Form 2: Non-Enrollment Form

Study site:  Study screening date: --

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| 1. Patient Information |

1. Sex:  Male  Female
2. Year of birth:   Estimated  Not Reported
3. Participant Initials:  DR-TB Registration Number:

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| --- | --- | --- |
| 1. **Reason for Non-Enrollment** (check only one reason for non-enrollment) | | |
|  | Patient does not meet eligibility criteria | |
|  | Patient declined to participate (Check all reasons for decline) | |
|  | 1. Patient is unwilling to discuss the study 2. Patient refused invasive testing 3. Patient is unwilling to sign the informed consent 4. Patient is unable to adhere to treatment and monitoring schedule | 1. Patient is unwilling to participate in the post-treatment follow-up 2. Patient is fearful of 9 month regimen’s adverse drug reactions 3. Patient is fearful of research 4. Other (Elaborate reason in Section C) |
|  |  | |
|  | Site has decided to not enroll patient (Check all reasons for site’s decision) | |
|  | 1. Patient does not understand the study and/or the informed consent form 2. Patient lives far away 3. Patient has personal issues or a family situation that may cause problems with adhering to the treatment protocol 4. Patient has current, significant psychiatric condition 5. Patient has history of substance use 6. Patient has history of alcohol use | 1. Patient has a social or medical condition, which in the investigators opinion, would make study participation unsafe (Elaborate in Section C) 2. Patient has symptoms of a comorbidity that require medical evaluation (Elaborate in Section C) 3. Patient has plans to move out of study area 4. Patient is argumentative / hostile to staff 5. Other (Elaborate in Section C) |
| 1. **Comments** | | |

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| 1. **Form Completion** |

PRINT name of person completing form: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date Non-enrollment Form completed: --