**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.