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Date of Proposal Submission: Click or tap to enter a date.

**Please return completed proposals to** [**vtn.research@hvtn.org**](mailto:vtn.research@hvtn.org)

*There must be at least 1 HVTN Investigator on the Project Team. The HVTN MOP section on auxiliary studies defines an HVTN Investigator as “any scientific staff member who is paid through a DAIDS cooperative agreement, grant, or contract for HVTN research.”*

**Project Team**

|  |  |  |  |
| --- | --- | --- | --- |
| Name  *please add an asterisk at the end of name(s) of the lead investigator(s)\** | Email address | Select ‘S’ for specimens and ‘D’ for data, for each person who will be using them. | HVTN Investigator?  (X=Yes) |
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**Lead Investigator’s Institution:** Click or tap here to enter text.

**What is being requested?**

*Requests must be for existing data, specimens, and/or reagents as described in the parent protocol(s):*

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| --- | --- |
| Participant data | Choose an item. |
| Participant specimens | Choose an item. |
| Reagents derived from study samples (e.g. plasmids) | Choose an item. |

***Important information regarding requests for specimens and/or data:***

* Data and specimens from ongoing clinical trials are generally not provided for auxiliary studies until the main objectives of the trial is complete. Data and specimen availability from ongoing trials are dependent on the discretion of the protocol team and HVTN Executive Management Team.
* Data and specimens from HVTN 705 are subject to the Imbokodo auxiliary studies process including an additional review by and a legal agreement with Janssen. More information can be found at: <https://www.hvtn.org/scientific-programs/scientific-programs-overview/hvtn-trials/hvtn-705-hpx2008-imbokodo-exploratory-ancillary-studies-rfp.html>
* All specimens and some data collected at African sites are covered by legal agreements required by their countries, (such as material transfer agreements (MTAs) or data transfer agreements (/DTAs). All specimens from Brazil are covered by MTAs. Requests for these specimens/data will require amendment of existing agreements and/or initiation of new ones, which may take 2-6 months or more. HVTN Regulatory Affairs will manage the process and will inform the proposal investigator of this requirement.
* Documentation of IRB/EC approval or determination that the work is not human subjects research is required from each institution at which the proposed work with HVTN specimens will be conducted. Specimens cannot be provided/used until after this documentation is sent to HVTN Regulatory Affairs. We will contact proposal investigators to request this and any other required information after the proposal completes the scientific approval process.
* Study proposals requesting specimens and/or data from sites outside of the US may require additional approvals before specimens/data can be provided/used. Before initiating the work of obtaining the approvals, HVTN Regulatory Affairs will discuss with proposal investigators and relevant sites the required approvals and the estimated timelines to obtain them. If a local regulatory approval is needed and the site has no funds to pay the submission fee, the proposal investigator will need to either pay the fee or drop the site’s specimens/data from their request. The proposal investigator would also need to pay for annual approval renewal for the life of their study. Investigators interested in specimens/data from sites outside the US are encouraged to contact in advance of proposal submission to inquire about the potential timeline for receiving such specimens/data. It generally takes 2-6 months to obtain these regulatory approvals but can take longer.
* Specimen requesters will be responsible for covering international shipment costs.

Background and Rationale

*Study rationale, relevant background information, implications of prior research, anticipated contribution of proposed study to HVTN research agenda (if any), and to the HIV vaccine field in general.*

Click or tap here to enter text.

Proposed study

Study hypotheses and objectives

1. *The primary hypotheses*

Click or tap here to enter text.

1. *The major study objectives and endpoints needed to achieve those objectives*

Click or tap here to enter text.

Study design/methods

*Outline the study design, including, as appropriate, details regarding:*

1. *Type of study (e.g., analysis of existing data; cross-sectional data analysis; new laboratory assays with existing stored specimens)*

Click or tap here to enter text.

1. *Outcomes to be measured*

Click or tap here to enter text.

1. *Sample size*

Click or tap here to enter text.

1. *Brief analysis plan*

Click or tap here to enter text.

* 1. *Specify any laboratory work or statistical analyses that will be done in the Core Laboratory or at the SDMC*

Click or tap here to enter text.

Study Deliverables

*Please describe plan for publication and/or presentation. Describe any reports that will be provided to the HVTN.*

Click or tap here to enter text.

Requested specimens, data and/or analysis

*Please contact* [*vtn.research@hvtn.org*](mailto:vtn.research@hvtn.org) *if you require assistance from the HVTN in completing this section.*

*Provide a detailed description of specimens/data required and assays/analyses to be conducted. Please specify the following:*

1. *Protocol(s)*

Click or tap here to enter text.

1. *Time point(s) or visit(s)*

Click or tap here to enter text.

1. *Treatment group(s)*

Click or tap here to enter text.

1. *For specimens, provide an overview of assays to be conducted*
   1. *Specimen type; minimum volume/number of cells requested*

Click or tap here to enter text.

* 1. *Provide a more detailed description of assay(s) to be conducted (e.g., drug assays, immunologic and virologic tests).*

Click or tap here to enter text.

* 1. *Provide inclusion or exclusion criterion for sample selection (e.g., participants with positive responses, females only).*

Click or tap here to enter text.

* 1. *Indicate what sample metadata will be required (e.g., treatment assignment, demographics, HLA type)*

Click or tap here to enter text.

1. *For study data, provide a detailed analysis plan including the data being requested as specifically as possible. Include the following when describing the request:*
   1. *Type of data (e.g., assay, clinical, survey)*

Click or tap here to enter text.

* 1. *Sample size and variables needed*

Click or tap here to enter text.

* 1. *Power calculations for primary objectives (if appropriate)*

Click or tap here to enter text.

* 1. *If a specific format for the data is required (e.g., SAS transfer file)*

Click or tap here to enter text.

Resources

HVTN Resources

*Please describe the level of HVTN involvement or support needed for this project. Items include specimen lists, laboratory assays, dataset preparation, analysis plan development and/or statistical analysis assistance.*

Click or tap here to enter text.

**If requesting specimens**, please list the name(s) of the Project Team member(s) who will use the specimens, the lab(s)/institution(s) at which the work with specimens will be conducted, and the location(s) of the lab(s)/institution(s):

|  |  |
| --- | --- |
| Project Team member 1 who will use specimens: | Click or tap here to enter text. |
| Lab/Institution: | Click or tap here to enter text. |
| Address of lab/institution: | Click or tap here to enter text. |

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| Project Team member 2 who will use specimens: | Click or tap here to enter text. |
| Lab/Institution: | Click or tap here to enter text. |
| Address of lab/institution: | Click or tap here to enter text. |

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| Project Team member 3 who will use specimens: | Click or tap here to enter text. |
| Lab/Institution: | Click or tap here to enter text. |
| Address of lab/institution: | Click or tap here to enter text. |

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| Project Team member 4 who will use specimens: | Click or tap here to enter text. |
| Lab/Institution: | Click or tap here to enter text. |
| Address of lab/institution: | Click or tap here to enter text. |

Version History

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