Auxiliary Study Proposal

**PLEASE NOTE:**

* If you are updating your proposal from the original submission, **use tracked changes** and include updates in section 7 (Version History).
* **Do not delete** any sections from this form.
* If there is specifically formatted information you wish to include (e.g., tables), you may insert additional pages outside of the formatted sections below.
* **Return** **completed proposals to** vtn.research@hvtn.org
1. **Study Summary**

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| **Title of Proposed Study**  |  |
| **Date of Proposal Submission**  | Click or tap to enter date. |
| Type of Study e.g., analysis of existing data, cross-sectional data analysis, or laboratory assays with existing stored specimens |  |
| **Brief background and rationale for the proposed study**  |  |
| **Study Aims with Outcomes to be Measured** |  |
| **Deliverables (**if applicable**)**e.g., data sharing, publications, and/or presentations of findings (including the HVTN) |  |
| **Public Posting**Please describe if you plan to post data to any public databases (e.g., GenBank, ImmPort, CAVD DataSpace, etc.) |  |
| **Urgency of Request**If you have a specific timeline within which you need to receive specimens/data, please indicate that here and provide the rationale (e.g. funding ending, grant/abstract deadline, presentation forum/date). [Click here](https://www.hvtn.org/scientific-programs/scientific-programs-overview/auxiliary-studies.html) for process details. |  |

1. **Submission and Regulatory Considerations – Please Read**
	1. Data and specimens from ongoing clinical trials are generally not provided for auxiliary studies until the main objectives of the trial are complete. Data and specimen availability from ongoing trials are dependent on the discretion of the protocol team and HVTN Executive Management Team.
	2. Requests for 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. All HVTN 705 requests must be on an Imbokodo proposal template. Please reach out to vtn.research@hvtn.org for the appropriate template.
	3. 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. When a site that requires MTA/DTAs is no longer funded or is closed, it may not be possible to meet the country’s legal requirements and thus those specimens/data cannot be shared by the HVTN.
	4. 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.
	5. 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. When a site that requires additional approvals is no longer funded or is closed, it may not be possible to meet the country’s legal requirements and thus those specimens/data cannot be shared by the HVTN ***Investigators interested in specimens/data from sites outside the US are encouraged to contact us 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.***
	6. Specimen requesters will be responsible for covering international shipment costs.

Contact vtn.research@hvtn.org with any questions.

1. **Project Team**
	1. The project team must include at least 1 HVTN Investigator (any scientific staff member paid through a DAIDS cooperative agreement, grant, or contract for HVTN research).
	2. List project team members who will access data or specimens or be otherwise involved in the study. Anyone not listed is not permitted to use the requested data/specimens.
	3. Regulatory approval times depend on numerous factors (the number of studies, study locations, and other considerations). It may be ideal to use data from a subset of study sites, limit the number of institutions to have access to raw international data, or collaborate directly with Fred Hutch/SCHARP/SDMC for data analysis. See “Submission and Regulatory Considerations” section above.
	4. ESI: Early-Stage Investigator

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| Name | Email | Institution | What type(s) of investigator are you?HVTNLeadESI | How will you be interactingwith the data and/or specimens? | Will you have access to participant level data? (only complete if requesting data) | Date added to project team |
|  |  |  |[ ] [ ] [ ]  Choose an item. |[ ]  Enter Date |
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1. **Data Request**
	1. Review the HVTN protocols to help you assess what you need for each request. Reach out to the HVTN investigator for assistance, if needed.
	2. Fully complete the table for each request with as much detail as possible.

**Table Definitions**

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| Column | What to Enter |
| Protocol Number | The parent HVTN protocol number(s) |
| Study Data Requested | Broad category of dataset you need – *clinical data, assay data, survey data,* etc. |
| Data Domain Requested (CRF data-only) | Specific domain (e.g*., Demographics, Adverse Events, Reactogenicity, Social-impact questionnaires*). |
| Dataset Criteria | e.g., sample size, visit number, treatment groups, female participants, etc. |
| Requested Format | Clinical Data: SAS file (Preferred file type), Upon request: Excel (.xlsx), CSV Assay data: CSV file |

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| --- | --- | --- | --- | --- |
| Protocol Number | Study Data Requested(e.g., assay data, clinical data, survey data) | Data Domain Requested(CRF data-only) | Dataset Criteria | Requested Format |
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1. **Specimen Request (if only requesting data, skip this section)**
	1. Review the HVTN protocol(s) to help you assess what you need for each request. Reach out to the HVTN investigator for assistance, if needed.
	2. Fully complete the table for each request with as much detail as possible.
	3. If requesting PBMC, state the number of FROZEN cells you need to have sufficient cells after thawing, assuming average 80% recovery.

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| Protocol Number | Specimen type(e.g., serum, plasma, PBMC, mucosal swab) | Visit number(s) requested | Preferred specimen volume or number of cells\* | Minimum specimen volume or number of cells | Specimen Selection Criteria(e.g., treatment groups, specific lab outcomes, specific demographics, etc.) | Planned Assay/ Analysis |
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**\***PBMCs are generally stored at 15 million per vial. Please inquire.

* 1. Please provide the name(s) and lab address(es) of the person who will be responsible for receiving the samples:

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| --- | --- | --- | --- |
| Name | Lab Address | Phone Number | Email |
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1. **Study Plan and Design**

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| **Assay and platform** **(**complete if requesting specimens**)**e.g., microbiome testing via 26S rRNA sequencing |  |
| **Brief Analysis Plan** **(**complete if requesting data and/or specimens**)**Describe outcomes and any comparisons made |  |
| **Data Analysis Support**Please indicate if you are anticipating needing support from the HVTN SDMC for data analysis. If so, we suggest you consult an SDMC statistician and add them to the Project Team in Section 3. Contact aux.sdmc@hvtn.org to discuss further. |  |

1. **Version History**

|  |  |  |
| --- | --- | --- |
| **Version** | **Date** | **Changes Made** |
| v1 | Enter Date | Original submission to the Auxiliary Studies Committee. |
| Choose an item. | Enter Date |  |
| Choose an item. | Enter Date |  |
| Choose an item. | Enter Date |  |
| Choose an item. | Enter Date |  |

1. **For Regulatory Use Only**

Sites/Countries to be Excluded: