CIBMTR®
A RESEARCH COLLABORATION BETWEEN THE MEDICAL COLLEGE OF WISCONSIN AND NMDP

Cellular Therapy Product

Registry Use Only

Sequence Number:

Date Received:

CIBMTR Center Number: ___ ___ ___ ___ ___

CIBMTR Research ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

Event date: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

Product Identifiers

NMDP cord blood unit ID: __ __ __ __ __ __ __ __ __ __ __ __ __ __ __

Registry donor ID: __ __ __ __ __ __ __ __ __ __ __ __ __ __ __

Non-NMDP cord blood unit ID: __ __ __ __ __ __ __ __ __ __ __ __ __ __ __

Global Registration Identifier for Donors (GRID): __

Donor DOB: __ __ __ __ - __ __ - __ __
YYYY MM DD

Donor age: __ __ ☐ Months *(use only if less than 1 year old)*

☐ Years

Donor sex ☐ Male ☐ Female ☐ Unknown

CIBMTR Center Number: ___ ___ ___ ___ ___ CIBMTR Research ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

Cellular Therapy Product Identification

If more than one type of cell therapy product is infused, each product type must be reported separately on a new F4003.

1. Is the product out of specification? *(only for commercially available products)*
   - ☐ Yes
   - ☐ No

Cell Product Source

2. Date of cell product collection: ___ ___ ___ ___ - ___ ___ - ___ ___
   YYYY MM DD

3. What is the tissue source of the cellular product? *(check all that apply)*
   - ☐ Bone marrow (BM) - ***Go to question 5***
   - ☐ Cord blood unit (CBU) - ***Go to question 5***
   - ☐ Peripheral blood - ***Go to question 5***
   - ☐ Tumor - ***Go to question 5***
   - ☐ Other tissue source - ***Go to question 4***

4. Specify other tissue source: _____

5. What is the cell type? *(check all that apply)*

Lymphocytes

- ☐ Lymphocytes (unselected) - ***Go to question 7***
- ☐ CD4+ lymphocytes - ***Go to question 7***
- ☐ CD8+ lymphocytes - ***Go to question 7***
- ☐ Regulatory T-cells (TREG) - ***Go to question 7***

Other Cells

- ☐ Mesenchymal stromal stem cells (MSCs) - ***Go to question 7***
- ☐ Unspecified mononuclear cells - ***Go to question 7***
- ☐ Other cell type – ***Go to question 6***

6. Specify other cell type: _____

7. Where was the cellular therapy product manufactured / processed?
   - ☐ Pharmaceutical / biotech company – ***Go to question 9***
   - ☐ Cell processing laboratory off site – ***Go to question 10***

☐ Cell processing laboratory at the same center as the product is being infused – ***Go to question 11***

☐ Other site – ***Go to question 8***

8. Specify other site:_____ – ***Go to question 10***

9. Specify pharmaceutical / biotech company

☐ Adaptimmune – ***Go to question 11***

☐ AlloVir – ***Go to question 11***

☐ Atara Biotherapeutics – ***Go to question 11***

☐ Autolus – ***Go to question 11***

☐ Bellicum Pharmaceuticals– ***Go to question 11***

☐ Bluebird Bio – ***Go to question 11***

☐ Celgene – ***Go to question 11***

☐ CRISPR Therapeutics – ***Go to question 11***

☐ Daiichi Sankyo – ***Go to question 11***

☐ FATE Therapeutics – ***Go to question 11***

☐ Iovance Biotherapeutics – ***Go to question 11***

☐ Janssen Pharmaceuticals– ***Go to question 11***

☐ Juno Therapeutics – ***Go to question 11***

☐ Kite Pharma – ***Go to question 11***

☐ Marker Therapeutics – ***Go to question 11***

☐ Mesoblast – ***Go to question 11***

☐ Miltenyi Biotec– ***Go to question 11***

☐ Novartis – ***Go to question 11***

☐ Orca Biosystems – ***Go to question 11***

☐ Poseida Therapeutics, Inc – ***Go to question 11***

☐ Rapa Therapeutics – ***Go to question 11***

☐ Other pharmaceutical company – ***Go to question 10***

Specify the institution / company where the cellular product was manufactured

10. Name: _____

City: _____

State: _____

Country: _____– ***Go to question 11***

CIBMTR Center Number: ___ ___ ___ ___ ___ CIBMTR Research ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

Collection Procedure

This section is for autologous products only. If this was an allogeneic infusion, continue to "Cell Product Manipulation" section.

11. Specify the method of product collection

- ☐ Apheresis / Leukapheresis – ***Go to question 13***
- ☐ Bone marrow aspirate – ***Go to question 13***
- ☐ Cord blood – ***Go to question 13***
- ☐ Peripheral blood draw – ***Go to question 13***
- ☐ Tumor biopsy sample – ***Go to question 13***
- ☐ Other method – ***Go to question 12***

12. Specify other method: _____

13. Number of collections: ___

Cell Product Manipulation

14. Were the cells in the infused product selected / modified / engineered prior to infusion?

- ☐ Yes – ***Go to question 15***
- ☐ No – **Go to question 29**

15. Specify the portion manipulated

- ☐ Entire product – ***Go to question 17***
- ☐ Portion of product – ***Go to question 16***

16. Was the unmanipulated portion of the product also infused?

- ☐ Yes
- ☐ No

17. Was the same manipulation method used on the entire product / all portions of the product?

- ☐ Yes
- ☐ No

18. Specify the method(s) used to manipulate the product *(check all that apply)*

- ☐ Cultured (ex-vivo expansion) – ***Go to question 29***
- ☐ Induced cell differentiation **– *Go to question 29***
- ☐ Cell selection - positive– ***Go to question 29***

- ☐ Cell selection - negative– ***Go to question 29***
- ☐ Cell selection based on affinity to a specific antigen– ***Go to question 29***
- ☐ Genetic manipulation (gene transfer / transduction) ***– Go to question 20***
- ☐ Other cell manipulation – ***Go to question 19***

19. Specify other cell manipulation: _____ ***– Go to question 29***

20. Specify the type(s) of genetic manipulation *(check all that apply)*

Viral transduction

- ☐ Lentivirus – ***Go to question 29***
- ☐ Retrovirus – ***Go to question 29***
- ☐ Transposon – ***Go to question 29***

Non-viral transfection

- ☐ Electroporation – ***Go to question 29***
- ☐ Other non-viral transfection - ***Go to question 21***

Gene editing

- ☐ Gene editing - ***Go to question 22***

Non-native protein expression

- ☐ Chimeric Antigen Receptor (CAR) – ***Go to question 24***
- ☐ Suicide gene – ***Go to question 26***
- ☐ T-cell receptor – ***Go to question 29***

Other genetic manipulation

- ☐ Other genetic manipulation – ***Go to question 28***

Non- viral Transfection

21. Specify other non-viral transfection: _____ – ***Go to question 29***

Gene Editing

22. Specify the gene edited *(check all that apply)*
    - ☐ HLA – ***Go to question 24***
    - ☐ PDL – 1 – ***Go to question 24***
    - ☐ TCR (T-cell receptor) – ***Go to question 24***
    - ☐ Other gene – ***Go to question 23***

23. Specify other gene: _____ – ***Go to question 29***

Non-native Protein Expression

24. Specify details of the CAR construct *(check all that apply)*

- ☐ CD3ζ – ***Go to question 26***
- ☐ CD27 – ***Go to question 26***
- ☐ CD28 – ***Go to question 26***
- ☐ ICOS – ***Go to question 26***
- ☐ OX40 – ***Go to question 26***
- ☐ 4-1BB – ***Go to question 26***
- ☐ Bicistronic – ***Go to question 26***
- ☐ Tandem – ***Go to question 26***
- ☐ Other construct – ***Go to question 25***

25. Specify other construct: _____ – ***Go to question 29***

26. Specify the suicide gene *(check all that apply)*

- ☐ iCasp9 – ***Go to question 28***
- ☐ Other – ***Go to question 27***

27. Specify other suicide gene:_____ – ***Go to question 29***

Other

28. Specify other genetic manipulation: _____

29. Was the product manipulated to recognize a specific target / antigen?

- ☐ Yes – ***Go to question 30***
- ☐ No – ***Go to question 36***

30. Specify target *(check all that apply)*

- ☐ Viral – ***Go to question 31***
- ☐ Tumor / cancer antigen – ***Go to question 33***
- ☐ Other target – ***Go to question 35***

Targets specific to viral infections

31. Specify viral target(s) *(check all that apply)*

- ☐ Adenovirus – ***Go to question 33***
- ☐ BK virus – ***Go to question 33***
- ☐ COVID-19 (SARS-CoV-2) – ***Go to question 33***
- ☐ Cytomegalovirus (CMV) – ***Go to question 33***

- ☐ Epstein-Barr virus (EBV) – ***Go to question 33***
- ☐ Human herpes virus 6 – ***Go to question 33***
- ☐ Human Immunodeficiency Virus (HIV) – ***Go to question 33***
- ☐ Human Parainfluenza 3 (HPIV3) – ***Go to question 33***
- ☐ JC Virus (Progressive Multifocal Leukoencephalopathy (PML)) – ***Go to question 33***
- ☐ Respiratory syncytial virus (RSV) – ***Go to question 33***
- ☐ Other virus – ***Go to question 32***

32. Specify other virus: _____ - ***Go to question 36***

Targets specific to tumors / cancer antigens

33. Specify the tumor / cancer antigen *(check all that apply)*

- ☐ AFP (alpha fetoprotein)
- ☐ BAFF-R
- ☐ BCMA
- ☐ B7H3
- ☐ CD11
- ☐ CD16
- ☐ CD19
- ☐ CD20
- ☐ CD22
- ☐ CD30
- ☐ CD33
- ☐ CD38
- ☐ CD56
- ☐ CD123
- ☐ CD138
- ☐ CD171
- ☐ CD229
- ☐ CLL1
- ☐ Claudin6
- ☐ Claudin18.2
- ☐ CS-1 (SLAMF7)
- ☐ EGFR
- ☐ EGFRvIII
- ☐ EphrinA2

- ☐ Folate receptor alpha
- ☐ GD2
- ☐ GPRC5D
- ☐ HER2
- ☐ HPV-16E6
- ☐ Integrin β7
- ☐ IL13Ra2
- ☐ Lewis-Y
- ☐ MAGE-A4
- ☐ MAGE-A10
- ☐ Mesothelin (MSLN)
- ☐ MUC16
- ☐ Mutant KRAS for TCR
- ☐ NKG2D
- ☐ NY-ESO-1
- ☐ PRAME
- ☐ PSCA (prostate stem cell antigen)
- ☐ ROR1
- ☐ SSX
- ☐ Survivin
- ☐ TACI
- ☐ WT-1
- ☐ Other tumor / cancer antigen – ***Go to question 34***

34. Specify tumor / cancer antigen: _____- ***Go to question 36***

Other target

35. Specify other target: _____

Cell Product Analysis

36. Is the percentage of genetically modified cells known?
    - ☐ Yes – ***Go to question 37***
    - ☐ No - ***Go to question 40***
    - ☐ Unknown – ***Go to question 40***

37. Date percentage genetically modified cells sample collected: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

38. Percent of genetically modified cells: ___ ___ ____%

39. Was the target percent of genetically modified cells achieved?
- ☐ Yes
- ☐ No

40. Was viability of cells done?
- ☐ Yes – ***Go to question 41***
- ☐ No – ***Go to question 43***
- ☐ Unknown – ***Go to question 43***

41. Date viability of cells done: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

42. Viability of cells: ___ ___ ___ %

Product Infusion

43. Specify the total number of planned infusions of this product: ___ ___ *(as part of this course of cellular therapy)*