

|  |
| --- |
| **Study Stage:**  Conduct-Termination |

**Purpose:** This form, used in those studies where the study article is blinded (masked), tracks when a participant’s study article is unblinded.

**Useful to:**  Research study teams that are conducting a blinded clinical trial.

**Instructions:**

* This form can be completed whenever a research participant’s study article has been unmasked/unblinded during the course of a clinical trial
* Include the participant identifier and reason for unblinding on the form.
* The form can be signed and dated by the research team member that authorized the unmasking or other research team members that are delegated this role
* Revise this form with any specific clinical trial unblinding practices that are outlined in the approved protocol or other study documents (i.e., the PI must approve the unblinding of a subject along with the Medical Monitor).

**Best Practice Recommendation:**

* If a Sponsor provides an Unblinding Form, complete as instructed. Otherwise, the following is recommended:
* Indicate who was given the unblinded study article information (PI, Participant, PCP, etc.).
* This form may be used for both single and double-blind studies, but the proper storage and access to this information, or use of it into CRFs may be different depending on the study and its requirements. Consider these issues in advance, and as appropriate, review or ask questions with the sponsor, investigator, and Research Pharmacy, so you know what your procedures should be.

***\*****You may substitute the word “unmasking” for “unblinding on this form*

|  |
| --- |
| **Reference(s): FDA guidance****for Industry and Investigators -** VI. OTHER SAFETY REPORTING ISSUES,**Part C**  [Safety Reporting Requirements for INDs and BA/BE Studies (fda.gov)](https://www.fda.gov/files/drugs/published/Safety-Reporting-Requirements-for-INDs-%28Investigational-New-Drug-Applications%29-and-BA-BE-%28Bioavailability-Bioequivalence%29-Studies.pdf) |

**Template History:**

**Last Updated:** 6/07/2022

**Version:** 2.3

|  |  |
| --- | --- |
| **Study Name:**  | **IRB HUM #:** |
| **Principal Investigator:** |  |

Participant ID #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of Unblinding: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

List any protocol or other study document procedures required for unblinding. If none specified, check N/A:

N/A ☐

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Have these procedures been followed: Yes No

Reason for Unblinding: (Select one)

* Completed study
* Safety concerns
* Accidental Unblinding
* Other explain: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name and title of person that requested the Unblinding \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name and title of person that authorized the Unblinding : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Participant’s Treatment Assignment: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Who was provided the treatment assignment information (e.g., participant, ER medical team, PI, etc.) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Was/were additional action(s) taken after Unblinding, such as participant withdrawal, decrease in dosage, etc.:

Signature of study team member who completed the form: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_