**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.*

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| --- | --- |
| 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*): |  |

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| **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

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| 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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_