Change Notes

2005 Revision 5 - Confirmation of HLA Typing

Public ID: 3871296 Version: 1.0

Notes:

- These change notes are based on a comparison with Form Builder report 3075541v 1.0 (2005 Revision 3 - Confirmation of HLA Typing)
- These change notes do not list changes to module public IDs. The module public IDs for all modules have changed. Please refer to the AGNIS Metadata Tool output or the Excel spreadsheet downloaded from the caDSR's Form Builder application for more detailed information
- The "Major" changes section of the notes includes those changes which are most likely to impact database mapping applications. They include changes such as the addition or removal of CDEs
- The "Minor" changes section of the notes includes those changes which are least likely to impact database mapping applications. They include changes such as modifications to question or instruction texts.

Header:

- o Old: This form must be completed for all non-NMDP allogeneic or syngeneic donors or recipients, or non-NMDP cord blood units. If the donor, recipient, or cord blood unit was secured through the NMDP, then report HLA typing on the appropriate NMDP forms.
  A separate copy of this form should be completed for each non-NMDP donor, recipient, or cord blood unit.
- o New: none

Footer:

- o Old: CIBMTR Form 2005 revision 3 (1-5) April 2010
- o New: CIBMTR Form 2005 revision 5.0 last updated October 2013

Module: Registry Use Only

Minor:

- Changed the question text for the following CDEs:

  - o 2527889v1.0 (Clinical Data Form Sequence Number)

- Old: Sequence number:
- New: Sequence Number:

- 2866943v1.0 (Clinical Data Form Received Date)

  - Old: Date received:
  - New: Date Received:

Module: Key Fields

New Module

Major: Module added

- Added the following CDEs:
  - 2527895v2.0 (Hematopoietic Cell Transplantation Recipient Institution::Center for International Blood and Marrow Transplant Research Facility Number)
  - 2527897v2.0 (Hematopoietic Cell Transplantation Recipient Identification Number)
  - 2866938v2.0 (Hematopoietic Cell Transplantation Occurrence Date)

Module: Key Field

Major: Module along with all CDEs removed.

Module: HCT Type

New Module

Major: Module added

- Module repetition count: 2

- Added the following CDEs:
  - 2730901v2.0 (Hematopoietic Cell Graft Source Name)
  - 3567333v1.0 (Hematopoietic Cell Graft Source Indicator)

- Added the permissible values for the following CDE 2730901v2.0 (Hematopoietic Cell Graft Source Name)

  - 2568334v1.0 (Autologous)
  - 2730898v1.0 (Allogeneic, unrelated)

- o 2730899v1.0 (Allogeneic, related)

- Added the permissible values for the following CDE 3567333v1.0 (Hematopoietic Cell Graft Source Indicator)

  - o 2567168v1.0 (Yes)

<u>Minor</u>:

- Added the instruction text for the following CDEs:
  - o 2730901v2.0 (Hematopoietic Cell Graft Source Name)
    - ▪ <u>New</u>: check all the apply

Module: Product Type

New Module

<u>Major</u>: Module added

- Module repetition count: 4

- Added the following CDEs:
  - o 2730912v2.0 (Hematopoietic Cell Graft Type Name)
  - o 3567334v1.0 (Hematopoietic Cell Graft Type Indicator)
  - o 2527917v2.0 (Hematopoietic Cell Graft Other Type Specify)

- Added the permissible values for the following CDE 2730912v2.0 (Hematopoietic Cell Graft Type Name)

  - o 2581613v1.0 (Bone marrow)
  - o 2581240v1.0 (PBSC)
  - o 3809647v1.0 (Single cord blood unit)
  - o 2730908v1.0 (Multiple cord blood units)
  - o 3870223v1.0 (Other product)

- Added the permissible values for the following CDE 3567334v1.0 (Hematopoietic Cell Graft Type Indicator)

  - o 2567168v1.0 (Yes)

<u>Minor</u>:

- Added the instruction text for the following CDEs:
  - o 2730912v2.0 (Hematopoietic Cell Graft Type Name)

<u>New</u>: check all the apply

- Added the instruction text for the following CDEs:
    - 2527917v2.0 (Hematopoietic Cell Graft Other Type Specify)

<u>New</u>: Answer only if the response to CDE 2730912 is "Other product."

Module: HLA Typing Source

<u>Major</u>: Module along with all CDEs removed.

Module: Donor / Cord Blood Unit Identification

New Module

<u>Major</u>: Module added

- Added the following CDEs:
    - 3875438v1.0 (HLA Typing And Source Type)
    - 3809537v1.0 (Hematopoietic Cell Graft Unrelated Tissue Donor Negation National Marrow Donor Program Identifier)
    - 3874258v1.0 (Hematopoietic Cell Graft Umbilical Cord Blood Type Negation National Marrow Donor Program Identifier)
    - 3811779v1.0 (Umbilical Cord Blood Maternal HLA Typing Availability Indicator)
    - 3812078v1.0 (Biological Relative And HLA Typing Source Type)
    - 3811783v1.0 (Biological Relative And HLA Typing Source Specify Text)
    - 3809532v1.0 (Person Birth Date Known Unknown Indicator)
    - 3190237v1.0 (Person Birth Date)
    - 3809551v1.0 (Person Age Known Unknown Indicator)
    - 3809533v1.0 (Person Age Value)
    - 3809811v1.0 (Person Age Time Unit of Measure Text Name)
    - 3171628v2.0 (Person Sex Type)
    - 3811774v1.0 (HLA Typing Person Donor Indicator)

- Added the permissible values for the following CDE 3875438v1.0 (HLA Typing And Source Type)

    - 2705056v1.0 (Recipient-final typing)
    - 3874728v1.0 (Recipient's biological relative)
    - 3874738v1.0 (Unrelated donor - confirmatory typing)
    - 2705057v1.0 (Cord blood unit - confirmatory typing)

- o   3874731v1.0 (Cord blood unit maternal HLA typing)

- Added the permissible values for the following CDE 3811779v1.0 (Umbilical Cord Blood Maternal HLA Typing Availability Indicator)
  - o   2567168v1.0 (Yes)
  - o   2567170v1.0 (No)

- Added the permissible values for the following CDE 3812078v1.0 (Biological Relative And HLA Typing Source Type)

  - o   3928787v1.0 (Recipient's mother - confirmatory typing)
  - o   3928786v1.0 (Recipient's father - confirmatory typing)
  - o   3928788v1.0 (Recipient's sibling - confirmatory typing)
  - o   3812064v1.0 (Recipient's syngeneic (identical) twin - confirmatory typing)
  - o   3812063v1.0 (Recipient's fraternal twin - confirmatory typing)
  - o   3928783v1.0 (Recipient's child - confirmatory typing)
  - o   3928781v1.0 (Recipient's aunt - confirmatory typing)
  - o   3928790v1.0 (Recipient's uncle - confirmatory typing)
  - o   3928785v1.0 (Recipient's cousin - confirmatory typing)
  - o   3004998v1.0 (Other biological relative)

- Added the permissible values for the following CDE 3809532v1.0 (Person Birth Date Known Unknown Indicator)
  - o   2934435v1.0 (Known)
  - o   2575365v1.0 (Unknown)
- Added the permissible values for the following CDE 3809551v1.0 (Person Age Known Unknown Indicator)
  - o   2934435v1.0 (Known)
  - o   2575365v1.0 (Unknown)
- Added the permissible values for the following CDE 3809811v1.0 (Person Age Time Unit of Measure Text Name)
  - o   2569689v1.0 (Months)
  - o   2670939v1.0 (Years)

- Added the permissible values for the following CDE 3171628v2.0 (Person Sex Type)
  - o   2561834v1.0 (male)
  - o   2581015v1.0 (female)

- Added the permissible values for the following CDE 3811774v1.0 (HLA Typing Person Donor Indicator)
  - 2567168v1.0 (Yes)
  - 2567170v1.0 (No)
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Module: HLA Typing by DNA Technology

Minor:

- Module Instruction Text change:
  - Old: A lab report may be attached to the completed report to provide additional information or typing result clarification for the form review process at the NMDP.
  - New: none.
- Question Text change:
  - Old: Is a copy of the lab report attached?
  - New: Was documentation submitted to the CIBMTR?
- Question Instruction Text change:
  - Old: none.
  - New: E.g. lab report

Module: HLA Typing by DNA Technology - Class I

Major:

- Added the following CDEs:
  - 3809813v1.0 (HLA-A Gene Genotyping Finding Status Indicator)
  - 3809814v1.0 (HLA-B Gene Genotyping Finding Status Indicator)
  - 3809815v1.0 (HLA-C Gene Genotyping Finding Status Indicator)
- Removed the following CDEs:
  - 3073218v1.0 (HLA-A Gene Genotyping Missing Value Reason Indicator)
  - 3073220v1.0 (HLA-B Gene Genotyping Missing Value Reason Indicator)
  - 3073222v1.0 (HLA-C Gene Genotyping Missing Value Reason Indicator)

Module: HLA Typing by DNA Technology - Class II

Major:

- Added the following CDEs:
  - 3809820v1.0 (HLA-DRB1 Gene Genotyping Finding Status Indicator)

- Removed the follow CDEs:
    - 3073224v1.0 (HLA-DRB1 Gene Genotyping Missing Value Reason Indicator)

Module: HLA Typing by DNA Technology - Class II (Optional)

Major:

- Added the following CDEs:
    - 3810662v1.0 (HLA-DRB3 Gene Genotyping Finding Status Indicator)
    - 3810663v1.0 (HLA-DRB4 Gene Genotyping Finding Status Indicator)
    - 3810664v1.0 (HLA-DRB5 Gene Genotyping Finding Status Indicator)
    - 3811025v1.0 (HLA-DQB1 Gene Genotyping Finding Status Indicator)
    - 3811026v1.0 (HLA-DPB1 Gene Genotyping Finding Status Indicator)
    - 3811030v1.0 (HLA-DQA1 Gene Genotyping Finding Status Indicator)
    - 3811038v1.0 (HLA-DPA1 Gene Genotyping Finding Status Indicator)

- Removed the following CDEs:
    - 3073226v1.0 (HLA-DRB3 Gene Genotyping Missing Value Reason Indicator)
    - 3073228v1.0 (HLA-DRB4 Gene Genotyping Missing Value Reason Indicator)
    - 3073233v1.0 (HLA-DRB5 Gene Genotyping Missing Value Reason Indicator)
    - 3073235v1.0 (HLA-DQB1 Gene Genotyping Missing Value Reason Indicator)
    - 3073237v1.0 (HLA-DPB1 Gene Genotyping Missing Value Reason Indicator)
    - 3073239v1.0 (HLA-DQA1 Gene Genotyping Missing Value Reason Indicator)
    - 3073243v1.0 (HLA-DPA1 Gene Genotyping Missing Value Reason Indicator)

Module - 2005 Revision 3: Antigens Defined by Serologic Typing

Major: Module removed. CDEs within this module have been broken out into several modules in Revision 5 as listed below.

- Removed the following CDEs from the entire form:
    - 2693502v1.0 (HLA-A Gene Serological Antigen Count)
    - 2693507v1.0 (HLA-B Gene Serological Antigen Count)

- 2693511v1.0 (HLA-C Gene Serological Antigen Count)
- 2704098v1.0 (HLA-Bw4 Antigen Present Laboratory Finding Yes or No Response)
- 2704108v1.0 (HLA-Bw6 Antigen Present Laboratory Finding Yes or No Response)
- 2695304v1.0 (HLA-DR Antigen Serological Antigen Count)
- 2704135v1.0 (HLA-DR51 Antigen Present Laboratory Finding Yes or No Response)
- 2704158v1.0 (HLA-DR53 Antigen Present Laboratory Finding Yes or No Response)
- 2695328v1.0 (HLA-DQ Antigen Serological Antigen Count)
- 2704199v1.0 (HLA-DP Antigen Serological Antigen Count)

Module: Antigens Defined by Serologic Typing - A Antigens

New Module

<u>Major</u>:

- Added the following CDEs:
    - 3811041v1.0 (HLA Typing Antigen Count)
- Added the following CDEs from Module: **Antigens Defined by Serologic Typing**
    - 2695256v1.0 (HLA-A Gene First Antigen Name)
    - 2695266v1.0 (HLA-A Gene First Antigen Name)

Module: Antigens Defined by Serologic Typing - B Antigens

<u>Major</u>:

- Added the following CDEs:
    - 3811041v1.0 (HLA Typing Antigen Count)
- Added the following CDEs from Module: **Antigens Defined by Serologic Typing**
    - 2695275v1.0 (HLA-B Gene First Antigen Name)
    - 2695284v1.0 (HLA-B Gene Second Antigen Name)

Module: Optional Antigen Reporting - Antigens Defined by Serologic Typing - C Antigens

Major:

- Added the following CDEs:
  - 3811041v1.0 (HLA Typing Antigen Count)
- Added the following CDEs from Module: **Optional Antigen Reporting: Antigens Defined by Serologic Typing**
  - 2695291v1.0 (HLA-C Gene First Antigen Name)
  - 2695297v1.0 (HLA-C Gene Second Antigen Name)

Module: Optional Antigen Reporting - Antigens Defined by Serologic Typing - Bw Specificity

Major:

- Added the following CDEs from Module: **Optional Antigen Reporting: Antigens Defined by Serologic Typing**:
  - **3811042v1.0 (HLA-Bw4 Antigen Present Indicator)**
  - **3811043v1.0 (HLA-Bw6 Antigen Present Indicator)**

Module: Optional Antigen Reporting - Antigens Defined by Serologic Typing - DR Antigens

Major:

- Added the following CDEs:
  - 3811041v1.0 (HLA Typing Antigen Count)
- Added the following CDEs from Module: **Optional Antigen Reporting: Antigens Defined by Serologic Typing**:
  - 2695308v1.0 (HLA-DR Antigen First Antigen Name)
  - 2695323v1.0 (HLA-DR Antigen Second Antigen Name)
  - 3811044v1.0 (HLA-DR51 Antigen Present Indicator)
  - 3811045v1.0 (HLA-DR52 Antigen Present Indicator)
  - 3811046v1.0 (HLA-DR53 Antigen Present Indicator)

Module: Optional Antigen Reporting - Antigens Defined by Serologic Typing - DQ Antigens

Major:

- Added the following CDEs:
  - 3811041v1.0 (HLA Typing Antigen Count)
- Added the following CDEs from Module: **Optional Antigen Reporting: Antigens Defined by Serologic Typing**:
  - 2695343v1.0 (HLA-DQ Antigen First Antigen Name)

- 2695347v1.0 (HLA-DQ Antigen Second Antigen Name)

Module: Optional Antigen Reporting - Antigens Defined by Serologic Typing - DP Antigens

<u>Major</u>:

- Added the following CDEs:
    - 3811041v1.0 (HLA Typing Antigen Count)
- Added the following CDEs from Module: **Optional Antigen Reporting: Antigens Defined by Serologic Typing**:
    - 2704246v1.0 (HLA-DP Antigen First Antigen Name)
    - 2704252v1.0 (HLA-DP Antigen Second Antigen Name)

Module: Author Information

<u>Major</u>:

- Added the following CDEs:
    - 3771111v1.0 (Form Entry Date)
- Removed the following CDEs:
    - 2828513v1.0 (Contact Person Location Telephone Number)
    - 2828511v1.0 (Contact Person Location Fax Number)