**Unblinding (Code Break) Form**

*One form to be completed for each unblinding/code break of a trial participant and stored within a confidential section within the site file. Knowledge of the unblinded intervention allocation should be restricted as much as possible until the trial has ended and full unblinding has occurred.*

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Name of trial (or Acronym): | | |  | | | | | | | | |
| EuDRACT No (*if applicable*): | | |  | | | | | | | | |
| Chief Investigator: | | |  | | | | | | | | |
| Principal Investigator at site: | | |  | | | | | Site: |  | | |
| Participant Trial Number: | | |  | | | | | | | | |
| Name and position of person **requesting** unblinding: | | | | |  | | | | | | |
| Participant Trial No: |  | Date of Unblinding: | | | |  | | Time of Unblinding: | | |  |
| **Mechanism for Unblinding/Code Break** (*please tick ✓ below*): | | | | | | | | | | | |
| Website request: | | | | □ | | | Telephone number: | | | □ | |
| Scratch Cards: | | | | □ | | | Envelopes: | | | □ | |
| Other □ (*please provide details*): | | | |  | | | | | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **Reason for Unblinding/Code Break** (*please tick ✓ below*): | | | |
| SUSAR: | □ | Urgent Safety Measure: | □ |
| Safety Committee / CI request: | □ | Erroneous\* (*See below*): | □ |
| Other □ (*please provide details*): |  | | |

\*Additional information for erroneous unblinding

|  |
| --- |
| Action taken to prevent recurrence: |
|  |
| Safety committee direction regarding continuation of participant and inclusion of participant data: |
|  |

Signature of person **requesting** unblinding:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Principal Investigator:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_