

Microbicide R&D to Advance HIV Prevention Technologies through Responsive Innovation and
Excellence (MATRIX)
Prime to USAID Review Process SOP

Original Effective Date: July 2022

Revision Effective Date: N/A

Version: 1.0

PURPOSE

The purpose of this standard operating procedure (SOP) is to define expectations and ensure clarity on the roles and responsibilities related to the review of deliverables created by the Prime or designees within the MATRIX Hubs and shared with USAID for approval prior to implementation.

SCOPE

This procedure applies to all Prime and USAID staff that assist in reviewing project deliverables for the MATRIX award.

The AOR (or alt-AOR if the AOR is unavailable) has the ultimate responsibility for ensuring that all applicable USAID staff follow this SOP while the Executive Director and Deputy Director from the Prime have the responsibility for ensuring all MATRIX implementing partners follow these procedures.

PROCEDURE

1. State and types of deliverables for review

- All documents given to USAID for review will be in their near final state as if ready for implementation or institutional review board (IRB)/independent ethics committee (IEC) review. These documents will be key documents such as protocols, protocol amendments, informed consent forms (ICF), and data collection instruments as well as those outlined within the Substantial Involvement section (A.11.e) of the award. Unless specially requested from the Prime, USAID does not need to review process-related documents. These documents are expected to be fully formed and devoid of any spelling/grammar and formatting errors.
- In some cases (e.g., a completely novel concept or troubleshooting) if the Prime determines an earlier draft of a deliverable will benefit from USAID review, the Prime can send to USAID along with an email clearly specifying the content to be reviewed with reasons why the Prime is asking for an earlier review. In such scenarios, USAID will focus *only* on the specific details/sections/content (not formatting or copy edits) requested by the Prime.

2. Review process

- Before submission to USAID for review, all deliverables will be reviewed and cleared by either the Executive Director and/or Deputy Director from the Prime as it relates to Hub origination. For example, the Executive Director will clear deliverables for early/late stage product development as well as clinical trials hubs while the Deputy Director will clear deliverables for participatory research (D2D), capacity strengthening (CaSE) and business case (BACH) hubs.
- To ensure that a deliverable is ready for USAID review, the Executive Director and/or Deputy Director from the Prime will sign off after reviewing and ‘white gloving’ the document by checking for copy edits (spelling and spelling), clarity, content, context and consistency. To reduce the Prime’s (Executive Director and/or Deputy Director) review burden and assist with ‘white gloving’, the Prime should ensure that all documents submitted by sub-recipients are carefully inspected for copy edits (spelling and spelling), clarity, content, context and consistency by the document authors.

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- Once signed off, the Executive Director and/or Deputy Director will email the deliverable to the USAID Core Project Management Team (cPMT) (Appendix A) and will designate the draft stage of the deliverable (v0.1, 0.2, v1.0 etc. (see section 5 below)), the urgency of the timeline as it relates to the annual approved workplan timelines (high, medium or low (see below section 4 for further details), and any necessary context that would aid the USAID review process.
- The USAID Senior Technical Advisors from cPMT will then shepherd the review process, funneling the deliverable(s) to the appropriate USAID extended project management team (ePMT) members (Appendix A) with a clear review deadline (approximately 7-10 working days).
- The Senior Technical Advisor will clean and collate all feedback and send, with a clear deadline, to either the AOR or alt-AOR for their final review, and for the opportunity to clarify and add any remaining feedback.
- The AOR or alt-AOR will share the feedback with the Prime, copying the cPMT. The Prime Executive Director and/or Deputy Director will channel feedback to the respective Hub/Pillar Co-leads or designees who will incorporate USAID feedback, as needed, and share subsequent revised versions with the Prime and, subsequently, USAID for sign-off and approval, respectively.

3. Response from the Prime to USAID feedback

- Revised deliverables will be returned to USAID with both edits in tracked changes and a clean version.
- If there are questions regarding the feedback provided by USAID, the Prime is welcome to request a meeting with the cPMT for further clarification and the cPMT will work to make themselves available within 5 business days of the meeting request.

4. USAID Receipt of revised deliverable from Prime

- Once a revised deliverable is received by USAID from the Prime, the cPMT Senior Technical Advisors will make a determination as follows:
 - Deliverable is considered final and is filed appropriately with relevant/supporting documents. The AOR/alt-AOR will confirm with the Prime organization that the deliverable is final and that the project management team has no additional feedback.
 - Deliverable requires additional attention. The Senior Technical Advisors may take several actions: **1)** engage relevant ePMT members to provide additional feedback **OR 2)** request a meeting with the Prime and document authors to provide verbal feedback and address any concerns/questions **OR 3)** if USAID's feedback is not appropriately addressed, respond back to the Prime suggesting changes to be made within 5 business days.
- Any deliverable that needs a third review will be flagged and a review process will be initiated to determine how to better streamline the communication. The Prime will send the final version with tracked changes and a clean version to the cPMT for filing, within 3 business days. (Appendix B)

4. Review timeline

- USAID appreciates the need for timely review to support the Prime and implementing partners and will work diligently to adhere to the review timelines.

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- Before sending any deliverable to USAID for review, the Prime will determine the priority level of the deliverable to determine the timeline for receiving feedback.
 - Low priority items will be sent back to the Prime within 10-18 business days,
 - Medium priority 7-14 business days,
 - High priority 3-7 business days. The priority will be relayed to USAID with the deliverable.
- Expedited Review: *Only recommended for the most urgent situations*, if USAID feedback needs to be provided within 1-3 business days, the Prime Executive Director and/or Deputy Director will communicate with the AOR and/or alt-AOR, as soon as possible to request an expedited review. The Prime will use the standing weekly meetings to provide context and advanced notice if urgent review is necessary. A request for an expedited USAID review should be rare and is not intended to replace the outlined USAID review process.
- The Prime is responsible for making reasonable determinations on deliverable priority, considering length and depth of the review required, and USAID is responsible for meeting all review deadlines.

5. Version Control

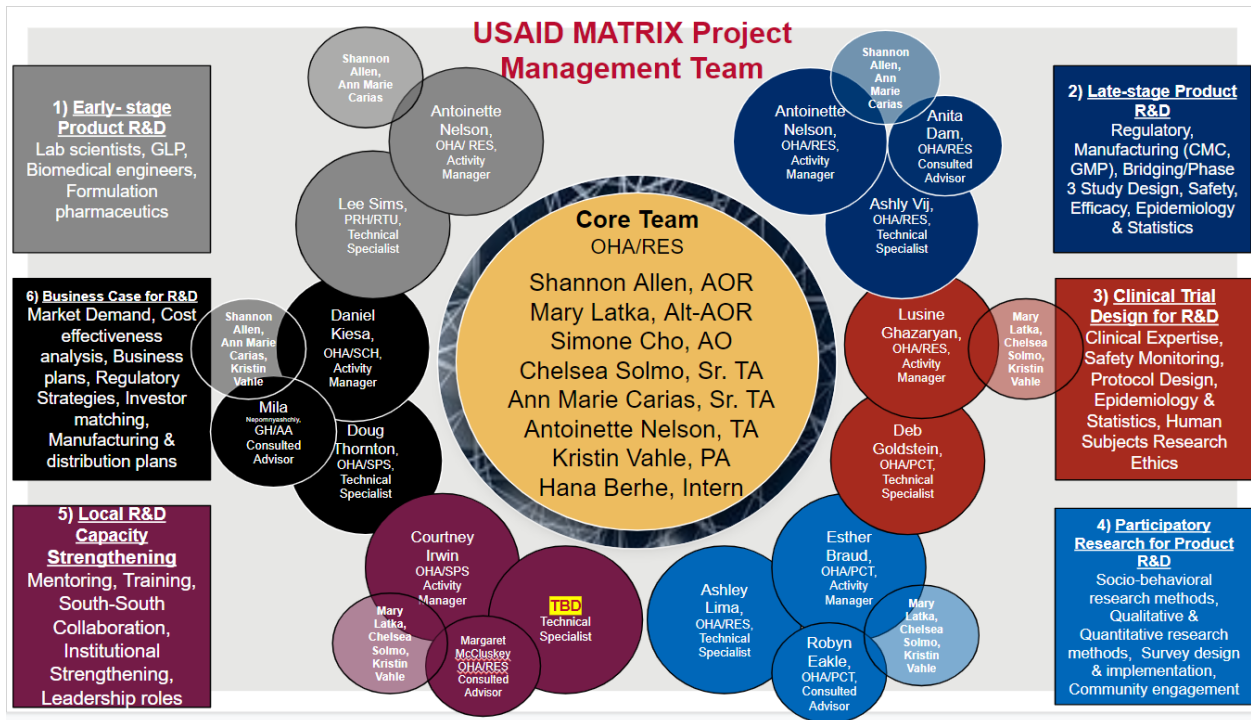
- All deliverables from the Prime will have page numbers on the footer of every page.
- Any first draft will be version 0.1 with subsequent drafts increasing by “0.1” in the version number e.g., 0.2, 0.3, ...0.9, 0.10, 0.11. Any final version of a deliverable (e.g., approved by an IRB; submitted for publication; shared publicly; or presented) will have the Version 1.0 identified on the first page. Any revisions to a final draft, say by an official amendment submitted to an IRB or a journal reviewer will increase the version number by “1.0” e.g., from 1.0 to 2.0 or from 2.0 to 3.0,. USAID would like to be informed of any significant changes to a final document, as an amendment or otherwise to determine whether the changes will require further review by USAID.

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APPENDICES

Appendix A: Matrix Management Team



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Appendix B: Review Timeline

