|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Participant’s Eligibility Investigator Sign-Off:** | | | | | | | | | | |
| **Is the participant eligible to take part in the study?** | | | | Yes | | |  | |  | |
|  | | | | No | | |  | |  | |
| **Investigator’s signature:** | | | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |  | |  | |
| **Date:** | | | | |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | D | D | M | M | Y | Y | Y | Y | | | | | |  | |
| **Investigator’s name** | | | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |  | | |  | |
| **Has the participant been randomised?** | | | | Yes | | |  | |  | |
|  | | | | No | | |  | |  | |
| ***If not*, please give the reason:** | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | |
|  | | |  | | | | | |  | |
| **Randomisation result:** | | | Arm A | | |  | | |  | |
|  | | | Arm B | | |  | | |  | |
| **Randomisation Date:** | |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | D | D | M | M | Y | Y | Y | Y | | | | | **Initials of person conducting randomisation:** | | | |  |  | | --- | --- | |  |  | | |