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|  | Diagram  Description automatically generated | **FORM - Consent Process Exception Request**  |

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| --- | --- |
| **Date:** |       |
| **FHIRB #:** |       |
| **Study Title:**  |       |
| **Site Name**, if applicable: |       |
| **Principal Investigator** (or site PI): | First Name:       | Middle Initial:       | Last Name:       |

Instructions

* Fred Hutch [IRB Policy 2.11 Informed Consent](https://extranet.fredhutch.org/en/u/irb/policies-and-procedures.html#informed) (Appendix A) presumes that the Principal Investigator, MD sub‑investigators, and attending physicians with the requisite health care provider credentials will obtain informed consent, especially for high-risk interventional trials. For lower risk trials, the policy outlines other roles that are presumptively qualified to conduct consent discussions. Prospective IRB approval is required for any deviations to this policy.
* To request a **consent process exception,** complete this form in its entirety to request permission for individuals who are not presumptively qualified per the IRB policy guidelines to conduct the informed consent process.
* **Answer all questions**, except when directed to follow a skip pattern. If a question is not applicable to the research, state “N/A”. If you do not answer a question, the IRB does not know whether the question was overlooked or whether it is not applicable. This may result in unnecessary “back and forth” for clarification.

Table of Contents

[**1. Consent Process Exception Request**](#_Toc173745265)

[**2. Required Attachments**](#_Toc173745266)

[**3. PI Acknowledgement and Signature**](#_Toc173745267)

1. Consent Process Exception Request

This study or participating site is requesting an exception to the consent process expectations, specifically who can conduct consent discussions, as outlined in Appendix A of [IRB Policy 2.11 Informed Consent](https://extranet.fredhutch.org/en/u/irb/policies-and-procedures.html#informed).

* 1. Provide detailed justification for this request. Specify why the IRB should consider this exception, in the context of this protocol being conducted at this site.

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* 1. Will the PI or sub-investigator with MD credentials be readily available for a more in-depth medical discussion with the potential participant upon request?

[ ]  Yes → Provide a description of this process:

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|       |

[ ]  No → Provide an explanation:

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|       |

1.3 For each exception requested, complete the table below. To include more than one individual, unlock the form to duplicate the table.

|  |  |
| --- | --- |
| **Individual’s Name and Role:** |       |
| Degrees/credentials: |       |
| Summary of **qualifications** of the proposed candidate obtaining consent: |       |
| Summary of relevant **training** for conducting consent discussions: |       |
| Summary of relevant **experience** for conducting consent discussions (include description of the study complexity for which consent has been obtained): |       |
| Has the individual been trained, or will they be trained, on this specific protocol? Describe.  |       |
| OPTIONAL: Any additional details you would like to provide.  |       |

2. Required Attachments

**[ ]** Current *Curriculum Vitae* or resume for the specific individuals proposed to conduct consent but who fall outside of the IRB’s policy guidelines.

[ ] Documentation of training or other attachments for these specific individuals.

*If submitting this form on behalf of an institution outside the Fred Hutch/University of Washington/Seattle Children’s Cancer Consortium, also attach:*

[ ]  The institution’s relevant SOPs related to consent training and/or who can conduct consent. Alternatively, include a document describing of how consent is normally conducted at this institution and by whom.

[ ]  Documentation of Human Subjects Training completed in the last three years for each of the individuals proposed to conduct consent but who fall outside the IRB’s policy guidelines.

3. PI Acknowledgement and Signature

As the lead Principal Investigator (PI) or site PI (as applicable), or as the designated proxy for this study/site, I provide assurances for the following:

A. All of the information provided in this submission is complete and correct;

B. The PI/site PI will conduct this research in accordance with requirements in *HRP-103 - Investigator Manual*.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|       |  |  |  |       |
| Name of Investigator or Designee\* |  | Signature of Investigator or Designee\* |  | Date |

[ ]  \*I am signing this form as a designee. By checking this box, I affirm the PI (or site PI) is aware of this submission and has given me permission to submit on their behalf. I will save documentation of the PI’s/site PI’s permission to submit this form.