**Instructions:** Use the table below to document a participant’s eligibility status for MTN-025 decliner population participation at the decliner screening/enrollment visit. Initial and date the bottom of the page. For each item, the reference/source document is listed. If ineligibility status is determined, the form may be stopped and the remaining questions may be 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. **The act of completing this checklist and final sign-off by designated staff is the act of enrollment into MTN-025- decliner population.** Complete the Eligibility Criteria – Decliner Population CRF for all screened decliner participants once the participant’s eligibility/enrollment status is determined.

|  |  |
| --- | --- |
| **Inclusion Criteria** | ***Yes No*** |
| **I1. Able and willing to provide written informed consent**  *Source: signed/marked Decliner Screening and Enrollment consent form* |  |
| **I2. Participated in MTN-020 (ASPIRE)**  *Source: site-specific identification/co-enrollment procedures, as outlined and documented per site SOPs (sites to modify to make specific)* |  |
| **I3. Declines MTN-025 (main) study trial participation**  *Source: Decliner Behavioral Eligibility Worksheet, item 1* |  |
| **I4. Able and willing to perform the Decliner Population study procedures**  *Source: Decliner Behavioral Eligibility Worksheet, item 2* |  |
| ***Note: In order for the participant to be eligible, all of the responses to items* I1- I4 *above must be “yes”*** | |
| **Exclusion Criteria** | ***Yes No*** |
| |  | | --- | | **E1. 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 or this checklist* | |  |

***Note: In order for the participant to be eligible, the response to item* E1 *above must be “no”.***

***Complete Eligibility Criteria – Decliner Population CRF for each participant screened for the decliner study, regardless of enrollment.***

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

*FOR PARTICIPANTS DETERMINED TO BE ELIGIBLE TO ENROLL IN MTN-025 decliner population, complete signatures below to confirm and verify final determination of eligibility. Only staff delegated the responsibility of primary eligibility determination per site DoA may complete the first signature line; only staff delegated the responsibility of secondary/verification of eligibility may complete the second signature line.*

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Signature of Investigator of Record (or designee) Date*

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*Signature of second staff member verifying eligibility Date*

**The act of completing this checklist and final sign-off by designated staff is the act of enrollment into MTN-025 – decliner population.**