OPTN

Notice of OPTN Data Collection Changes

Update Post-Transplant Histocompatibility Data

Sponsoring Committee:	**Histocompatibility**
Data Collection Affected:	**OPTN Data System: Donor Histocompatibility Form (DHF)** **Recipient Histocompatibility Form (RHF)** **Discrepant HLA Typings Report**
Public Comment:	**January 23, 2024 –March 19, 2024**
Board Approved:	**June 17-18, 2024**
Effective Date:	**Pending implementation and notice to OPTN members**

Purpose of Data Collection Changes

The following changes will be made to post-transplant histocompatibility data collection within the OPTN Computer System:

- Update post-transplant histocompatibility data collection forms to be consistent with current histocompatibility testing methods
- Add data collection for virtual crossmatching to inform recipient treatment and evaluate impacts of the practice on recipient outcomes, graft outcomes, and cold ischemic time
- Generate Discrepant HLA Typings reports for all potential HLA critical discrepancies which will increase awareness of, allow for a system-wide perspective of, and better inform future policy updates related to critical HLA discrepancies

Proposal History

The Histocompatibility Committee (Committee) formed a subcommittee that performed a comprehensive review of the data elements, as well as generation and branching logic, for the Donor Histocompatibility Form (DHF), Recipient Histocompatibility Form (RHF), and Discrepant HLA Typings Report. These data collection instruments are completed within the Data System for the Organ Procurement and Transplantation Network post-transplant. Proposed data collection changes were presented to the Data Advisory Committee (DAC) prior to and after the completion of the comprehensive review and received endorsement from the DAC. The proposal was released for public comment in Winter 2024. Overall, the proposal received support during public comment. Some modifications were made post-public comment in response to suggestions received,

Summary of Changes

These data collection changes impact required data elements and response options in the Donor Histocompatibility Form, Recipient Histocompatibility Form, and Discrepant HLA Typings Report. Overall, the number of required data collection elements will be reduced. Although there are additions and modifications the net reductions will be four data elements from the DHF and eight from the RHF. There

is, however, a projected increase of occurrences that the Discrepant HLA Typings Report will generate. Based on 2022 data, there would be 70 donor critical HLA discrepancies in the country that would have been generated for with the amended logic, with a median of one donor discrepancy across all histocompatibility labs with critical HLA discrepancies. While these reports generate for all labs involved in the discrepancy, some of these reports are already being generated and most labs should not have a significantly increased number of Discrepant HLA Typings Reports to reconcile and complete.

Implementation

Histocompatibility laboratories will need to become familiar with the revised data collection requirements, including new data collection for virtual crossmatching. In addition, labs may have an increased number of Discrepant HLA Typings Reports to fill out expected to be roughly a median of one report per lab per year with the amended logic.

These changes require technical implementation within the OPTN Computer System, for the Donor Histocompatibility Form, Recipient Histocompatibility Form, and Discrepant HLA Typings Report. Multiple data elements will be removed and others added. Logic for when the Discrepant HLA Typings Report generates and how the entered data is viewed after resolution and associated with donor and recipient records will change.

This proposal requires the submission of official OPTN data that are not presently collected by the OPTN. The OPTN contract requires that data collected pursuant to the OPTN's regulatory requirements in §121.11 of the OPTN Final Rule will be collected through OMB approved data collection forms. Forms will be submitted for OMB approval under the Paperwork Reduction Act of 1995. This will require a revision of the OMB-approved data collection instruments, which may impact the implementation timeline.

Affected Data Collection

New language is underlined (example) and language that is deleted is struck through (~~example~~).

Table 1: Data Modifications: OPTN Data System (Donor Histocompatibility)

Data Field	Form	Response Option Description
Date Typing Completed	Donor Histocompatibility Form	MM/DD/YYYY
~~Date Typing Completed Class I~~	Donor Histocompatibility Form	~~MM/DD/YYYY~~
Target Source	Donor Histocompatibility Form	Peripheral Blood, Lymph Nodes, Spleen, Buccal Swab or Other (Multi-select)
~~Target Source for Class I~~	Donor Histocompatibility Form	~~Peripheral Blood, Lymph Nodes, Spleen, Buccal Swab or Other (Multi-select)~~

Data Field	Form	Response Option Description
~~Typing Method Class I~~	Donor Histocompatibility Form	~~Serology, DNA (Multi-select)~~
~~Date Typing Completed Class II~~	Donor Histocompatibility Form	~~MM/DD/YYYY~~
~~Typing Method Class II~~	Donor Histocompatibility Form	~~Serology, DNA (Multi-select)~~
~~Target Source for Class II~~	Donor Histocompatibility Form	~~Peripheral Blood, Lymph Nodes, Spleen, Buccal Swab or Other (Multi-select)~~

Table 2: Data Modifications: OPTN Data System (Recipient Histocompatibility)

Data Field	Form	Response Option Description
Most Recent CPRA	Recipient Histocompatibility Form: Recipient Information	Display calculated CPRA from Waitlist (Displays for kidney, pancreas, lung, heart, liver, intestine, and vascular composite allografts)
Prospective Virtual Crossmatch Performed	Recipient Histocompatibility Form: Test Information	Yes, No
~~Date HLA Typing Completed Class I~~	Recipient Histocompatibility Form: Section I-Recipient HLA Typing	~~MM/DD/YYYY~~
Date HLA Typing Completed	Recipient Histocompatibility Form: Section I-Recipient HLA Typing	MM/DD/YYYY
~~Typing Method Class I~~	Recipient Histocompatibility Form: Section I-Recipient HLA Typing	~~Serology, DNA (Multi-select)~~
~~Date HLA Typing Completed Class II~~	Recipient Histocompatibility Form: Section I-Recipient HLA Typing	~~MM/DD/YYYY~~
~~Typing Method Class II~~	Recipient Histocompatibility Form: Section I-Recipient HLA Typing	~~Serology, DNA (Multi-select)~~

Data Field	Form	Response Option Description
Were any HLA antibodies detected ~~by:~~ pre-transplant?	Recipient Histocompatibility Form: Section II-HLA Antibody Screening	~~Cytotoxicity?~~ ~~Yes, No, Not Done~~ ~~Solid-phase?~~ ~~Yes, No, Not Done~~ Yes, No, Not Done
Were there ~~current~~ pre-transplant donor specific HLA antibodies?	Recipient Histocompatibility Form: Section II-HLA Antibody Screening	Yes, No, Unknown
~~Were there historical donor specific HLA antibodies?~~	Recipient Histocompatibility Form: Section II-HLA Antibody Screening	~~Yes, No, Unknown~~
~~CPRA (%) – Most Recent~~	Recipient Histocompatibility Form: Section II-HLA Antibody Screening	~~(Free text)~~
~~CPRA (%) – Peak~~	Recipient Histocompatibility Form: Section II-HLA Antibody Screening	~~(Free text)~~
Date of most recent HLA antibody screening used for Virtual Crossmatch	Recipient Histocompatibility Form: Section III-Virtual Crossmatch	MM/DD/YYYY
Date of the most recent recipient crossmatch serum	Recipient Histocompatibility Form: Section ~~III~~ IV- Physical Crossmatch	MM/DD/YYYY
Donor ~~C~~cell source	Recipient Histocompatibility Form: Section ~~III~~ IV- Physical Crossmatch	Peripheral blood, lymph nodes, spleen, buccal swab or other
Which T-cell crossmatch tests were performed?	Recipient Histocompatibility Form: Section ~~III~~ IV- Physical Crossmatch	~~Cytotoxicity no AHG~~, ~~Cytotoxicity AHG~~, Cytotoxicity, Flow Cytometry, Solid Phase, Not tested (multi-select, each one triggers a sub-response for positive, negative, or indeterminate single select)

Data Field	Form	Response Option Description
Which B-cell crossmatch tests were performed?	Recipient Histocompatibility Form: Section ~~III~~ IV- Physical Crossmatch	~~Cytotoxicity no AHG~~, ~~Cytotoxicity AHG~~, Cytotoxicity, Flow Cytometry, Solid Phase, Not tested (multi-select, each one triggers a sub-response for positive, negative, or indeterminate single select)
~~Which historical crossmatch tests were performed?~~	Recipient Histocompatibility Form: Section ~~III~~ IV- Physical Crossmatch	~~Cytotoxicity no AHG, Cytotoxicity AHG, Flow Cytometry, Solid Phase, Not tested (multi-select, each one triggers a sub-response for negative or positive single select)~~
~~Donor Retyped Class I~~	Recipient Histocompatibility Form: Section ~~IV~~ V - Donor Retyping	~~Yes, No, Unknown~~
~~Date Typing Completed Class I~~	Recipient Histocompatibility Form: Section ~~IV~~ V - Donor Retyping	~~MM/DD/YYYY~~
Date HLA Typing Completed	Recipient Histocompatibility Form: Section ~~IV~~ V - Donor Retyping	MM/DD/YYYY
~~Typing Method Class I~~	Recipient Histocompatibility Form: Section ~~IV~~ V - Donor Retyping	~~Serology, DNA (Multi-select)~~
~~Donor Retyped Class II~~	Recipient Histocompatibility Form: Section ~~IV~~ V - Donor Retyping	~~Yes, No, Unknown~~
~~Date HLA Typing Completed Class II~~	Recipient Histocompatibility Form: Section ~~IV~~ V - Donor Retyping	~~MM/DD/YYYY~~
~~Typing Method Class II~~	Recipient Histocompatibility Form: Section ~~IV~~ V - Donor Retyping	~~Serology, DNA (Multi-select)~~

Table 3: Data Modifications: OPTN Data System (Discrepant HLA Typings)

Data Element	Form	Response Option Description
Resolved Reason for Discrepancy	Discrepant HLA Typings Report	~~Low Cell Numbers~~ ~~Poor Cell Viability~~ ~~Low Antigen Expression~~ ~~PBL Vs LN/Spleen~~ ~~Serology Vs Molecular Typing~~ Incorrect Assignment Parent Vs Split(s) Incorrect Split ~~Crossreactive Antigen~~ ~~Blank Antigen~~ ~~Unable to Type/Identify Antigens~~ Incorrect Specimen Transcription Error ~~Correct Typing~~ Other, specify (with free text box) Null Allele This Typing Confirmed Correct Reagent/Assay Issue Incorrect Allele Assignment P-group Equivalency Ambiguous Assignment (with free text box)
~~Discrepancy Not Resolvable~~	Discrepant HLA Typings Report	~~Check box~~