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|  | Diagram  Description automatically generated | **FORM - International Research Performance Site Assessment Supplement** |

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

If a performance site is located outside the United States, please respond to the following questions to the fullest extent possible. This information will assist the IRB in its review of the unique ethical considerations that may apply to the study being conducted at a foreign performance site.

1. Will the investigator be collaborating with local people or groups (e.g., researchers, universities, community leaders, etc.)?

[ ]  Yes → Describe.

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[ ]  No

1. Will participants be compensated?

[ ]  Yes → Describe the compensation and explain how the compensation being offered is appropriate for the local setting.

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[ ]  No

1. Will the study site likely encounter low literate or illiterate participants?

[ ]  Yes → What plans are in place to make accommodations for this?

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[ ]  No

1. What is the primary language(s) in the region(s) where the research will be conducted?

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1. Are the investigators who will be interacting with subjects fluent in the primary language of the subjects?

[ ]  Yes

[ ]  No → Describe the steps that will be taken to ensure that subjects and investigators are able to communicate with each other:

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1. Will the consent be translated into the local language(s)?

[ ]  Yes → Describe how you will ensure participant understanding of the research and that participation is voluntary.

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[ ]  No → Explain why the consent document will not be translated into the local language.

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[ ]  N/A → There is a full waiver of consent for this study.

1. Will you collect specimens and retain these specimens for future research?

[ ]  Yes → Can a participant change his/her mind about allowing specimens for future research and remain in the study?

[ ]  Yes → Explain how the study ensures that the specimens are withdrawn from the repository if requested by a study participant.

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[ ]  No

[ ]  No

1. Is this study also being reviewed by a local ethics committee familiar with the laws/ethical codes that might apply to the country?

[ ]  Yes → Describe this review.

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[ ]  No

1. Thoroughly describe the local laws and regulations, including the cultural norms for research (such as age of majority, who may provide consent or permission for a family member to participate in research, for example) the IRB should consider in its review of the study being conducted at a foreign site.

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1. Export Controls: Will this research be conducted in a country subject to U.S. sanctions or embargo?

See <https://centernet.fredhutch.org/cn/u/ethics-compliance-program/export-control.html> for a current list of comprehensively sanctioned countries.

[ ]  Yes → Consult with the Compliance Office at intl-compliance@fredhutch.org for a review of the proposed study. Describe the outcome of your consultation below:

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[ ]  No

1. Does the research involve taking electronic data collection tools (e.g., laptops, iPads, and their associated technology) and/or other study materials and equipment to the foreign site, **or** storing data on a public cloud?

[ ]  Yes → Consult with the Compliance Office at intl-compliance@fredhutch.org for a review of the tools, materials and equipment to ensure compliance with export control regulations. Describe the outcome of your consultation below:

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[ ]  No

1. Are there country or region-specific data protection laws (e.g., the European Union’s GDPR, China’s PIPL, or South Africa’s POPIA) in place that may affect the research process?

[ ]  Yes → Do you have regulatory support in country to advise you on these data protection laws?

[ ]  Yes → Describe.

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[ ]  No → Contact intl-compliance@fredhutch.org and provide the outcome of your consultation below:

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[ ]  No

[ ]  Don’t know → Contact intl-compliance@fredhutch.org and provide the outcome of your consultation below:

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