INSTRUCTIONS: All sections of this template must be completed by investigators wishing to propose studies that require data and/or specimens collected under the Imbokodo (HVTN 705/HPX 2008) protocol. Send completed proposals to imbokodo@hvtn.org for review. Additional details about the proposal submission process can be found at [hvtn.org/imbokodo-rfp](http://www.hvtn.org/imbokodo-rfp).

PLEASE REVIEW PRIOR TO PROPOSAL DEVELOPMENT: All specimens and some data from the Imbokodo trial are covered by legal agreements, such as material transfer agreements (MTAs) or data transfer agreements (DTAs). Requests for these specimens or data require amendment of existing agreements and/or initiation of new ones: this process may take 2–6 months. Investigators requesting specimens must provide to HVTN Regulatory Affairs the documentation of IRB/EC approval or an institutional determination that the work is not human subjects research or does not need to be reviewed by the institution. HVTN Regulatory Affairs will initiate additional approvals if required at the clinical research sites. A legal agreement between Janssen, the HVTN’s institution [Fred Hutchinson Cancer Center (Fred Hutch)] and the institution of the Lead investigator is also required and is expected to take 2-6 months to execute. Note that an MTA template has been carefully drafted by Janssen and Fred Hutch. To ensure efficient and timely implementation of Imbokodo/HPX2008 Auxiliary Study Proposals, the MTA template has been set up to be applicable and acceptable to multiple institutions and therefore we can only consider and review minor changes that are required to ensure your institution can comply with appropriately referenced applicable laws, regulations, and internal policies. In case of questions on the MTA template, please send inquiries to Imbokodo@hvtn.org. Specimens and data will only be provided to the Lead investigator after approvals and agreements are completed. Any further sharing of the specimens and/or data with Project Team members is governed by the terms of the agreement between Janssen, Fred Hutch, and the Lead investigator’s institution. The Lead investigator’s institution is responsible for Project Team member compliance with the MTA. Results of Imbokodo Study proposals must be reviewed prior to presentation or publication, as outlined in the process workflow document posted at [hvtn.org/imbokodo-rfp](http://www.hvtn.org/imbokodo-rfp).

*<<Insert title of proposed study>>*

**Project Team** *(Please include name, role, & email address for all team members.)*

|  |  |
| --- | --- |
| **Lead Investigator:** |  |
| Institution: |       |
| Phone:  |       | Email: |       |
| **HVTN Investigators:** | Name | Email | Role |
|       |       | [ ]  Use of study specimens[ ]  Use of study data[ ]  Other (no use of data/specimens) |
|       |       | [ ]  Use of study specimens[ ]  Use of study data[ ]  Other (no use of data/specimens) |
| **Non-HVTN Collaborators:** |       |       | [ ]  Use of study specimens[ ]  Use of study data[ ]  Other (no use of data/specimens) |
|       |       | [ ]  Use of study specimens[ ]  Use of study data[ ]  Other (no use of data/specimens) |

# Request type (choose one):

[ ]  Participant specimens only\*

[ ]  Participant data only

[ ]  Both participant specimens & data\*

**\* If requesting specimens**, fully complete the table below.

|  |  |
| --- | --- |
| Name(s) of Project Team member(s) who will use specimens:  |  |
| Institution(s) at which work with specimens will be conducted: |  |
| Shipping address for each lab/institution where specimens will be used: |  |

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# Background/Rationale (Up to 1 page)

*Provide rationale for the proposed study, relevant background information, implications of prior research, anticipated contribution of proposed study to HVTN research agenda (if applicable), and to HIV research in general:*

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# Proposed study details (Up to 2 pages)

1. Study hypotheses and objectives

*Outline the primary hypotheses & the major study objectives and endpoints needed to achieve those objectives:*

1. Study design/methods

*Outline the study design, including details regarding:*

1. *Type of study (e.g., analysis of existing data; cross-sectional data analysis; new laboratory assays with existing stored specimens):*
2. *Outcomes to be measured:*
3. *Sample size:*
4. Study Deliverables

*Please describe plan for data sharing, publication and/or presentation of findings, including estimated timelines for completion of study deliverables:*

1. **Funding Source**

*Please describe the source & status of funding for this proposed study and note any funding timelines or associated requirements for sharing/publishing data:*

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# Requested specimens, data and/or analysis

*Please provide a detailed description of specimens/data required and assays/analyses to be conducted**:*

1. **Cohort/Sample Description**:
	1. **Timepoint(s) or visit(s) required**:
	2. **Applicable treatment group(s)** (e.g., vaccine/placebo, subset of all available, etc.):
	3. **Other participant characteristics** (e.g., cases/controls or specific region):
2. **For study data requests:**
	1. **Provide a detailed description of the data being requested** (type of data, sample size, required variables, desired data format):
	2. **Provide a summary of the analysis plan** (Note: if analysis support is required from HVTN, please describe in Section 6):
3. **For specimen requests**:
	1. **Specimen type and minimum volume/number of cells requested per participant**:
	2. **Provide specific inclusion or exclusion criterion for sample selection** (e.g., for HIV status requirements, indicate whether this applies at time of sampling or final status at end or study):
	3. **Indicate what sample metadata will be required** (e.g., treatment assignment, demographics):
4. **For each assay that will be run using study samples**:
	1. **Provide a detailed description of the assay(s) to be conducted** (including methodology and any relevant publications):
	2. **Describe the level of assay qualification and/or validation** (details can be outlined in table below):

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# Quality Assurance

**Provide an overview of the quality management systems in place at your institution** (or attach relevant documents)

1. Type of quality system (e.g., GLP/GCLP/CLIA/Not applicable):
2. Overview ofdata/specimen management systems, equipment maintenance plans, data security plans, etc.:
3. Assay performance characteristics (enter “N/A” for any items that are not applicable):

|  |  |
| --- | --- |
| **Assay Name/Type** *(e.g., Intracellular Cytokine Staining/Flow Cytometry)* |      |
| **Assay Status** (choose one, and provide explanation, if necessary) | [ ]  **In development:** Assay not yet designed/optimized with reagents/controls; has variation in methodology on day-to-day basis.[ ]  **Developed:** Assay designed and optimized with appropriate reagents/controls; may have some variation in methodology on day-to-day basis.[ ]  **Standardized:** Assay conducted per a standardized operating procedure (SOP) for which all technicians must read and document their understanding. No methodology variation is allowed, and SOP must list all steps, reagents, and equipment and be maintained with formal document management and comply with industry standard requirements for SOPs. [ ]  **Qualified:** Assay conducted per an SOP, with assessment of the FDA-indicated parameters for bioanalytical method validation (specificity, precision, accuracy, linearity, limit of detection and limit of quantitation). No pre-set pass/fail criteria for each parameter. [ ]  **Validated:** Assay conducted per an SOP, with pass/fail criteria pre-set for all FDA-indicated parameters for bioanalytical method validation (specificity, precision, accuracy, linearity, limit of detection and limit of quantitation). A validation report describes the results and indicates whether the pass/fail criteria were met for each parameter.  |
| **Assay Limits** *(Provide LOD, LLOQ, ULOQ)* |      |
| **Linear Range** |      |
| **Dilution Linearity** |      |
| **Specificity** |      |
| **Selectivity** |      |
| **Repeatability** *(Lower, mid, and high-quality controls)* |      |
| **Reproducibility** *(Lower, mid, and high-quality controls)* |      |
| **Sample Stability** *(Summarize long term, freeze-thaw, and benchtop stability)* |      |
| **Reagent Info** *(Summarize critical reagents, bridging, reagent stability and robustness testing)* |      |
| **Other** *(Any other relevant information you wish to provide)* |      |

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# Additional HVTN Support

*Please describe the level of HVTN involvement or support needed for this project (e.g. specimen lists, laboratory assays, dataset preparation and/or data transfer management, analysis plan development, statistical analysis assistance).*

NOTE: *Request fulfillment is dependent on HVTN resource availability.*

1. **HVTN Lab Center Support:**

*Specify any laboratory work that is requested from HVTN Central Laboratories:*

1. **HVTN Statistical & Data Management Center (SDMC) support:**

*Specify any support you will require for data management and/or statistical analysis:*