

**Instructions:** Use the table below to document a participant's eligibility status for participation in MTN-041. Please mark "Yes," "No" or "N/A" upon assessment of each applicable eligibility criterion (based on the participant cohort) and initial and date at the bottom of each page. If ineligibility status is determined, the form may be stopped and the remaining questions may be left blank; chart note why items of the checklist were left blank. If the participant is confirmed eligible, the IoR (or designee) should sign and date this checklist and a second staff member should sign to verify eligibility.

<b>ELIGIBILITY CRITERIA</b>			
<b><i>Inclusion Criteria – All Cohorts</i></b>		<b>Yes</b>	<b>No</b>
<b>1. Able and willing to provide informed consent</b>	Source: Signed/Marked Screening and Enrollment Consent Form	<input type="checkbox"/>	<input type="checkbox"/>
<b>2. Able and willing to complete the required study procedures</b>	Source: Behavioral Eligibility Worksheet	<input type="checkbox"/>	<input type="checkbox"/>
<b><i>Inclusion Criteria – Currently/Recently Pregnant/Breastfeeding Women</i></b>		<b>Yes</b>	<b>No</b> <b>N/A</b>
<b>3. Age 18 – 40 years (inclusive)</b>	Source: As specified in site SOP	<input type="checkbox"/>	<input type="checkbox"/>
<b>4. Currently or recently (within two years) pregnant or breastfeeding (by self-report)</b>	Source: Behavioral Eligibility Worksheet	<input type="checkbox"/>	<input type="checkbox"/>
<b><i>Inclusion Criteria – Male Partners</i></b>		<b>Yes</b>	<b>No</b> <b>N/A</b>
<b>5. Age 18 or older</b>	Source: As specified in site SOP	<input type="checkbox"/>	<input type="checkbox"/>
<b>6. Identifies as a primary sexual partner of a woman who is currently or was recently (within two years) pregnant or breastfeeding</b>	Source: Behavioral Eligibility Worksheet	<input type="checkbox"/>	<input type="checkbox"/>
<b><i>Inclusion Criteria – Grandmothers</i></b>		<b>Yes</b>	<b>No</b> <b>N/A</b>
<b>7. Age 18 or older</b>	Source: As specified in site SOP	<input type="checkbox"/>	<input type="checkbox"/>
<b>8. Identifies as a maternal or paternal grandmother whose daughter or daughter-in-law is currently or was recently (within two years) pregnant or breastfeeding</b>	Source: Behavioral Eligibility Worksheet	<input type="checkbox"/>	<input type="checkbox"/>
<p><i>Note: The term "daughter-in-law" includes women who are/were not married to their male partner during or after pregnancy</i></p>			

<i>ELIGIBILITY CRITERIA, CONTINUED</i>				
<i>Inclusion Criteria – Service Provider Key Informants</i>		<i>Yes</i>	<i>No</i>	<i>N/A</i>
9. Age 18 or older Source: As specified in site SOP		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Currently working as a clinician (e.g., obstetrician, nurse, pharmacist, etc.), traditional care provider (e.g., TBA, healer, midwife, etc.), social service provider (e.g., social worker, family planning counselor, etc.) or community health worker in one of the study countries, verified per site SOPs Source: Behavioral Eligibility Worksheet; refer to MTN-041 Accrual and Eligibility SOP		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Experienced in providing services to pregnant and/or breastfeeding women Source: Behavioral Eligibility Worksheet		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Inclusion Criteria – Community Leader Informants</i>		<i>Yes</i>	<i>No</i>	<i>N/A</i>
12. Age 18 or older Source: As specified in site SOP		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Currently acting in a community leadership role (e.g., local chief, religious leader, etc.) Source: Behavioral Eligibility Worksheet		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Exclusion Criteria</i>		<i>Yes</i>	<i>No</i>	<i>N/A</i>
1. <b>All Participants:</b> Has any condition that, in the opinion of the Investigator of Record (IoR)/designee, would preclude informed consent, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives Source: Chart notes and/or this checklist		<input type="checkbox"/>	<input type="checkbox"/>	
2. <b>Currently/Recently Pregnant/Breastfeeding Women:</b> Known HIV-positive status (per self-report or recent health record) Source: Self-report or health passport, ANC, HIV test card or similar health record		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**For the participant to be eligible, all responses to Inclusion Criteria for applicable cohort must be “Yes” and responses to Exclusion Criteria for applicable cohort must be “No.”**

**The act of completing this checklist and final sign-off by designated staff is the act of enrollment into MTN-041.**

**Final Sign-off of Participant Eligibility to Enroll:**

FOR PARTICIPANTS DETERMINED TO BE ELIGIBLE TO ENROLL IN MTN-041, complete signatures below to confirm and verify final determination of eligibility. Only staff delegated the responsibility of eligibility determination per site Delegation of Authority/Staff Roster may sign for eligibility confirmation/verification.

\_\_\_\_\_  
Signature of Investigator of Record (or designee)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of second staff member verifying eligibility

\_\_\_\_\_  
Date