# Data Collection Worksheet

**Please Note:** The Data Collection Worksheet (DCW) is a tool to aid integration of a PhenX protocol into a study. The PhenX DCW is not designed to be a data collection instrument. Investigators will need to decide the best way to collect data for the PhenX protocol in their study. Variables captured in the DCW, along with variable names and unique PhenX variable identifiers, are included in the PhenX Data Dictionary (DD) files.

## Donor Information for this HCT

(from Center for International Blood & Marrow Transplant Research form 2400)

1. Specify donor

[ ] Autologous

[ ] Allogenic, related

[ ] Allogenic, unrelated

2. Specify product type (check all that apply)

[ ] Bone marrow

[ ] PBSC

[ ] Single cord blood unit

[ ] Other product

Specify other product _____

3. Is the product genetically modified? (**if autologous, go to the Drug Product Case Report Form below. If allogeneic related, go to question 4. If allogeneic unrelated, go to question 7.**)

[ ] Yes

[ ] No

4. If allogenic, specify the related donor type

[ ] Syngeneic (monozygotic twin)

[ ] HLA-identical sibling (may include non-monozygotic twin)

[ ] HLA-matched other relative (does NOT include a haplo-identical donor)

[ ] HLA-mismatched relative

5. Specify the biological relationship of the donor to the recipient

[ ] Mother

[ ] Father

[ ] Child

[ ] Sibling

[ ] Fraternal twin

[ ] Maternal aunt

[ ] Maternal uncle

[ ] Maternal cousin

[ ] Paternal aunt

[ ] Paternal uncle

[ ] Paternal cousin

[ ] Grandparent

[ ] Grandchild

[ ] Other biological relative

Specify other biological relative:_____

6. Degree of mismatch (related donors only)

[ ] HLA-mismatched 1 allele

[ ] HLA-mismatched ≥ 2 alleles (does not include haplo-identical donor)

7. Specify unrelated donor type

[ ] HLA matched unrelated

[ ] HLA mismatched unrelated

**Drug Product CRF (only for Autologous Donor Products)**

(from Cure Sickle Cell Disease Initiative Common Data Element (CureSCi CDE) Project)

Drug Product Starting Material:

[ ] Hematopoietic Progenitor Cell, Apheresis (HPC-A)

[ ] Hematopoietic Progenitor Cell, Marrow (HPC-M)

[ ] Hematopoietic Progenitor Cell, Cord Blood (HPC-C)

Manufacture Information

Date of Drug Product Manufacture_____

[ ] Proportion of CD34+ cells _____

[ ] Total Colonies Formed: _____ per _____ cells

Expression of globin chain of interest:

[ ] Qualitative Assay: [ ] Positive [ ] Negative

[ ] Quantitative Assay: _____

Were any additional drug product potency assays performed on drug product?

[ ] Yes [ ] No

If yes, describe and report result_____

Type of Modification:

[ ] Integrating Vector

[ ] Gene Editing Nuclease

[ ] Stem Cell Expansion

**POPULATE SECTION A FOR INTEGRATING VECTOR CELL PRODUCT**

**POPULATE SECTION B FOR GENE EDITED CELL PRODUCT**

Section A

Type of Integrating Vector: [ ] Retrovirus [ ] Lentivirus [ ] Other_____

[ ] Drug Product VCN_____

[ ] Percentage of cells positive for integrating vector _____

[ ] Drug Product VCN/cell _____

Section B

Type of Editing: [ ] CRISPR-Cas 9 [ ] ZFN [ ] TALEN [ ] Cytosine Base Editing

[ ] Other_____

Mode of nuclease delivery: [ ] mRNA by EP [ ] RNP by EP [ ] AAV [ ] Other

gRNA target gene_____ Mode of Delivery_____

**Donor Template used?** [ ] Yes [ ] No

If Yes, mode of delivery: [ ] ssODN [ ] AAV [ ] Other [ ] Drug Product:

On-target Indels_____ Verified off-target indels_____

Conversion _____%



Protocol source: https://www.phenxtoolkit.org/protocols/view/850501