**This form should be used for genetically modified cells**

1. **Product Administration**

Date of Administration: \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)

Protocol Primary Treatment Indication (select one only)

[ ]  Sickle Cell Disease (Genotype \_\_\_\_\_\_)

Subject gender:

[ ]  Male

[ ]  Female

Subject date of birth: \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)

CIBMTR Recipient ID#

(If registered) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Volume available for administration (mL): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Actual volume administered (mL): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Cell concentration: \_\_\_\_\_\_\_\_\_ - \_\_\_\_\_\_\_\_\_ 10 [ ]

per [ ]  kg

[ ]  m2

\_\_\_\_\_\_\_\_\_\_\_ (24 hr clock)

\_\_\_\_\_\_\_\_\_\_\_ (24 hr clock)

Was product administration delayed or stopped prematurely? [ ]  No [ ]  Yes

If Yes, explain: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Administered by (Print name and Title): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Route of product administration: (check route of administration)

[ ]  Intravenous

[ ]  Bone Marrow

Device system used for delivering product:

[ ]  Catheter

[ ]  Other, specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Product administration frequency:

[ ]  One-time administration

[ ]  Multiple administrations

Current product administration is number: \_\_\_\_\_\_\_\_ of \_\_\_\_\_\_\_\_

Date of first product administration: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Did the recipient provide written consent for data submission for the purpose of research studies?

[ ]  No

[ ]  Yes

Will outcome data be collected for this administration?

[ ]  No

[ ]  Yes

1. **REACTION(S) POST PRODUCT ADMINISTRATION**

|  |  |
| --- | --- |
| **Did the subject experience any post product administration reactions?** |  [ ]  **No** [ ]  **Yes *(If YES, check all that apply)*** |
| **Reaction** | **Reaction Occurred (Check if Yes)** | **Reaction Time Post Product Administration (Hours)** | **Severity** | **Resolved** |
| [ ]  Chills | [ ]  | [ ]  0-1 [ ]  >1-24 [ ]  >24-48 | [ ]  Mild [ ]  Moderate [ ]  Severe | [ ]  No [ ]  Yes [ ]  Unknown |
| [ ]  Fever | [ ]  | [ ]  0-1 [ ]  >1-24 [ ]  >24-48 | [ ]  Mild [ ]  Moderate [ ]  Severe | [ ]  No [ ]  Yes [ ]  Unknown  |
| [ ]  Rigors | [ ]  | [ ]  0-1 [ ]  >1-24 [ ]  >24-48 | [ ]  Mild [ ]  Moderate [ ]  Severe | [ ]  No [ ]  Yes [ ]  Unknown |
| [ ]  Dyspnea | [ ]  | [ ]  0-1 [ ]  >1-24 [ ]  >24-48 | [ ]  Mild [ ]  Moderate [ ]  Severe | [ ]  No [ ]  Yes [ ]  Unknown |
| [ ]  Bradycardia  | [ ]  | [ ]  0-1 [ ]  >1-24 [ ]  >24-48 | [ ]  Mild [ ]  Moderate [ ]  Severe | [ ]  No [ ]  Yes [ ]  Unknown |
| [ ]  Tachycardia | [ ]  | [ ]  0-1 [ ]  >1-24 [ ]  >24-48 | [ ]  Mild [ ]  Moderate [ ]  Severe | [ ]  No [ ]  Yes [ ]  Unknown |
| [ ]  Hypertension | [ ]  | [ ]  0-1 [ ]  >1-24 [ ]  >24-48 | [ ]  Mild [ ]  Moderate [ ]  Severe | [ ]  No [ ]  Yes [ ]  Unknown |
| **Reaction** | **Reaction Occurred (Check if Yes)** | **Reaction Time Post Product Administration (Hours)** | **Severity** | **Resolved** |
| [ ]  Hypotension | [ ]  | [ ]  0-1 [ ]  >1-24 [ ]  >24-48 | [ ]  Mild [ ]  Moderate [ ]  Severe | [ ]  No [ ]  Yes [ ]  Unknown |
| [ ]  Hemoglobinuria | [ ]  | [ ]  0-1 [ ]  >1-24 [ ]  >24-48 | [ ]  Mild [ ]  Moderate [ ]  Severe | [ ]  No [ ]  Yes [ ]  Unknown |
| [ ]  Hemoglobinemia | [ ]  | [ ]  0-1 [ ]  >1-24 [ ]  >24-48 | [ ]  Mild [ ]  Moderate [ ]  Severe | [ ]  No [ ]  Yes [ ]  Unknown |
| [ ]  Urticaria | [ ]  | [ ]  0-1 [ ]  >1-24 [ ]  >24-48 | [ ]  Mild [ ]  Moderate [ ]  Severe | [ ]  No [ ]  Yes [ ]  Unknown |
| [ ]  Rash | [ ]  | [ ]  0-1 [ ]  >1-24 [ ]  >24-48 | [ ]  Mild [ ]  Moderate [ ]  Severe | [ ]  No [ ]  Yes [ ]  Unknown |
| [ ]  Pain | [ ]  | [ ]  0-1 [ ]  >1-24 [ ]  >24-48 | [ ]  Mild [ ]  Moderate [ ]  Severe | [ ]  No [ ]  Yes [ ]  Unknown |
| [ ]  Nausea | [ ]  | [ ]  0-1 [ ]  >1-24 [ ]  >24-48 | [ ]  Mild [ ]  Moderate [ ]  Severe | [ ]  No [ ]  Yes [ ]  Unknown |
| [ ]  Vomiting | [ ]  | [ ]  0-1 [ ]  >1-24 [ ]  >24-48 | [ ]  Mild [ ]  Moderate [ ]  Severe | [ ]  No [ ]  Yes [ ]  Unknown |
| [ ]  Other, specify: | [ ]  | [ ]  0-1 [ ]  >1-24 [ ]  >24-48 | [ ]  Mild [ ]  Moderate [ ]  Severe | [ ]  No [ ]  Yes [ ]  Unknown |
| Other reaction specified:  |  |
| List medication(s)/treatment for reaction or symptoms: |

## **General Instructions**

This form should be used for genetically modified cells. All elements on this form are Supplemental.