**Instructions:** Use of this checklist is intended at study visits for both MTN-015 and MTN-020 on the same day. When an item is performed, complete “Staff Initials” cell. If not done but required, write “ND” and staff initials in “Staff Initials” cell, and provide more details in the chart notes as needed. Do not initial for other staff members. If other staff members are not available to initial items themselves, write and initial/ date a note documenting who completed the procedure, e.g., “done by {name}” or “done by nurse.” If visit procedures are split across more than one date, ensure the date is captured in the comments cell for procedures conducted on a date different than that provided above.

| **MTN-020 PTID: Visit Code:** | | | | | | | | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Visit:** | | | **Monthly** | | | **Quarterly** | | | **Semi-Annual** | | | | **PUEV/ Early Term.** | | | |
| **MTN-015 PTID: Visit Code:** | | | | | | | | | | | | | | | | |
| **Non-ART Visit:** | | | | **Month 1** | | | **Month 3** | | | **Semi-Annual** | | | | **Annual** | | |
| **ART Visit:** | | **Week 2** | | | **Month 1** | | | **Month 3** | | | **Semi-Annual** | | | | **Annual** | |
| **Seroconverter Visit Procedure** | | | | | | | | | | | | **Required at Visits:** | | | | **Staff Initials** |
| 1 | Confirm identity and PTID | | | | | | | | | | | All | | | |  |
| 2 | Check for co-enrollment in other studies:   * NOT enrolled in another study ==> CONTINUE * Enrolled in a study (other than MTN-015) ==> Consult PSRT | | | | | | | | | | | All | | | |  |
| 3 | Review previous MTN-020 and MTN-015 visit documentation | | | | | | | | | | | All | | | |  |
| 4 | Review elements of informed consent as needed | | | | | | | | | | | All | | | |  |
| 5 | For non-ART participants:  **If use of ART is reported, STOP.** Complete Non-ART Study Visit, ART Enrollment, and ART Initiation Information forms. Generate ART follow-up visit calendar and determine which ART follow-up visit should be conducted. Then **SWITCH** to the appropriate ART follow-up visit items on this checklist | | | | | | | | | | | MTN-015: All non-ART visits | | | |  |
| 6 | Review/update MTN-020 locator information. If updates are needed, make certified copies of MTN-020 locator form and file in the MTN-015 study binder (or transcribe onto the MTN-015 locator form) | | | | | | | | | | | All | | | |  |
| 7 | Administer Behavior Assessment CRF | | | | | | | | | | | MTN-020: Quarterly,  Semi-ann, PUEV/ Early term. | | | |  |
| 8 | Administer Vaginal Practices CRF | | | | | | | | | | | MTN-020: Semi-ann, PUEV/ Early term. | | | |  |
| 9 | Administer Ring Worries CRF  *[If MTN-020 LoA#2 is approved, administer at visit following HIV confirmation. Otherwise, conduct at next MTN-020 quarterly visit]* | | | | | | | | | | | MTN-020: Visit following HIV confirmation | | | |  |
| 10 | Non-ART participant: Administer MTN-015 Follow-Up Behavioral Questionnaire  ART participant: Did participant initiate ART within 24 months of date of seroconversion?   * No – Do not administer questionnaire * Yes – Administer Follow-Up Behavioral Questionnaire | | | | | | | | | | | MTN-015: Months 3, 12, 24 | | | |  |
| 11 | Administer PUEV/Discontinuers ACASI  *[If MTN-020 LoA#2 is approved, administer at visit following HIV confirmation. Otherwise, conduct at next MTN-020 quarterly visit]* | | | | | | | | | | | MTN-020: Visit following HIV confirmation | | | |  |
| 12 | Collect urine (15-60 mL) and send to lab (label with MTN-020 labels) for:   * Urine hCG (pregnancy) | | | | | | | | | | | MTN-020: All  MTN-015: As indicated | | | |  |
| * NAAT for GC/CT (first catch urine) | | | | | | | | | | | MTN-020: Semi-ann  MTN-015: Annual | | | |  |
| 13 | Collect follow-up medical/menstrual/medications history: review/update Adverse Event Log(s) (AE-1 and GAE-1), and Concomitant Medications Log   * Make a certified copy of MTN-020 AE-1 and GAE-1 and file in MTN-015 study binder. When applicable, transcribe events onto MTN-015 HIV/AIDS associated Events Log form * Make certified copies of MTN-020 concomitant medications log with new entries and file in MTN-015 study binder (or transcribe onto MTN-015 concomitant medications log form) * If applicable, transcribe medication used for OI Prophylaxis on MTN-015 Non-ART Medications Log form | | | | | | | | | | | All | | | |  |
| 14 | If applicable, transcribe ART medication on MTN-015 ART Log Form | | | | | | | | | | | MTN-015: All ART visits | | | |  |
| 15 | ART participant: Administer ART Adherence form | | | | | | | | | | | MTN-015: ART Month 3, Semi-ann, Annual | | | |  |
| 16 | Provide contraceptive counseling | | | | | | | | | | | MTN-020: All  MTN-015: Semi-ann, Annual | | | |  |
| 17 | Prescribe contraceptives; complete MTN-020 Family Planning CRF.   * Prepare a certified copy of MTN-020 FP CRF for filing in MTN-015 study binder (or transcribe MTN-020 results onto the MTN-015 non-ART Medications Log form) | | | | | | | | | | | MTN-020: If indicated | | | |  |
| 18 | Review pregnancy test results:   * NOT pregnant ==> CONTINUE. * Pregnant, pregnancy newly identified at today’s visit:   + Initiate MTN-020 Pregnancy Management Worksheet *[site to delete if not using]*   + Complete MTN-020 Pregnancy Report and History CRF. Transcribe results onto MTN-015 Pregnancy Report and History CRF.   + Contact PSRT and refer to PMTCT/HAART per site SOPs * Pregnant, pregnancy first identified at a previous visit:   + If applicable, refer to MTN-016; document in chart notes.   + Follow-up PMTCT referrals per site SOPs | | | | | | | | | | | All | | | |  |
| 19 | Perform and document targeted physical exam. Complete MTN-020 Abbreviated Physical Exam CRF.  Prepare certified copy of MTN-020 Abbreviated Physical Exam CRF and file in the MTN-015 study binder (or transcribe results onto the MTN-015 Physical Exam form) | | | | | | | | | | | MTN-020: Quarterly, Semi-ann, PUEV/ Early term.  MTN-015: All | | | |  |
| 20 | Perform and document pelvic exam per MTN-020 and MTN-015 Combined Follow-up Pelvic Exam Checklist and site SOPs.   * If required for MTN-020, document exam on MTN-020 CRFs, then prepare certified copies to file in MTN-015 study binder (or transcribe results onto MTN-015 forms) * If required only for MTN-015, document exam on MTN-015 forms. If any AEs are identified, document on MTN-020 GAE-1, or AE log CRFs. | | | | | | | | | | | MTN-020: Semi-ann, PUEV/ Early term.  MTN-015: All | | | |  |
| 21 | If STI/RTI/UTI is diagnosed, provide treatment.   * If updates to MTN-020 Concomitant Medication log, prepare certified copies to file in MTN-015 study binder (or transcribe results onto MTN-015 concomitant medications log) * Complete/update MTN-020 GAE-1, or AE log CRFs as needed * Update MTN-015 Medical History Log as needed | | | | | | | | | | | All | | | |  |
| 22 | Provide and explain all available findings and results. Refer for findings as indicated. | | | | | | | | | | | All | | | |  |
| 23 | Assess clinical stage and potential need for CTX and/or ART. Provide or refer for follow-up care as needed based on all available information/findings. Document follow-up in chart notes. | | | | | | | | | | | MTN-015: All | | | |  |
| 24 | Provide and document:   * HIV-related (including secondary prevention) counseling * STI risk reduction counseling * Provide Condoms * Follow-up on previous referrals (if applicable) * New referrals (if applicable) | | | | | | | | | | | MTN-020: All  MTN-015: Semi-ann, Annual | | | |  |
| 25 | Document any Adverse Events on appropriate MTN-020 AE-1 or MTN-020 GAE-1 Log CRF(s) as needed. Update MTN-015 Medical History Log form as needed. If applicable, record/update clinical events on MTN-015 HIV/AIDS Associated Events Log. Prepare certified copies and file in MTN-015 binder. | | | | | | | | | | | All | | | |  |
| 26 | Determine amounts required and collect blood (review items # 27-33 to determine total amounts):   * \_ x 10 mL lavender top (EDTA) tubes * \_ x 5 mL lavender top (EDTA) tube * \_ x 5 mL red top (no additive) tube   [additional blood needed for clinically indicated testing also may be collected at this time] | | | | | | | | | | | All | | | |  |
| 27 | Prepare blood for liver and renal function tests   * \_\_ x 5 mL red top (no additive)tube for AST, ALT, Alk Phos, Total Bilirubin | | | | | | | | | | | MTN-015 (Non-ART): Month 3; Semi-Ann, Annual  MTN-015 (ART): Semi-Ann, Annual | | | |  |
| 28 | Prepare blood for PBMC archive (*for sites with capacity*)   * Collect ~50 mL EDTA whole blood | | | | | | | | | | | MTN-015: All  (*except* ART Month 1) | | | |  |
| 29 | Prepare blood for plasma archive. Plasma may be taken from EDTA samples for MTN-015 PBMC, if applicable.   * Collect ~10 mL EDTA whole blood to yield at least 3 mL * If indicated, collect additional 10 ml EDTA whole blood for resistance testing | | | | | | | | | | | MTN-015: All | | | |  |
| 30 | Prepare blood for complete blood count (~2mL) | | | | | | | | | | | MTN-015 (Non-ART): Month 3; Semi-Ann, Annual  MTN-015 (ART): Semi-Ann, Annual | | | |  |
| 31 | Prepare blood for syphilis serology (X x X mL red top, no additive, tube)    Document per MTN-020 SOP for source documentation; prepare certified copies of results in MTN-015 study binder. | | | | | | | | | | | MTN-020: if indicated, PUEV  MTN-015: Annual | | | |  |
| 32 | Prepare blood for CD4+ T cell count (~2mL) | | | | | | | | | | | MTN-015: All | | | |  |
| 33 | Prepare blood for HIV RNA Viral Load (~2mL) | | | | | | | | | | | MTN-015: All | | | |  |
| 34 | Complete   * MTN-015 Specimen Storage form * MTN-015 LDMS Tracking Sheet | | | | | | | | | | | MTN-015: All visits | | | |  |
| 35 | Conduct Social Harms assessment | | | | | | | | | | | MTN-020: Quarterly, and if indicated  MTN-015 (Non-ART): Month 3; Semi-Ann, Annual  MTN-015 (ART): All visits | | | |  |
| 36 | Schedule next visit. Provide contact information and instructions to report symptoms and/or request information, counseling, or condoms before next visit. | | | | | | | | | | | All | | | |  |
| 37 | Provide reimbursement | | | | | | | | | | | All | | | |  |