**Instructions:**

This checklist should be used for every scheduled rectal exam; it should not be used for clinically indicated rectal exams. The “Required at visits” column indicates when the item is required during follow-up per-protocol. 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.” Samples must be collected in the order listed on the checklist.

| **Rectal Exam Checklist - (Enrollment and Follow Up)** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Procedures** | | | **Required at visits:** | | **Staff Initials** | | **Comments** |
| 1 | Review chart notes and other relevant documentation | | All | |  | |  |
| 2 | Prepare exam equipment, documentation, and specimen collection supplies; per SSP section 8.4.2 | | All | |  | |  |
| 3 | Explain exam procedures to participant and position participant in appropriately per SSP section 8.4.2 | | All | |  | |  |
| 4 | Perform visual/perianal exam per SSP section 8.4.3. Document findings on Anorectal Exam CRF | | All | |  | |  |
| 5 | Collect rectal swab for HSV1/2 testing, if indicated. Document results on STI Test Results CRF | | Only If Indicated | |  | |  |
| 6 | Collect anal swab for HPV typing. Document results on Specimen Storage CRF | | Enrollment Only | |  | |  |
| 7 | Perform digital rectal examination per SSP section 8.4.5 | | All | |  | |  |
| 8 | Prepare anoscope for specimen collection per SSP section 8.5.1 | | Enrollment; Period 1/2/3 Initiate, Mid- and –End Visits | |  | |  |
| 9 | Evaluate for abnormalities. Document findings on Anorectal Exam CRF. Refer for/provide treatment if needed. | | All | |  | |  |
| 10 | Collect rectal swab for GC/CT testing per SSP section 8.5.2. Document results on STI Test Results CRF | | Enrollment; Period 1/2/3 End; other visits if indicated | |  | |  |
| 11 | Collect the rectal sponge for adherence PK. Document collection on Specimen Storage CRF and LDMS Tracking Sheet | | Period 1/2/3 Mid- and –End Visits;  Initiate 2/3 | |  | | See SSP 8.5.3 for protocol specified collection timepoints/requirements |
| 12 | Collect the rectal sponge for PD. Document collection on Specimen Storage CRF and LDMS Tracking Sheet | | Enrollment; Period 1/2/3 Initiate, Mid- and –End Visits | |  | | See SSP 8.5.3 for protocol specified collection timepoints/requirements |
| 13 | Slowly remove anoscope, if applicable  ***Note: For those in the Rectal Tissue/Fluid Subset, anoscope should remain in place. See item 15.*** | | Enrollment; Period 1/2/3 Initiate, Mid- and –End Visits | |  | |  |
| 14 | Evaluate any abnormal findings. Refer for/provide treatment if needed | | All | |  | |  |
| **Was the participant chosen to take part in the rectal tissue/fluid subset?**  **🞎 Yes. Complete items 15-22**  **🞎 No. End of checklist** | | | | | | | |
| **Rectal Tissue/Fluid Subset ONLY: Complete items 15-22** | | | | | | | |
| **Procedures** | | **Required at visits:** | | **Staff Initials** | | **Comments** | |
| 15 | Collect the rectal sponge for mucosal immunology (archive) per SSP section 8.6.2. Document collection/storage on Rectal Biopsy/Fluid Subset Specimens CRF and LDMS Tracking Sheet  **Note: May be collected same time as** **rectal sponges for PD and PK (#11 -#12 above).** | Enrollment; Period 1/2/3 End | |  | |  | |
| 17 | Prepare and perform rectal enema per SSP section 8.6.3. | Enrollment; Period 1/2/3 End | |  | |  | |
| 18 | Prepare sigmoidoscope for specimen collection per SSP section 8.6.4 |  | |  | |  | |
| 19 | Evaluate for abnormalities. Document findings on Rectal Biopsy/Fluid Subset Specimens CRF |  | |  | |  | |
| 20 | Collect rectal biopsies per SSP section 8.6.4. Document collection/storage on Rectal Biopsy/Fluid Subset Specimens CRF and LDMS Tracking Sheet | | | | | | |
| At **Enrollment/Period 1 Initiate visit**, the following biopsies are required:   * Collect four (4) biopsies for PD * Collect seven (7) biopsies for Mucosal T Cell Phenotyping * Collect two (2) biopsies for Mucosal Gene Expression Array Determination * Collect one (1) biopsy for Histology * Collect one (1) biopsy for Proteomics | Enrollment Only | |  | |  | |
| During **follow up**, the following biopsies are required:   * **Collect five (5) biopsies for PK** * Collect four (4) biopsies for PD * Collect seven (7) biopsies for Mucosal T Cell Phenotyping * Collect two (2) biopsies for Mucosal Gene Expression Array Determination * Collect one (1) biopsy for Histology * Collect one (1) biopsy for Proteomics | Period 1/2/3 End | |  | |  | |
| 21 | Remove sigmoidoscope slowly |  | |  | |  | |
| 22 | Obtain vital signs and document in chart notes. | Enrollment; Period 1/2/3 End | |  | |  | |