**Instructions:** When an item is performed, complete “Staff Initials” cell. If not done but required, write “N/D” 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.

| **Decliner Visit Procedure** | **Staff Initials** | **Comments:** |
| --- | --- | --- |
| 1 | Confirm identity, age, and prescreening ID per site SOP *Note: if participant presents for decliner screening and enrollment and does not have a prescreening ID already assigned, complete this process* |  |  |
| 2 | Explain, conduct, and document Decliner Screening & Enrollment informed consent process:* Willing and able to provide written informed consent ==> CONTINUE.
* NOT willing and able to provide written informed consent ==> STOP. NOT ELIGIBLE.
 |  |  |
| 3 | Assign PTID (if not done during a previous visit) by completing a row on the PTID name-linkage log |  |  |
| 4 | Administer Decliner Behavioral Eligibility Worksheet * ELIGIBLE thus far ==> CONTINUE.
* NOT ELIGIBLE ==> STOP.
 |  |  |
| 5 | Conduct confirmation and final determination of decliner eligibility status by review/completion of Decliner Eligibility Checklist. * ELIGIBLE ==> CONTINUE. ==> sign the Decliner Eligibility Checklist and proceed to eligibility verification
* NOT ELIGIBLE ==> STOP. DO NOT enroll.
 |  |  |
| 6 | Verify participant eligibility by review of Decliner Eligibility Checklist (must be different staff member than step 5): * ELIGIBLE ==> CONTINUE 🡪 sign the Decliner Eligibility Checklist
* NOT ELIGIBLE ==> STOP. DO NOT enroll.

**Participant considered is enrolled once eligibility checklist is completed and final sign off is completed by designated staff.** |  |  |
| 7 | Administer Demographics CRF |  |  |
| 8 | Administer Baseline Behavior Assessment CRF  |  |  |
| 9 | FOR QUALITATIVE SITES ONLY (delete if not a qualitative site): If indicated/selected, conduct decliner In-Depth-Interview per qualitative visit checklist  |  |  |
| 10 | Complete Enrollment – Decliner Population CRF |  |  |
| 11 | Complete row in Decliner Screening and Enrollment Log |  |  |
| 12 | Provide reimbursement |  |  |
| 13 | For enrolled participants, QC and then submit all required Case Report Forms from the Decliner Screening and Enrollment visits into Medidata Rave.* Pre-Screening Outcome (if not already completed)
* Eligibility Criteria – Decliner Population
* Enrollment – Decliner Population
* Demographics
* Baseline Behavioral Assessment
 |  |  |