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|  | Diagram  Description automatically generated | **FORM: Consent Supplement** |

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

Use this supplement to request a waiver of consent, an alteration of consent, and/or a waiver of the consent signature requirement.

☞ **Complete only the sections you need. Leave the other sections blank.**

I’m requesting the following type(s) of waiver(s):

[ ]  [Section A](#_Section_A_—): Waiver of Consent

[ ]  [Section B](#_Section_B_—): Alteration of Consent

[ ]  [Section C](#_Section_C_—Waiver): Waiver of Documentation of Consent (waiver of the signature requirement)

[ ]  [Section D](#_Section_D_—): Waiver of Consent for Screening, Recruiting, or Determining Eligiblity (only for studies first approved before 01/21/2019)

Special circumstances:

For research involving public benefit and service programs conducted by or subject to the approval of state or local officials, please contact our office for assistance.

For research with funding from the Department of Justice (DOJ), please contact our office for assistance.

# Section A — Waiver of Consent

☞ **Only complete this section if you are requesting a waiver of consent for activities other than screening (see** [**Section D**](#_Section_D_—) **for screening waivers).**

1. For what aspects of the study are you requesting the waiver of consent?

[ ]  All aspects of the research: **Full waiver** of consent

[ ]  Only certain aspects of the research or specific cohorts: **Partial waiver** → Explain:

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1. Describe why the research, or aspects of the research, involve no more than minimal risk to participants (only minimal risk activities qualify for a waiver):

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1. Describe why the waiver of informed consent will not adversely affect the rights and welfare of the participants:

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1. Describe why the study activities could not practicably be carried out without the requested waiver:

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1. Describe whether participants (or legally authorized representatives, if applicable) will be provided with additional pertinent information after screening:

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1. If the research involves using identifiable private information or identifiable biospecimens, describe why the research could not practicably be carried out without using such information or biospecimens *in an identifiable format*.

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Note: If you are accessing individual protected health information (e.g., medical records) without having the participant sign a HIPAA authorization, please also complete [*HRP-257 - FORM - HIPAA Supplement*](https://extranet.fredhutch.org/en/f/irb/hipaa-supp-waiver-authorization.html)*.*

# Section B — Alteration of Consent

☞ **Only complete this section if you are requesting an alteration of consent:** Approval to leave out or change some of the required [elements of consent](https://extranet.fredhutch.org/en/u/irb/informed-consent.html) during your consenting process.

1. Which specific elements of consent are you requesting to leave out or change? (Review <https://extranet.fredhutch.org/en/u/irb/informed-consent.html> to learn about the elements of consent.)

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1. Describe why the research involves no more than minimal risk to participants (only minimal risk activities qualify for an alteration of consent):

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1. Describe why the alteration of consent will not adversely affect the rights and welfare of the participants:

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1. Describe why the study activities could not practicably be carried out without the requested alteration:

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1. Describe whether participants (or legally authorized representatives, if applicable) will be provided with additional pertinent information after participation:

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1. If the research involves using identifiable private information or identifiable biospecimens, describe why the research could not practicably be carried out without using such information or biospecimens *in an identifiable format.*

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# Section C — Waiver of Documentation of Consent

☞ **Only complete this section if you are requesting a waiver of documentation of consent (waiving the signature requirement only).** This means you are seeking approval for a process in which the [elements of consent](https://extranet.fredhutch.org/en/u/irb/informed-consent.html) are provided in written format and consent is obtained, but the participant does not sign a consent form.

For which aspects of the study are you requesting a waiver of the signature requirement?

[ ]  All aspects of the research

[ ]  Only certain aspects or cohorts in the research → Explain:

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**☞ Only select one option below.**
Note:If your study is FDA regulated, only the first option is possible.

[ ]  Option 1: The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

OR

[ ]  Option 2: All of the following are true, and the study is not FDA-regulated:

* The consent document would be the only record that would link the participant and the research; and
* The principal risk would be potential harm resulting from a breach of confidentiality; and
* Each participant or legally authorized representative will be asked whether the participant wants documentation linking the participant with the research.

OR

[ ]  Option 3: All of the following are true, and the study is not FDA-regulated and the study was approved on or after January 21, 2019:

* The participants will be members of a distinct cultural group or community in which signing forms is not the norm; and
* The research presents no more than minimal risk of harm to participants; and
* There is an appropriate alternative mechanism for documenting that informed consent was obtained.

Describe the distinct cultural group or community in which signing forms is not the norm, and the alternative mechanism for documenting consent.

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Note: If you are accessing individual protected health information (e.g., medical records) without having the participant sign a HIPAA authorization, please also complete [*HRP-257 - FORM - HIPAA Supplement*](https://extranet.fredhutch.org/en/f/irb/hipaa-supp-waiver-authorization.html)*.*

# Section D — Waiver of Consent for Screening, Recruiting, or Determining Eligiblity

☞ **Only complete this section if your research was first approved by the IRB before January 21, 2019, and you are requesting a waiver of consent related to screening, recruiting, or determining eligibility.**

The January 21, 2019 cut-off means your study was approved under the “pre-2018 Common Rule” requirements. If you are unsure whether this applies to your research, or if your file has undergone *de novo* review, please contact our office for help in assessing whether this type of waiver is relevant to the research. Studies first approved after January 21, 2019, do not require a waiver for gathering information for screening, recruiting, or determining eligibility

This waiver only applies to gathering of information, not to physical procedures such as a blood draw or ECG to determine eligibility.

1. Describe the screening activities you would like to do before obtaining consent:

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1. Describe why the screening activities involve no more than minimal risk to participants (only minimal risk activities qualify for a waiver):

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1. Describe why the waiver of consent for screening will not adversely affect the rights and welfare of the participants:

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1. Describe why the study screening activities could not practicably be carried out without the requested waiver or alteration:

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1. Describe whether participants (or legally authorized representatives, if applicable) will be provided with additional pertinent information after screening:

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Note: If you are accessing individual protected health information (e.g., medical records) to determine eligibility without having the participant sign a HIPAA authorization, please also complete [*HRP-257 - FORM - HIPAA Supplement*](https://extranet.fredhutch.org/en/f/irb/hipaa-supp-waiver-authorization.html).