### ELIGIBILITY

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Initials ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Is the subject HIV negative at screening?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Is the subject between the ages of 18-35 years old (inclusive)?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Does the subject report two or more sexual partners in the last 3 months?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Did the subject provide an Informed Consent?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Does the subject understand Portuguese?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Did the subject pass TOU (80% after 3 attempts)?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Score #1:</td>
<td>Score #2:</td>
<td>Score #3:</td>
<td></td>
</tr>
<tr>
<td>7. Is the subject available for the next 24 months to complete study visits?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Has the subject provided his/her contact information?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Has the subject provided contact information for one alternative personal contact?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Is the subject free of any preexisting medical, psychological, or social condition that would interfere with study participation?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Subject is NOT participating and has NOT participated in another HIV prevention study?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. If the subject is female, is her pregnancy test negative?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>If Male:</td>
<td>N/A</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* If any check box is marked "NO" (other than #1), the subject is **NOT ELIGIBLE** for enrollment into the study. If #1 is checked "No" then #13 must be checked "Yes", otherwise the subject is **NOT ELIGIBLE**.

13. If #1 is checked "No", is subject being enrolled for masking purposes? |     |     |             |
|   if #1 is "Yes":  | N/A  |     |             |

14. Is subject **ELIGIBLE** to participate in the study?              |     |     |             |

---

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### Demographic

<table>
<thead>
<tr>
<th>Site</th>
<th>Subject Number</th>
<th>Cohort Development</th>
<th>Visit:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 CISPOC</td>
<td></td>
<td>RV-363</td>
<td></td>
</tr>
<tr>
<td>2 CIDI</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Date of Visit

**DD/MON/YYYY**

#### Demographic

1. **Gender:**
   - [ ] 0 Male
   - [ ] 1 Female

2. **Date of Birth:**
   - **DD/MON/YYYY:**
   - **Age:** [ ] years old

3. **Place of Birth:**
   - Country
   - City(Village)
   - Province

4. **Highest level of education:**
   - [ ] 0 None
   - [ ] 1 Primary school, not complete
   - [ ] 2 Primary school, complete
   - [ ] 3 Secondary school, not complete
   - [ ] 4 Secondary school, complete
   - [ ] 5 Attended or attending college or university

5. **Approximate monthly income (in meticais):**
   - [ ] 0 None
   - [ ] 1 < 2,500.00 MT
   - [ ] 2 2,501.00 – 5,000.00 MT
   - [ ] 3 5,001.00 – 10,000.00 MT
   - [ ] 4 10,001.00 MT – 20,000 MT
   - [ ] 5 > 20,000 MT

---

**Form Completed By:** _____ _____ _____

**Date Completed:** **DD/MON/YYYY**

**QA Initial/Date**

**1st Data Entry Initials/Date**

**2nd Data Entry Initials/Date**

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### Screening Medical History

**Site**
- 1 CISPOC
- 2 CIDI

**RV-363**

**Cohort Development**

**Visit:**

**Date of Visit**

<table>
<thead>
<tr>
<th>QA Initial/Date</th>
<th>1st Data Entry Initials/Date</th>
<th>2nd Data Entry Initials/Date</th>
</tr>
</thead>
</table>

**Screening Medical History**

1. Has ever received a blood transfusion
   - [ ] 0 No
   - [ ] 1 Yes
   - [ ] 88 Refused To Answer
   - [ ] 99 Do Not Know

2. Has been tested for HIV
   - ( * If “No” → skip to Q #5)
   - [ ] 0 No *
   - [ ] 1 Yes
   - [ ] 88 Refused To Answer
   - [ ] 99 Do Not Know

3. The last HIV test was done
   - [ ] 1 Less than 6 months ago
   - [ ] 2 Between 6 months and 12 months ago
   - [ ] 3 More than 1 year ago
   - [ ] 88 Refused To Answer
   - [ ] 99 Do Not Know

4. The result of the last HIV test was
   - [ ] 0 Negative
   - [ ] 1 Positive
   - [ ] 88 Refused To Answer
   - [ ] 99 Do Not Know

5. Has been tested for Hepatitis
   - ( * If “No” → skip to Q #9)
   - [ ] 0 No *
   - [ ] 1 Yes
   - [ ] 88 Refused To Answer
   - [ ] 99 Do Not Know

6. The last Hepatitis test was done
   - [ ] 1 Less than 6 months ago
   - [ ] 2 Between 6 months and 12 months ago
   - [ ] 3 More than 1 year ago
   - [ ] 88 Refused To Answer
   - [ ] 99 Do Not Know

7. The result of the last Hepatitis test was
   - ( * If “Negative” → Skip to Q #9)
   - [ ] 0 Negative *
   - [ ] 1 Positive
   - [ ] 88 Refused To Answer
   - [ ] 99 Do Not Know

8. The type of Hepatitis was
   - [ ] 1 Hepatitis B
   - [ ] 2 Hepatitis C
   - [ ] 88 Refused To Answer
   - [ ] 99 Do Not Know

9. Has ever been tested for TB
   - ( * If “No” → Skip to Q #12)
   - [ ] 0 No *
   - [ ] 1 Yes
   - [ ] 88 Refused To Answer
   - [ ] 99 Do Not Know

**Source/CRF**

SMH

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10. The result of the last TB test was *(If “Negative” → Skip to Q #12)*
   - □ 0 Negative *
   - □ 1 Positive
   - □ 88 Refused To Answer
   - □ 99 Do Not Know

11. If positive, subject has been treated for TB previously or at this visit?
   - □ 0 No
   - □ 1 Yes
   - □ 88 Refused To Answer
   - □ 99 Do Not Know

12. Has been diagnosed with Sexually Transmitted Infection (STI), in the past 3 months
   - □ 0 No
   - □ 1 Yes
   - □ 88 Refused To Answer
   - □ 99 Do Not Know

13. Has been diagnosed with malaria in the past 3 months
   - □ 0 No
   - □ 1 Yes
   - □ 88 Refused To Answer
   - □ 99 Do Not Know

14. Has a history of alcohol abuse
   - □ 0 No
   - □ 1 Yes
   - □ 88 Refused To Answer
   - □ 99 Do Not Know

15. Has a history of non-injectable drug abuse
   - □ 0 No
   - □ 1 Yes
   - □ 88 Refused To Answer
   - □ 99 Do Not Know

16. Has a history of injecting drug use *(If “No” → skip to Q #18)*
   - □ 0 No *
   - □ 1 Yes
   - □ 88 Refused To Answer
   - □ 99 Do Not Know

17. Has a history of sharing needles
   - □ 0 No
   - □ 1 Yes
   - □ 88 Refused To Answer
   - □ 99 Do Not Know

18. The age at first sexual intercourse
   - □ 0 No *
   - □ 1 Yes
   - □ 88 Refused To Answer
   - □ 99 Do Not Know

Age: ____________

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### Screening Male Medical History

1. Has been circumcised
   - [ ] 0 No *
   - [ ] 1 Yes
   - [ ] 88 Refused To Answer
   - [ ] 99 Do Not Know
   *(If “No” → Skip to Q #4)*

2. Subject age the day of circumcision
   - [ ] 1 Neonatal Circumcision
   - [ ] 88 Refused To Answer
   - [ ] 99 Do Not Know
   
3. Where was the circumcision done
   - [ ] 1 Hospital
   - [ ] 88 Refused To Answer
   - [ ] 99 Do Not Know
   - [ ] 2 Traditional

4. Was the subject referred to counseling for male circumcision education and procedures at this visit?
   **Ask this question only if question # 1 answer is “No”**
   - [ ] 0 No
   - [ ] 1 Yes

5. Number of sexual partners in the **last 3 months:***

6. How many of these sexual partners were concurrent?

---

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### Screening Female Medical History

1. **Has received reproductive tract surgery, including tubal sterilization**
   - ☐ 0 No
   - ☐ 1 Yes *
   - ☐ 88 Refused To Answer
   - ☐ 99 Do Not Know
   
   * If “Yes”, specify: ____________________________________

2. **Has had history of irregular menses**
   - ☐ 0 No
   - ☐ 1 Yes *
   - ☐ 88 Refused To Answer
   - ☐ 99 Do Not Know
   
   * If “Yes”, specify: ____________________________________

3. **Has had any gynecological problems**
   - ☐ 0 No
   - ☐ 1 Yes *
   - ☐ 88 Refused To Answer
   - ☐ 99 Do Not Know
   
   * If “Yes”, specify: ____________________________________

4. **Current desire to get pregnant in the next year**
   - ☐ 0 No
   - ☐ 1 Yes
   - ☐ 2 Maybe
   - ☐ 88 Refused To Answer
   - ☐ 99 Do Not Applicable

5. **Number of sexual partners in the last 3 months:** [ ] [ ] [ ]

6. **How many of these sexual partners were concurrent?** [ ] [ ] [ ]

---

**Form Completed By:** _____ _____ _____ **Date Completed:** ___/___/____

QA Initial/Date 1st Data Entry Initials/Date 2nd Data Entry Initials/Date

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### MH – Interim Visits and Exit Visit – page 1 of 2

<table>
<thead>
<tr>
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<th>Cohort Development</th>
<th>Visit:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>CISPOC</td>
<td>_________</td>
<td>______</td>
</tr>
<tr>
<td>2</td>
<td>CIDI</td>
<td>Subject Number ___</td>
<td></td>
</tr>
</tbody>
</table>

Date of Visit

**Medical History – Interim Visits and Exit Visit**

1. **Was subject referred for follow-up medical evaluation(s) for STI or Malaria or both at the previous study visit?**
   - [ ] 0 No *
   - [ ] 1 Yes
   - *(If “No” → skip to Q #4)*

2. **If subject was referred, was he/she diagnosed with:**
   - **STI:**
     - [ ] 0 No
     - [ ] 1 Yes *
     - *(If “Yes” → is it)*
     - [ ] 1 Documented Report
     - [ ] 2 Per Subject Report
   - **Malaria:**
     - [ ] 0 No
     - [ ] 1 Yes *
     - *(If “Yes” → is it)*
     - [ ] 1 Documented Report
     - [ ] 2 Per Subject Report

3. **Did subject receive treatment for:**
   - [ ] STI ➔ [ ] 1 Documented Report
   - [ ] 2 Per Subject Report
   - [ ] Malaria ➔ [ ] 1 Documented Report
   - [ ] 2 Per Subject Report
   - [ ] Neither

**QA Initial/Date**

**1st Data Entry Initials/Date**

**2nd Data Entry Initials/Date**

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### Medical History – Interim Visits and Exit Visit

#### 4. At this visit or in the last 3 months, subject has experienced the following symptoms of **STI**?

*(Check all that apply)*

- [ ] None
- [ ] Rectal discharge
- [ ] Penile/vaginal discharge
- [ ] Rectal bleeding
- [ ] Lower abdominal pain
- [ ] Genital ulceration
- [ ] Penile/vaginal itching or burning
- [ ] Dysuria
- [ ] Pain during intercourse
- [ ] Genital condylomata
- [ ] Rectal pain or pain with defecation
- [ ] Unknown
- [ ] Other, specify ________________________________________

#### 5. At this visit or in the last 3 months, subject has experienced the following symptoms of **malaria**?

*(Check all that apply)*

- [ ] None
- [ ] Fatigue
- [ ] Fever
- [ ] Nausea or vomiting
- [ ] Chills
- [ ] Unknown
- [ ] Headache
- [ ] Other, specify ________________________________________

---

**Form Completed By:** _____ _____ _____

**Date Completed:** _____/_____/______

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# Vital Signs/Physical Exam

**Site**
- 1. CISPOC
- 2. CIDI

**RV-363**

**Cohort Development**

**Subject Number**

**Visit:**

**Date of Visit**

- **Completed By:**
- **Date Completed:**

**Vital Signs**

<table>
<thead>
<tr>
<th>Height (cm)</th>
<th>Weight (kg)</th>
<th>Temperature (°C)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**SITTING MEASUREMENTS**

<table>
<thead>
<tr>
<th>Pulse (beats/min)</th>
<th>Respiration (breaths/min)</th>
<th>Systolic BP (mmHg)</th>
<th>Diastolic BP (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Physical Examination**

- **Complete:**
- **Targeted:**

Examine the following and check appropriate box for each body system:

**BODY SYSTEM**

- **Normal**
- **Abnormal**
- **Not Done**

- *ONLY COMMENT ON ABNORMALITIES*

- **General Appearance**
- **Skin**
- **HEENT**
- **Lymphatic**
- **Pulmonary**
- **Cardiovascular**
- **Abdominal**
- **Genitourinary**
- **Musculo-skeletal**
- **Psychiatric**
- **Neurologic**
- **Other, specify**

- **Respond to the question below at Screening visit only:**

Is subject free of any medical condition that would preclude their study participation?  
- **0** No  
- **1** Yes

**Form Completed By:**

**Date Completed:**

**QA Initial/Date**

**1st Data Entry Initials/Date**

**2nd Data Entry Initials/Date**

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**Medical Assessment**

1. **Did subject report any social problem because he/she is in the study?**
   - [ ] 0 No  
   - [ ] 1 Yes *
   - [ ] 8 Not Applicable - *(must be checked at screening only)*

2. **Was subject referred for an STI evaluation test at this visit?**
   - [ ] 0 No  
   - [ ] 1 Yes

3. **Was subject provided a prescription for an STI at this visit?**
   - [ ] 0 No  
   - [ ] 1 Yes

4. **Was the subject referred for malaria evaluation at this visit?**
   - [ ] 0 No  
   - [ ] 1 Yes

5. **Was a malaria test completed at this visit?**
   - [ ] 0 No  
   - [ ] 1 Yes *
   - *(If “Yes” complete Malaria Lab Test)*

6. **Was subject provided a prescription for malaria at this visit?**
   - [ ] 0 No  
   - [ ] 1 Yes

7. **Did subject report any pregnancy problem?**
   - [ ] 0 No, specify reason: ______________________________
   - *(If “Yes” complete below)*

   - [ ] 1 Yes *
   - [ ] 8 Not Applicable, Male

   **Date of Sample**
   - DD/MON/YYYY: ___/___/_____  
   - Pregnancy result:  
     - [ ] 0 Negative
     - [ ] 1 Positive

---

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# HIV Test

<table>
<thead>
<tr>
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<td>_______</td>
</tr>
<tr>
<td>2</td>
<td>CIDI</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Date of Visit**

*DD/MON/YYYY*  ____/____/____

- [ ] Missed Visit
- [ ] Not Done

## HIV Testing

- [ ] Not Applicable, *Previously Seroconverted*

**Date of Sample**

*DD/MON/YYYY*  ____/____/____/____

### Test

<table>
<thead>
<tr>
<th>Test</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Determine HIV Rapid Test</td>
<td>0 Non-Reactive</td>
</tr>
<tr>
<td></td>
<td>1 Reactive</td>
</tr>
<tr>
<td></td>
<td>9 Not Done</td>
</tr>
<tr>
<td>2. Unigold HIV Test</td>
<td>0 Non-Reactive</td>
</tr>
<tr>
<td><strong>If discordant from Determine do Elisa</strong></td>
<td>1 Reactive</td>
</tr>
<tr>
<td></td>
<td>2 Not Required</td>
</tr>
<tr>
<td></td>
<td>9 Not Done</td>
</tr>
<tr>
<td>3. ELISA</td>
<td>0 Non-Reactive</td>
</tr>
<tr>
<td></td>
<td>1 Reactive</td>
</tr>
<tr>
<td></td>
<td>2 Not Required</td>
</tr>
<tr>
<td></td>
<td>9 Not Done</td>
</tr>
</tbody>
</table>

**Form Completed By:**  ____  ____  ____  **Date Completed:**  ____/____/____/____

**QA Initial/Date**  

**1st Data Entry Initials/Date**  

**2nd Data Entry Initials/Date**  

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<td></td>
</tr>
</tbody>
</table>

**HIV Viral Burden**

- **0** Not Detected
- **1** Detected, < 20 copies/mL
- **2** Equal to _____________ copies/mL
- **3** > 10,000,000 copies/mL

**Date of Visit**

**Date of Sample**

**Form Completed By:**

**Date Completed:**

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<table>
<thead>
<tr>
<th>Lymphocytes</th>
<th>LYM</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Site</strong></td>
<td><strong>RV-363</strong></td>
</tr>
<tr>
<td>1</td>
<td><strong>CISPOC</strong></td>
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<tr>
<td>2</td>
<td><strong>CIDI</strong></td>
</tr>
<tr>
<td>Subject Number</td>
<td></td>
</tr>
</tbody>
</table>

| Date of Visit | | |
| **DD/MON/YYYY** | | |
| | | |

| Date of Sample | | |
| **DD/MON/YYYY** | | |
| | | |

**Lymphocytes**

| CD3 + T-Lymphocyte (cells/ul) | | |
| | | |
| | | |

| CD3 + T-Lymphocyte (%) | | |
| | | |
| | | |

| CD3 + CD4 + Helper T-Lymphocyte (cells/ul) | | |
| | | |
| | | |

| CD3 + CD4 + Helper T-Lymphocyte (%) | | |
| | | |
| | | |

| CD3 + CD8 Suppressor T-Lymphocyte (cells/ul) | | |
| | | |
| | | |

| CD3 + CD8 Suppressor T-Lymphocyte (%) | | |
| | | |
| | | |

**Instruction:** ‘**Not Applicable**’ check box to be used only if those specific Lymphocytes test(s) will **not** be complete at **your site**

| Form Completed By: | | |
| | | |
| | | |

| Date Completed: | | |
| **DD/MON/YYYY** | | |
| | | |

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### Hematology

<table>
<thead>
<tr>
<th>Test</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>WBC (Thous/µL)</td>
<td></td>
</tr>
<tr>
<td>RBC (MILL/µL)</td>
<td></td>
</tr>
<tr>
<td>HGB (G/DL)</td>
<td></td>
</tr>
<tr>
<td>HCT (%)</td>
<td></td>
</tr>
<tr>
<td>MCV (fL)</td>
<td></td>
</tr>
<tr>
<td>MCH (pg)</td>
<td></td>
</tr>
<tr>
<td>MCHC (g/dL)</td>
<td></td>
</tr>
<tr>
<td>RDW-SD (fL)</td>
<td></td>
</tr>
<tr>
<td>RDW-CV (%)</td>
<td></td>
</tr>
<tr>
<td>PLT (Thous/µL)</td>
<td></td>
</tr>
<tr>
<td>MPV (fL)</td>
<td></td>
</tr>
</tbody>
</table>

### Differential

<table>
<thead>
<tr>
<th>Test</th>
<th>Value</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>NEUT (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NEUT # (Thous/µL)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LYMPH (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LYMPH # (Thous/µL)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MXD (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MXD # (Thous/µL)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MONO (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MONO # (Thous/µL)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EOS (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EOS # (Thous/µL)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BASO (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BASO # (Thous/µL)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Instruction:** ‘Not Applicable (NA)’ check box to be used only if those specific Differential test(s) will not be complete at your site.

**Date of Visit**

DD/MON/YYYY: __/__/____

**Date of Sample**

DD/MON/YYYY: __/__/____

**Date Completed:**

DD/MON/YYYY: __/__/____

**Form Completed By:** ____ ____ ____

**Date Completed:** ____ ____ __________

**QA Initial/Date:** __________________________

**1st Data Entry Initials/Date:** __________________________

**2nd Data Entry Initials/Date:** __________________________

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<thead>
<tr>
<th>Test</th>
<th>Value 1</th>
<th>Value 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALT/SGPT (U/L)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Creatinine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Bilirubin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Direct Bilirubin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glucose</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Serum Chemistry**

**Date of Sample**

DD/MON/YYYY: 

- ALT/SGPT (U/L): 
- Creatinine: 
- Total Bilirubin: 
- Direct Bilirubin: 
- Glucose: 

**Date Completed:**

DD/MON/YYYY: 

Form Completed By: 

Date Completed: 

QA Initial/Date: 

1st Data Entry Initials/Date: 

2nd Data Entry Initials/Date: 

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**Syphilis Test**

<table>
<thead>
<tr>
<th>Site</th>
<th>RV-363</th>
<th>Cohort Development</th>
<th>Visit:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>CISPOC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>CIDI</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Subject Number** __________

**Date of Visit**

**DD/MON/YYYY**  __/__/__/__/__/____

☐ Not Done

**Syphilis Lab Test**

Was syphilis serology done?  ☐ 0 No  ☐ 1 Yes *

( * if “Yes” complete below)

**Date of Sample**

**DD/MON/YYYY**  __/__/__/__/__/____

**Syphilis Initial**

<table>
<thead>
<tr>
<th>Test</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>9</th>
</tr>
</thead>
<tbody>
<tr>
<td>RPR</td>
<td>Negative</td>
<td>Positive 1: ____________ titer</td>
<td>Indeterminate</td>
<td>Not Done</td>
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</table>

**Confirmatory**

<table>
<thead>
<tr>
<th>Test</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>8</th>
<th>9</th>
</tr>
</thead>
<tbody>
<tr>
<td>TPPA</td>
<td>Negative</td>
<td>Positive</td>
<td>Indeterminate</td>
<td>Not Required</td>
<td>Not Done</td>
</tr>
</tbody>
</table>

---

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**Malaria Test**

**Site**
- [ ] 1 **CISPOC**
- [ ] 2 **CIDI**

**RV-363**  
**Cohort Development**

**Visit:**

**Subject Number**

<table>
<thead>
<tr>
<th>Subject Number</th>
<th>__</th>
<th>__</th>
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</thead>
</table>

**Date of Visit**

<table>
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<tr>
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<th>__</th>
<th>__</th>
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<th>__</th>
<th>__</th>
</tr>
</thead>
</table>

**Malaria Lab Test**

**Date of Sample**

<table>
<thead>
<tr>
<th>Date of Sample</th>
<th>DD/MON/YYYY</th>
<th>__</th>
<th>__</th>
<th>__</th>
<th>__</th>
<th>__</th>
</tr>
</thead>
</table>

**Instruction:** ‘Not Applicable’ choice to be used only if some of the Malaria test(s) will **not** be complete at your site.

1. **Malaria rapid diagnostic test (RDT) result:**
   - [ ] 0 Negative
   - [ ] 1 Plasmodium falciparum
   - [ ] 2 Plasmodium vivax
   - [ ] 3 Mixed infection
   - [ ] 4 Equivocal or invalid
   - [ ] 8 Not Applicable
   - [ ] 9 Not Done

2. **Smear Microscopy:**
   - [ ] 1 Plasmodium falciparum
   - [ ] 2 Other, specify
   - [ ] 8 Not Applicable
   - [ ] 9 Not Done

   **Other, specify:**
   ____________________________________________

   **Parasite density:**
   - [ ] 1 +
   - [ ] 2 ++
   - [ ] 3 +++
   - [ ] 4 ++++
   - [ ] 5 ++++
   - [ ] 6 Indeterminate
   - [ ] 8 Not Applicable

**Form Completed By:**

<table>
<thead>
<tr>
<th>Form Completed By</th>
<th>__</th>
<th>__</th>
<th>__</th>
<th>__</th>
<th>__</th>
<th>__</th>
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</thead>
</table>

**Date Completed:**

<table>
<thead>
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<th>DD/MON/YYYY</th>
<th>__</th>
<th>__</th>
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<th>__</th>
</tr>
</thead>
</table>

**QA Initial/Date**

<table>
<thead>
<tr>
<th>QA Initial/Date</th>
<th>__</th>
<th>__</th>
<th>__</th>
<th>__</th>
<th>__</th>
<th>__</th>
</tr>
</thead>
</table>

**1st Data Entry Initials/Date**

<table>
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<tr>
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<th>__</th>
<th>__</th>
<th>__</th>
<th>__</th>
<th>__</th>
<th>__</th>
</tr>
</thead>
</table>

**2nd Data Entry Initials/Date**

<table>
<thead>
<tr>
<th>2nd Data Entry Initials/Date</th>
<th>__</th>
<th>__</th>
<th>__</th>
<th>__</th>
<th>__</th>
<th>__</th>
</tr>
</thead>
</table>

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TERMINATION FROM STUDY

Site
☐ 1 CISPOC
☐ 2 CIDI

RV-363 | Cohort Development | Last Visit:

Subject Number __ __ __ __ __ __ __ __

Termination From Study

Date of Termination from Study __ __ __ __ __ __

What was the last visit # completed by the subject? ______________________

Reason for Termination

☐ 1 Completed the final scheduled study visit

☐ 2 Subject decision (subject has indicated that participation is terminated permanently and no further contact is permitted) (Check all that apply)

☐ Pregnant does not want to continue

☐ Unable to continue keeping visits

☐ Significant social harm event

☐ HIV+ does not want to continue

☐ Moved from the area

☐ Incarceration

☐ Withdraw consent

☐ Other, specify ______________________

☐ 3 Death, complete additional information below, complete Death Report form and inform MHRP COO and Mozambique Ethics Committee immediately within 48 hours

Date of Death __ __ __ __ __ __

Primary Cause of Death

☐ 0 Unknown

☐ 1 Other, specify ______________________

☐ 4 Non-compliance with visit schedule/Investigator decision

☐ 5 Protocol violation, specify ________________________________________________

☐ 6 Concurrent illness/medication reason, specify __________________________________

☐ 7 Reaction to blood collection, specify _________________________________________

☐ 8 Lost to follow-up

☐ 9 Other reason, specify ______________________________________________________

PI/Designee Print Name: ___________________________ PI/Designee Signature: ___________________________

Date Completed: __ __ __ __ __ __ __ __

Source/CRF TOS

QA Initial/Date ___________________________ 1st Data Entry Initials/Date ___________________________

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### Consent to use of Specimens

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>No</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>I agree to allow my samples to be used for the genetic testing as described for this study.</td>
<td>□ 0</td>
<td>□ 1</td>
</tr>
<tr>
<td>2.</td>
<td>I agree to the storage of my samples and to the future use of these samples in scientific studies as approved by the Ethics Review Boards.</td>
<td>□ 0</td>
<td>□ 1</td>
</tr>
<tr>
<td>3.</td>
<td>I agree to allow my samples to be used for genetic testing in future scientific studies as approved by the Ethics Review Boards</td>
<td>□ 0</td>
<td>□ 1</td>
</tr>
<tr>
<td>4.</td>
<td>I agree to allow my samples to be shipped to laboratories in other countries</td>
<td>□ 0</td>
<td>□ 1</td>
</tr>
</tbody>
</table>

**Instruction:** Please complete this CRF each time a participant is consented (i.e. screening visit) and re-consented, as well as if there is a change in consent for the use of specimens.

**Informed Consent Form (ICF) Version #:** __________

---

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CRF REVIEW STATEMENT

I have reviewed all data contained in this case report form binder and verified that the contents are consistent with observations and source records. They accurately reflect the condition of the subject before, during and at the completion of the study.

Principal Investigator's/Desigee

Date Completed:

__________________________            ___________________________                             _________________________
Name                        Signature

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