/registry have obtained appropriate IRB approval.*

1. What information and/or biospecimens will be collected and stored for future use in or sharing with other research projects (including both your own future projects and any sharing with other researchers)?

[ ]  Whole blood

[ ]  Buffy coats (lymphocytes) or other blood derivatives (e.g., serum, blood clots)

[ ]  Establishment of permanent cell lines

[ ]  Tumor samples

[ ]  Data/Information from medical records

[ ]  Other sources of DNA/RNA/etc. Specify:

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[ ]  Other. Specify:

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1. Identify the source of the information and/or biospecimens going into the repository.

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1. List all identifiable information that will accompany the biospecimens, data or medical records (e.g., name, date of birth, address, etc.), and provide justification for the need to maintain identifiers.

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1. If a code is used to link subject identity to their data/specimens, explain how the code is derived and describe where the key to the code is secured and who will have access to it.

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1. Where will the database/repository physically be located?

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1. Does the foundational informed consent document(s) used when originally collecting the information and/or biospecimens address the collection and storage for future analysis/use?

[ ]  Yes → The consent document includes a clear description of

* the operation of the repository/database;
* the specific types of future research to be conducted;
* the conditions under which information and/or biospecimens may be released to recipient-investigators;
* procedures for participant withdrawal from the repository; and,
* procedures for protecting the privacy of participants and maintaining the confidentiality of data.

[ ]  No → Explain:

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1. Describe in detail the process that the gatekeeper will use.

7.a How will the gatekeeper receive requests to release information and/or biospecimens from the repository?

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7.b How will decisions be made about which requestors will be provided information and/or biospecimens from the repository?

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7.c How will the gatekeeper confirm the requestor has appropriate IRB approval or an IRO determination (e.g., Not Human Research or Exempt determination) that allows the appropriate use of the information and/or biospecimens from this repository?

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1. Describe the processes for preparing the information and/or biospecimens for release to requestors or to other research projects. If the information and/or biospecimens will be de-identified, coded or anonymized, describe the process.

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1. State how long the repository/database will exist and how the information and/or biospecimens will be destroyed.

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1. Describe the security measures used to maintain the confidentiality of the stored information and/or biospecimens.

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1. Additional documentation required:

11.a Are you planning to release information and/or biospecimens within the Cancer Consortium?

[ ]  Yes → Submit a copy of the template confidentiality pledge that each recipient will be required to complete before they can receive materials from the repository. For a model pledge, to go <https://extranet.fredhutch.org/en/f/irb/model-repository-access-confidentiality.html>.

[ ]  No → Go to 11.b.

11.b Are you planning to release information and/or biospecimens outside the Cancer Consortium?

[ ]  Yes → You will be required to obtain a Data Use Agreement or Materials Transfer Agreement before you can release information and/or biospecimens to investigators outside the Cancer Consortium.

* Fred Hutch researchers, review <https://centernet.fredhutch.org/cn/u/business-dev/form-questionnaire.html> or contact Business Development at MTA@fredhutch.org for more information.
* UW researchers, contact the Agreements Group at mta-group@uw.edu.

[ ]  No

12. Ongoing documentation requirements for recipients of materials from this repository/registry:

You must keep a listing of recipients and research projects who receive information or biospecimens from this repository or registry. You must also maintain a copy of each confidentiality pledge, MTA, or other similar document, signed by an Investigator accessing the repository or registry. If the study is subject to a continuing review, the list of recipients and copies of completed confidentiality pledges or MTAs must be submitted with each continuing review.

[ ]  I acknowledge

If you plan to use the information and/or biospecimens from this repository in specific research projects, IRB approval for these research projects should be obtained under *separate* IRB submissions (except where you have specific approval by the IRB for research to be conducted under this repository file).

[ ]  I acknowledge