



MATRIX Clinical Trials Hub Procedure: Protocol Chair Selection

Standard Operating Procedure (SOP)#: CTH003, Version 1
Effective Date: 03/22/2023

1.0 Purpose:

1.1 To establish and describe the procedures for selecting Protocol Chairs and/or Co-Chairs to lead implementation of the MATRIX (Microbicide R&D to Advance HIV Prevention Technologies through Responsive Innovation and eXcellence) Collaborative’s clinical research protocols.

1.1.1 Involvement of Global South partners in clinical study leadership as either Protocol Chairs or Co-Chairs will be actively encouraged and supported.

2.0 Scope:

2.1 This procedure is applicable to all clinical research protocols (active and/or placebo product) implemented within MATRIX.

3.0 Authority:

U.S. Agency for International Development (USAID)
U.S. President's Emergency Plan for AIDS Relief (PEPFAR)
U.S. Food & Drug Administration (FDA)
Microbicide R&D to Advance HIV Prevention Technologies through Responsive Innovation and eXcellence (MATRIX)

4.0 References: (Check for the most up-to-date version of the following)

- 4.1** 2 CFR Part 200 *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards*
- 4.2** 22 CFR Part 225 *Protection of Human Subjects*
- 4.3** USAID Automated Directives System (ADS) Chapter 201 ... *Program Cycle Operational Policy*
- 4.4** USAID ADS Chapter 303 *Grants and Cooperative Agreements to Non-Governmental Organizations*
- 4.5** ICH E6 Standard *Good Clinical Practice (GCP)*

4.6	MATRIX Policy	<i>Good Documentation Practice (GDP)</i>
4.7	MATRIX Policy	<i>Human Subjects Research</i>
4.8	MATRIX List of Definitions	
4.9	Attachment #1	<i>Protocol Chair Solicitation Email (sample)</i>
4.10	Attachment #2	<i>Protocol Chair Selection Voting Ballot (template)</i>
4.11	Attachment #3	<i>Protocol Chair Responsibilities Guidance (template)</i>

5.0 Definitions:

See *MATRIX List of Definitions*.

6.0 Responsibilities:

6.1 Clinical Trials Hub Co-lead Principal Investigators (PI)

- 6.1.1** Provide general oversight of Protocol Chair/Co-Chair selection process.
- 6.1.2** Moderate discussion of Protocol Chair/Co-Chair expectations during the call to delineate Protocol Chair/Co-Chair responsibilities that takes place following the Chair selection announcement.

6.2 MATRIX Prime Program Manager

- 6.2.1** Manage communications/logistics related to Protocol Chair/Co-Chair selection process:
 - 6.2.1.1** Solicit interest from Protocol Team members in nominating either themselves or a qualified colleague to lead implementation of their planned clinical research study (see Attachment 1 for sample solicitation email).
 - 6.2.1.2** Collect materials from applicant investigators and notify MATRIX leadership of interested applicants.
 - 6.2.1.3** Request addition of Protocol Chair Selection vote to Steering Committee (SC) call agenda.
 - 6.2.1.4** Distribute materials from applicant investigators to SC members.
 - 6.2.1.5** Collect Protocol Chair/Co-Chair selection votes and, if applicable, “abstain” declarations from SC members.
 - 6.2.1.6** Notify MATRIX leadership of voting totals.

- 6.2.1.7** Notify Protocol Team and Prime of Protocol Chair/Co-Chair selection decision.
- 6.2.2** Following the Chair selection announcement and in collaboration with Prime colleagues, schedule a 1-hour call to delineate Protocol Chair/Co-Chair responsibilities.
 - 6.2.2.1** Call invitees will include the newly selected Protocol Chair/Co-Chairs, the MATRIX Executive Director or Deputy Director, the Clinical Trials Hub co-lead PI, the MATRIX Clinical Research Manager(s) (CRM), the MATRIX Prime Program Manager, and the Product Developer PIs.
 - 6.2.2.2** Guidance regarding expectations and workload will be provided to call invitees prior to the call (see Attachment 3 for Protocol Chair Responsibilities Guidance template).
- 6.2.3** Save all Protocol Chair/Co-Chair application materials, voting ballots, and other relevant documentation according to MATRIX's Good Documentation Practice (GDP) Policy.

6.3 MATRIX Protocol Team Members

- 6.3.1** Individual members will either self-nominate or nominate a colleague as Protocol Chair/Co-Chair for their planned clinical research study by emailing their application to the MATRIX Prime Program Manager.
 - 6.3.1.1** Nominees should include their CV and a letter of interest summarizing their interest in the protocol, qualifications and experience for the role, and an estimate of the percent effort/time they can dedicate to the role.
 - 6.3.1.2** Nominees' schedules should allow them to devote about 20% effort to the role as well as lead Protocol Team calls, participate in study monitoring/safety calls, and promptly respond to requests/queries from other team members.
- 6.3.2** Provide additional guidance to SC members regarding preferred Chair/Co-Chair characteristics for specific studies during the SC call discussion prior to Chair Selection vote.

6.4 MATRIX Steering Committee (SC) Members

- 6.4.1** Review Protocol Chair/Co-Chair nomination materials from interested investigators prior to scheduled Protocol Chair Selection vote.
- 6.4.2** Discuss merits of applicant investigators during the SC call.
- 6.4.3** Submit voting ballots or, if applicable, "abstain" declarations prior to or after the SC call.

6.5 MATRIX Executive Director and/or Deputy Director

- 6.5.1** Moderate Protocol Chair/Co-Chair selection discussion and voting during the SC call.
 - 6.5.2** Notify MATRIX Prime Program Manager (via email or on a call) of Chair/Co-Chair selection decision.
 - 6.5.3** Notify SC members of Chair/Co-Chair selection decision at next scheduled SC call following the Chair selection vote.
 - 6.5.4** Moderate discussion of Protocol Chair/Co-Chair expectations during the call to delineate Protocol Chair/Co-Chair responsibilities that takes place following the Chair selection announcement.
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7.0 Procedure:

NOTE: Protocol Chair selection always occurs after site selection for all clinical research protocols. Therefore, Protocol Teams are already established and a protocol version 0.1 draft or higher is likely available prior to Chair selection.

7.1 Solicit Protocol Team Member Nominations for Protocol Chair/Co-Chair

- 7.1.1** Once study sites are selected for a clinical research protocol, the MATRIX Prime Program Manager or designee sends an email to the Protocol Team inviting them to participate in the Protocol Chair/Co-Chair nomination process (see Attachment 1 for sample solicitation email).
 - 7.1.1.1** Protocol Teams initially consist of Product Developer representatives, investigators and study coordinators from the newly selected sites, and members of the Clinical Trials and Design to Delivery Hubs.
 - 7.1.1.2** The solicitation email includes the protocol concept or, if available, the protocol version 0.1 draft or higher, and requests that Protocol Team members nominate either themselves or a colleague to lead implementation of the study.
 - 7.1.1.2.1** Self-nominees are instructed to include their current CV and a letter of interest summarizing their interest in the protocol, their qualifications and experience for the role, and an estimate of the percent effort/time they can dedicate to the role.

7.1.1.2.2 Those nominating a colleague are instructed to include their nominee's CV and letter of interest along with their endorsement of the nominee for the position.

7.2 Interested Protocol Team Members Respond to Call for Protocol Chair/Co-Chair

7.2.1 Interested Protocol Team members respond to the call for Protocol Chair/Co-Chair by submitting their own or their nominee's current CV and letter of interest (and endorsement if applicable) via email to the MATRIX Prime Program Manager or designee before the specified deadline.

7.3 Notify MATRIX Executive Director and Deputy Director of Applicant Investigators

7.3.1 Once the deadline for Protocol Chair/Co-Chair nominations is met, the MATRIX Prime Program Manager or designee notifies (via email or on a call) the MATRIX Executive Director, MATRIX Deputy Director and Clinical Trials Hub co-lead PI of which investigators applied for the position.

7.4 Add Protocol Chair/Co-Chair Selection Vote to MATRIX SC Agenda

7.4.1 The MATRIX Prime Program Manager or designee requests (via email or on a call) that "Protocol Chair Selection" be added to the next MATRIX SC meeting agenda and creates a study-specific ballot for the Protocol Chair/Co-Chair selection vote (see Attachment 2 for voting ballot template).

7.5 Distribute Protocol Chair/Co-Chair Selection Review Packet to MATRIX SC Members

7.5.1 The MATRIX Prime Program Manager or designee creates and distributes a packet to all MATRIX SC members via email prior to the next MATRIX SC meeting.

7.5.1.1 The packet includes copies of the protocol concept or, if available, the protocol version 0.1 draft or higher, all nominees' CVs and letters of interest, and one blank Protocol Chair Selection Voting Ballot.

7.5.2 The MATRIX Prime Program Manager or designee then saves a copy of the packet and a record of recipients according to MATRIX's GDP Policy.

7.6 Mitigate Conflicts of Interest (CoI) among MATRIX SC Members

7.6.1 Prior to open discussion, any SC members who are being considered for the position of Protocol Chair or Co-Chair are asked to leave the call and to abstain from voting.

7.6.1.1 SC members with a CoI complete the ballot by checking the "abstain" category, and their vote is listed as "abstain" in the final tally of votes collated by the MATRIX Prime Program Manager or designee.

7.7 Discussion during MATRIX SC Meeting and Voting

- 7.7.1** Discussion by MATRIX SC members takes into consideration each applicant's study-relevant scientific expertise and leadership experience, past performance on previous studies/projects, and ability to dedicate about 20% effort to the role as well as lead Protocol Team calls, participate in study monitoring/safety calls, and promptly respond to requests/queries from other team members.
- 7.7.2** MATRIX SC voting members cast their votes using the provided ballot and submit it to the MATRIX Prime Program Manager or designee via email after the meeting.

7.8 Tally Votes and Establish Consensus

- 7.8.1** The MATRIX Prime Program Manager or designee tallies the ballot votes.
 - 7.8.1.1** Reminder emails will be sent one week after Protocol Chair/Co-Chair selection discussion to all SC voting members who have not yet submitted their ballots.
- 7.8.2** Once a quorum of the ballots has been received, the MATRIX Prime Program Manager or designee emails the results to the MATRIX Executive Director, MATRIX Deputy Director, and Clinical Trials Hub co-lead PI.
 - 7.8.2.1** A voting quorum is defined as having received ballots from a majority of SC members, such that any outstanding ballot(s) would not affect the Protocol Chair/Co-Chair selection results.
 - 7.8.2.2** Quorum requirement may be waived if number of applicant investigators equals the number of Chair/Co-Chair positions needed for the study.
- 7.8.3** The MATRIX Prime Program Manager or designee then saves the completed ballots, tallies and other relevant documentation according to MATRIX's GDP Policy.

7.9 Announce Protocol Chair/Co-Chair Selection Decision

- 7.9.1** Upon receiving confirmation from the MATRIX Executive Director and/or Deputy Director, the MATRIX Prime Program Manager or designee sends an email to the Protocol Team, copying the Prime, notifying them of the voting results.
 - 7.9.1.1** The Protocol Chair/Co-Chair announcement may be included with regular Protocol Team communications sent by the MATRIX Prime Program Manager, e.g., as part of the call agendas sent prior to the weekly Protocol Development Team calls.

7.9.2 The MATRIX Prime Program Manager or designee then saves copies of the email notification according to MATRIX’s GDP Policy.

7.9.3 The MATRIX Executive Director or MATRIX Deputy Director notifies SC members of the voting results at the next scheduled SC call following the Chair selection vote.

7.10 Schedule Call to Delineate Protocol Chair/Co-Chair responsibilities

7.10.1 Following the Chair selection announcement, the MATRIX Prime Program Manager emails the MATRIX Prime staff assigned to schedule calls to request they solicit relevant Protocol Team members’ availability for a 1-hour call to delineate Protocol Chair/Co-Chair responsibilities.

7.10.1.1 This call should take place within two weeks of the Chair selection announcement but no later than final review of the protocol prior to submission to USAID for version 1.0 approval.

7.10.1.2 Call invitees will include the newly selected Protocol Chair/Co-Chairs, the MATRIX Executive Director or Deputy Director, the Clinical Trials Hub co-lead PI, the MATRIX CRM(s), the MATRIX Prime Program Manager, and the Product Developer PI(s).

7.10.1.3 Guidance regarding expectations and workload is added to the call invite prior to the call (see Attachment 3 for Protocol Chair Responsibilities Guidance template).

8.0 Document History

Version / Date Effective	Summary of Changes	Revised by / Approved by
A / [03/22/2023]	Original Release	L. Duran / N. Mgodi / S. Hillier

9.0 Approvals

DocuSigned by:
Luis Duran 7/25/2023

Prime Program Manager Signature
 Signer Name: Luis Duran
 Signing Reason: I am the author of this document
 Signing Time: 7/25/2023 | 8:23:48 AM PDT
 4F4E4A7E27804D9387497FBC68D468A2
 Date (month/day/year)

Clinical Trials Hub Co-Lead PI Signature
 Signer Name: Nyaradzo Mgodi
 Signing Reason: I approve this document
 Signing Time: 7/25/2023 | 1:18:19 PM PDT
 CA2EE955FFE04C83BFE4F075EC10A21E
 Date (month/day/year)

Executive Director's Signature
 Signer Name: Sharon Hillier
 Signing Reason: I approve this document
 Signing Time: 7/25/2023 | 8:28:10 AM PDT
 437BF8C12B1541729992EA42A322B571
 Date (month/day/year)

MATRIX SOP #CTH003, Version 1, Attachment 1
MATRIX Protocol Chair Solicitation Email Sample

NOTE: A Call for Chairs email should include a brief description of the study (referring to an attached protocol concept or draft) and instructions to nominate candidates, including a deadline for responses.

To: [*MATRIX-XXX Protocol Team members*]
Cc: [*MATRIX Prime*]
Subject: Call for Nominations for Protocol Chair/Co-Chair for MATRIX-[*XXX*]

Dear MATRIX colleagues,

I am writing today to request nominations for Protocol Chair/Co-Chair of MATRIX-[*XXX*], [*Insert Study Title*].

This study will [*Insert brief description of primary objective(s), study design, product(s) studied, and product use duration; also study population if not already included in study objective*]. Please refer to the attached protocol [*concept/draft*] for further details about this study.

If you would like to be considered for the position of Protocol Chair or Co-Chair, please nominate yourself by sending your CV and a letter of interest via email to duanl2@mwri.magee.edu, hillsl@mwri.magee.edu, and nmgodi@uz-ctrc.org by close of business [*Insert due date*].

The letter of interest should contain a brief summary of your interest in the protocol, your qualifications and experience for the role, and an estimate of the percent effort/time you could dedicate to the role. You may also nominate a colleague for Chair or Co-Chair. In that case, we ask that you send the nominee's CV and letter of interest along with your endorsement of the nominee for the position. **NOTE:** If selected, Protocol Chair/Co-Chair nominees' schedules should allow them to devote ~20% effort to the role as well as lead Protocol Team calls, participate in study monitoring/safety calls, and promptly respond to requests/queries from other team members.

The MATRIX Steering Committee will review the applications and hold a Protocol Chair/Co-Chair selection vote at its next monthly meeting on [*Insert meeting date*]. Please feel free to contact me if you have any questions.

Best regards,

[*MATRIX Prime Program Manager*]

PROTOCOL CHAIR SELECTION VOTING BALLOT

MATRIX-[XXX]
[Insert Study Title]

(Please RANK your selections below)
1 = First Choice; 2 = Second Choice, 3 = Third Choice, etc.

Protocol Chair/Co-Chairs

_____ [*Insert Candidate A*]

_____ [*Insert Candidate B*]

_____ [*Insert Candidate C*]

_____ [*Insert Candidate D*]

_____ [*Insert Candidate E*]

_____ I abstain from voting due to a conflict of interest.

Voting Steering Committee Member

MATRIX SOP #CTH003, Version 1, Attachment 3
MATRIX Protocol Chair Responsibilities Guidance Template (Version 1)

Responsibilities expected from the MATRIX-[XXX] Protocol Chair/Co-Chairs

The Protocol Chairs/Co-Chairs play a key role in the successful leadership and execution of MATRIX clinical studies. They will provide scientific expertise and operational leadership during the development, implementation, and reporting of the study, as well as assume responsibility for the completion of Protocol Team responsibilities.

Specific duties of the Protocol Chair/Co-Chairs include:

- Leading Protocol Team meetings and calls;
- Leading protocol development (if still ongoing at time of Chair selection);
- Monitoring study implementation across sites;
- Monitoring participants' safety through active membership in the Protocol Safety Review Team (PSRT);
- Establishing study-specific ad hoc working groups within the Protocol Team to complete specific activities, as needed;
- Facilitating final decision making within the Protocol Team to achieve agreement on scientific or operational issues brought before it and, if no agreement can be reached, referring the issue to the MATRIX Prime/Clinical Trials Hub (CTH) for resolution;
- Participating in communications planning for data reviews and results dissemination with Prime/CTH;
- Serving as primary spokesperson in the dissemination of results; and
- Coordinating and leading the writing of abstracts and manuscripts, including overseeing analysis and writing teams during manuscript preparation (e.g., designating writing-team members, reviewing schedules, monitoring progress, and communicating publication plans, as required).

Protocol Development

Typically, study sites are selected within 2 months of receiving the protocol concept from the Product Developer (PD), Protocol Chair/Co-Chair selection occurs within 1 month of site selection, and the protocol reaches Version 1.0 within 6 months of receiving the protocol concept from the PD. Therefore, protocol development and regularly scheduled Protocol Team calls will likely begin prior to Protocol Chair/Co-Chair selection for all MATRIX clinical studies.

Once selected, however, the Protocol Chair/Co-Chairs assumes primary leadership of the protocol development process, if still ongoing at time of Chair/Co-Chair selection. During this time, the Protocol Chair/Co-Chairs will work closely with the protocol writer(s) and other team experts (e.g., clinicians, site staff, laboratory staff, statistical and data management staff, clinical research management staff, etc.) to ensure that all USAID queries and team member feedback are adequately addressed prior to submission of Version 1.0 to USAID for approval.

If the protocol needs to be modified after Version 1.0, the Protocol Chair/Co-Chairs will lead the team in drafting, reviewing, and finalizing any Clarification Memo or Full Version Amendment documents prior to submission to USAID for approval.

Study Implementation

After Version 1.0, the Prime/CTH (and/or PD, if applicable) Clinical Research Manager(s) (CRM) will oversee study implementation. They will review site-specific informed consents, be responsible for Study-Specific Procedures (SSP) manual development, and work closely with the Prime/CTH (and/or PD, if applicable) Statistical and Data Management team and other team members as CRFs are drafted. They will also work with Design to Delivery (D2D) Hub representatives on the team to ensure that all socio-behavioral research (SBR) components are progressing and will be ready in time for implementation.

It would be useful to continue with bi-weekly (or weekly, if needed) Protocol Team calls for team members to touch base, clarify potential implementation issues, discuss pending protocol concerns, and resolve any outstanding queries or requests.

In addition, we have a stellar Prime/CTH team who will serve on study management teams to support the development and implementation of MATRIX clinical study protocols, including:

- Prime/CTH co-leads – Drs. Sharon Hillier and Nyaradzo Mgodzi;
- D2D Hub co-leads – Drs. Leila Mansoor and Ali Minnis;
- Protocol Safety Physicians – Drs. Katie Bunge and Catherine Chappell;
- CRM – Ingrid Macio and Jamie Heggarty;
- Statistical and Data Management – Dr. Leslie Meyn and Tracy Zamborsky; and
- Laboratory Management/QA/QC – Ted Livant and May Beamer.

Study Close-out/Manuscript Development

Protocol Teams will be provided information regarding the projected final participant follow-up visit date for each participating study site and the study overall. After the study is complete, the MATRIX CRM(s) will oversee the study-specific close-out procedures. While the data is being cleaned, many individuals will have ideas for papers/abstracts/etc. It is the responsibility of the Protocol Chair/Co-Chair and CRM(s) to navigate this. The Protocol Chair/Co-Chair is responsible for overseeing analysis and writing teams during manuscript preparation (i.e., designates writing team members, reviews schedules, monitors progress, communicates publication plans, responds to reviewers, and advocates for additional resources, as required).

NOTE: The Protocol Chair/Co-Chairs will need to provide copies of current Curriculum Vitae (CV)/biosketch, Good Clinical Practice (GCP) and Human Subjects Protection (HSP) training certifications, current medical license (if applicable), and complete Financial Disclosure Forms (FDF) per *US 42 CFR 50* (and also per *US 21 CFR 54* if IND study and Chair/Co-Chair is listed on a site FDA Form 1572) as soon as possible after being selected and no later than study start (i.e., first site activation).