Imbokodo (HVTN705/HPX2008)
Request for Proposals (RFP) Process Workflow

Contents

Purpose

This document provides an overview of the process to request specimens and/or data collected from participants enrolled in the HVTN705/HPX2008 (Imbokodo) clinical trial. The HIV Vaccine Trial Network (HVTN) and Janssen are committed to making data and specimens available to external researchers through this process, which is managed by the Imbokodo Exploratory and Ancillary Study Management Group (Imbokodo SMG). Additional details, including the Imbokodo Study Proposal Template, can be found at hvtn.org/imbokodo-rfp .

Primary Contributors

Liz Briesemeister, HIV Vaccine Trials Network (HVTN) Regulatory Affairs
Mary Gross, HVTN Laboratory Center
Laura Pattacini, Janssen Clinical Immunology
April Kaur Randhawa, HVTN Statistical & Data Management Center
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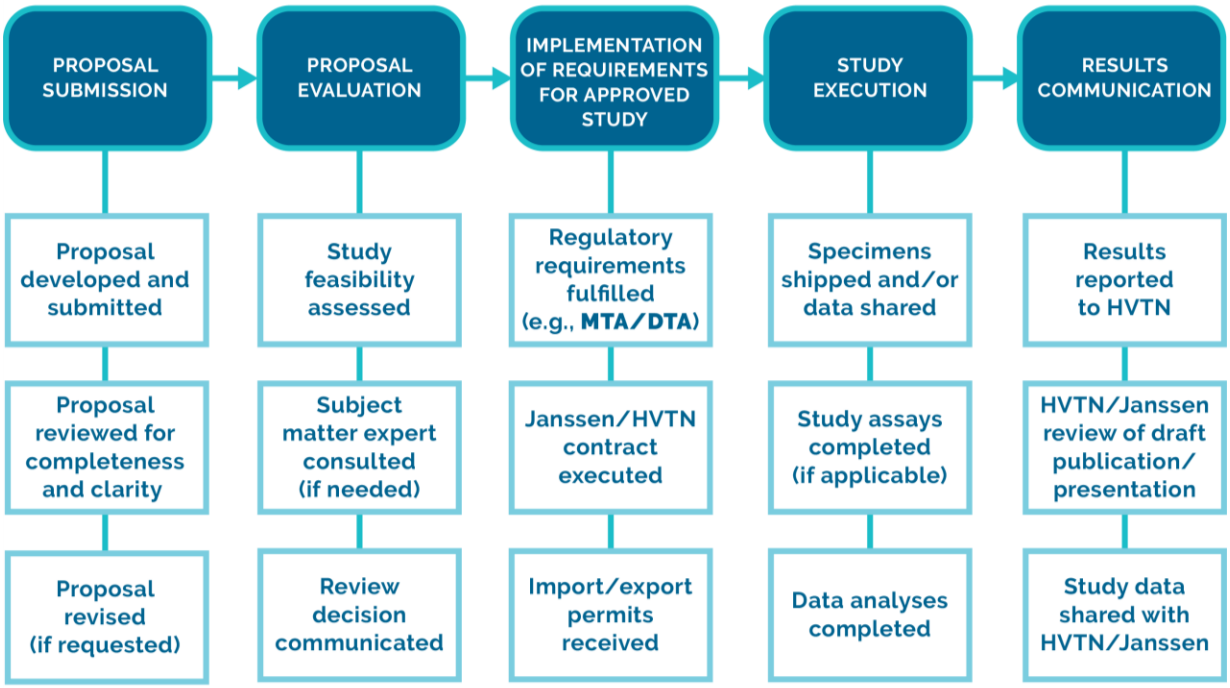
Imbokodo (HVTN 705/VAC89220HPX2008)
Exploratory & Ancillary Studies Process

Overview



1. Proposal submission

1.1. HVTN, NIH/NIAID/DAIDS, and Janssen Vaccines and Prevention will jointly issue a Request for Proposals (RFP), including a description of available samples, and a link to submit proposals using the Imbokodo Study Proposal Template. This information will be posted on hvtn.org/imbokodo-rfp.

1.2. Proposal Investigator(s) complete the Imbokodo Study Proposal Template (Appendix III) and submit via email to imbokodo@hvtn.org. Investigators that initiate discussions about proposals via other channels will be directed to complete the Imbokodo Proposal Template and submit to SMG via email.

1.3. Submissions and inquiries will be managed by the Imbokodo Exploratory & Ancillary Study Management Group (SMG).The SMG will perform an initial review of proposals to check for completeness and will work with Proposal Investigator(s) to revise information as needed for proposal evaluation.

2. Proposal evaluation

2.1. The SMG and the HVTN Auxiliary Studies Committee (ASC) will complete a feasibility assessment, including review of specimen availability, comparison with similar proposals, and determination of whether Subject Matter Expert (SME) consultation is required. In some cases, the SMG will request a meeting with proposal investigators and/or SME to discuss proposal details and outstanding questions.

2.2. The SMG will compile comments and questions that arise during the feasibility assessment and send to the Proposal Investigator(s). The Proposal Investigator(s) must

address all comments via email or study proposal updates before the proposal can be submitted to the Review Committee.

2.3. The SMG will send the finalized proposal, along with a summary of the feasibility assessment to the Review Committee via email. The review committee includes the Imbokodo Protocol Team Leadership and Oversight Group (OG) members (see Appendix II for full membership list).

2.4. The Review Committee will share their questions, comments, and recommendations by email (approve as-is, approve with modifications, modify and resubmit, or reject). Required Approvers (indicated in Appendix II) must provide feedback in writing by email. A meeting may be required to discuss further (e.g., if there is disagreement or if further clarification is needed). In these cases, the Study Management Group can assist with setting up a teleconference.

2.5. The SMG will record Approver decisions in Imbokodo Proposal Tracking Sheet, inform Proposal Investigator(s) of the decision, and communicate applicable next steps for proposal implementation.

3. Implementation of requirements for approved studies

3.1. HVTN Regulatory Affairs will email the Proposal Investigator(s) and all Project Team members listed in the proposal to inform them of the regulatory requirements to be completed (including contracting with Janssen, MTA/DTA updates, etc.) before specimens and data can be shared.

3.2. Janssen Legal team will set up two-way legal agreements between Proposal Investigator(s) and Janssen Vaccines and Prevention. Janssen Legal team will send completed agreements to the SMG.

3.3. Upon approval decisions for the initial round of proposals following the RFP, HVTN Regulatory will initiate all required MTA/DTA requests for the proposals in the batch at the same time.

NOTE: MTA/DTA timelines are approximately 2–3 months for specimens/data originating from clinical research sites in the Republic of South Africa (RSA), and 6 months or longer for other sites.

3.4. HVTN Regulatory will track completion of all regulatory requirements, including Janssen's legal agreement, and upon completion of the final requirement for a proposal, notifies the Imbokodo SMG, HVTN SDMC, and HVTN Laboratory Center (LC) that data and/or specimens may be shared with Investigators.

3.5. <u>For specimen requests</u>:

3.5.1. HVTN SDMC facilitates specimen selection, if applicable.

3.5.2. HVTN LC works with BARC repository to obtain export permits to ship specimens out of RSA. Generally, receiving labs will also need to have an active import permit for specimens to ship into their respective country.

NOTE: RSA export permits timelines are approximately 3 months after the RSA MTA is amended.

3.5.3. Once regulatory & contracting requirements are completed, and export permits have been obtained (if applicable), HVTN LC initiates specimen requests from BARC repository, if applicable.

NOTE: only after receiving notification from HVTN Regulatory Affairs that all regulatory requirements have been completed and specimens and/or data can be shared.

4. Study Execution

4.1. HVTN LC works with labs to develop & share Lab Study Plans, if applicable (e.g., when assays are being run by an HVTN lab with established SDMC data management/analysis pipelines.)

4.2. For data requests and proposals requesting analysis support, HVTN SDMC implements data transfer plans and/or analysis plans as applicable, based on proposal requirements.

4.3. HVTN SDMC shares data with Study Investigator(s) , if applicable

4.4. Once data/specimens are received by Proposal Investigator(s), the study may proceed as agreed upon. If questions or concerns arise during conduct or analysis of the study, the Proposal Investigator is responsible for contacting the SMG.

5. Communication of Study Results

5.1. Proposal Investigator(s) must submit a study report to imbokodo@hvtn.org that includes a summary/abstract, description of study design, laboratory/statistical methods, results, and conclusion/discussion. It is also acceptable to submit draft manuscripts. The study report/draft manuscript is sent to the Imbokodo Study Management Group, for distribution to protocol team leadership and Janssen Medical Affairs for review; reviewers are expected to send comments within 30 business days.

NOTE: Study reports are required to be submitted prior to any publication or presentation of results.

5.2. If applicable, Proposal Investigators submit conference abstracts to imbokodo@hvtn.org so that they may be circulated to stakeholders for review; reviewers are expected to send comments within 10 business days.

5.3. Proposal Investigator(s) must inform Study Management Group when results are published, by emailing imbokodo@hvtn.org.

5.4. Proposal Investigator(s) share final analysis datasets by submitting to HVTN SDMC (further instructions will be provided to study investigators for approved proposals; datasets should not be emailed).

Appendix I: Acronyms & Definitions

Approvers	Members of the Imbokodo exploratory/Ancillary Study Review Committee and the Imbokodo Exploratory and Ancillary Study Management Group. This group is responsible for reviewing RFPs and assisting applicants with their proposals.
ASC	HVTN Auxiliary Studies Committee: the HVTN team that oversees review and execution of exploratory and ancillary studies for all HVTN protocols. This committee is managed by the HVTN LOC and includes members from the HVTN LOC, SDMC, and LC.
BARC	Bio Analytical Research Corporation South Africa, a location at which clinical trial specimens are stored in a repository
DTA	Data Transfer Agreement
FHCC	Fred Hutchinson Cancer Center
HVTN	HIV Vaccine Trials Network
Imbokodo Exploratory & Ancillary Study Management Group (SMG)	Comprised of members of the HVTN LOC, HVTN SDMC, HVTN LC, and representatives from Janssen (see Appendix IV for membership list).
Janssen Compound Development Team (CDT)	Comprised of the compound development team lead and members from the following areas: Regulatory Affairs, Clinical Development, Legal, Market Access, CMC (Chemistry, Manufacturing and Controls), Biomarkers, Preclinical, Statistics, Global Medical Safety, Statistics, and Project management.
LC	HVTN Laboratory Center: PI Dr. Julie McElrath leads the HVTN LC, which is comprised of centralized HVTN Immunology Endpoint Laboratories located at the FHCC, at Duke University, Dartmouth University, the Cape Town HVTN Immunology Laboratory (CHIL), and the National Institute for Communicable Diseases (NICD), along with other affiliated specialty testing, diagnostic, and specimen processing laboratories. A dedicated Laboratory Operations unit headquartered at FHCC also oversees the quality of HVTN-associated laboratories.
LOC	HVTN Leadership & Operations Center
MTA	Material Transfer Agreement
OG	Oversight Group (defined in Appendix II)
Proposal Investigator(s)	The researcher(s) who are applying for use of specimens or data from the Imbokodo protocol; these individuals are responsible for completing the study proposal and conducting the study according to regulatory and contractual agreements.
Review Committee	The group of individuals responsible for administering a decision regarding the acceptance or rejection of an RFP. This group is composed of the Imbokodo Protocol Team Leadership and the Imbokodo Oversight Group. Specific contacts are listed in the appendices of this document.
RFP	Request for Proposal
RSA	Republic of South Africa
SDMC	HVTN Statistical & Data Management Center
SME	Subject Matter Expert

Appendix II: Contact information

A. Imbokodo Exploratory/Ancillary Study Management Group

HVTN LOC	HVTN Regulatory Affairs	Vtn.core.reg@hvtn.org
	Nicole Na	nna@fredhutch.org
HVTN SDMC	April Kaur Randhawa	arandhaw@fredhutch.org
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Janssen Medical Department	Ludo Lavreys	Llavrev1@its.jnj.com

B. Imbokodo Exploratory/Ancillary Study Review Committee

Imbokodo Protocol Team Leadership		
Chair	Glenda Gray	ggray@fredhutch.org
Co-chairs	Kathy Mngadi	kmngadi@auruminstitute.org
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	*Frank Tomaka	ftomaka@its.jnj.com
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	John Hural	jhural@fredhutch.org
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Imbokodo Oversight Group**		
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Larry Corey	lcorey@fredhutch.org	
Nina Russell	Nina.Russell@gatesfoundation.org	
Susan Barnett	Susan.Barnett@gatesfoundation.org	
Peter Gilbert	pgilbert@fredhutch.org	
Mary Marovich	mary.marovich@nih.gov	
*Maria Pau	MPau@its.jnj.com	

**Active review required*

***Not including members who are also part of Protocol Team Leadership*