NOTE: Written agreements must be reviewed biennially by the histocompatibility section director/ technical supervisor, and/or clinical consultant, and the clinical transplant program director, and be revised as necessary.

If the laboratory participates as a member of the United Network for Organ Sharing (UNOS), the written agreements must address all elements defined in the Organ Procurement and Transplantation Network (OPTN) Bylaws when applicable:

- *The sample requirements for typing and crossmatching*
- *The loci and level of resolution typed*
- *A process for requesting extended HLA typing*
- *A process for reporting and verifying HLA and unacceptable antigen data at the time of registration on the waiting list and any time there are changes*
- *A process for reporting HLA typing results to the OPTN Contractor*
- *A process for resolving HLA typing discrepancies and errors*
- *The maximum turnaround time from receipt of sample to reporting of results to the transplant program*
- *A process to obtain sensitization history for each patient*
- *The frequency of periodic sample collection*
- *The frequency of antibody screenings*
- *The criteria for crossmatching including the optimal time limits between recipient testing and crossmatch performance*
- *The assay format that will be used for antibody screening and for crossmatching*
- *The criteria for determining unacceptable antigens used during organ allocation*
- *The duration for which specimens need to be stored for repeat or future testing*
- *If desensitization is performed, a protocol for monitoring antibody levels*
- *If the laboratory registers candidates for the transplant process, a process for blood type verification*
- *If post-transplant monitoring is performed, a protocol for monitoring antibody levels.*

If the laboratory supports a program or donor registry that is accepted through the Foundation for the Accreditation of Cellular Therapy (FACT), the agreements must contain the requirements defined in the 7th edition of the FACT Standards.

If a laboratory supports a program or donor registry that is participating in the National Marrow Donor Program (NMDP)/Be The Match, the agreement must contain the provisions defined in the November 2017 NMDP U.S. Transplant Center Participation Criteria.

Agreements with OPOs must also include the following:

- *Process for prioritizing donors for histocompatibility testing*
- *All methods used for crossmatching, interpretation, and reporting of results if crossmatching is done by the OPO*

REFERENCES

1) Organ Procurement and Transplantation Network (OPTN) Bylaws. Appendix C. Membership Requirements for Histocompatibility Laboratories. US Department of Health and Human Services. December 5, 2022.
2) Foundation for the Accreditation of Cellular Therapy (FACT) and Joint Accreditation Committee ISCT and EBMT (JACIE). FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration. 8th Edition, December 14, 2021.
3) National Marrow Donor Program (NMDP)/Be The Match. US Transplant Center Participation Criteria. Document #A00228. Effective January 30, 2023.

HSC.39450 Histocompatibility Testing Requests — Phase II

There are records of histocompatibility testing requests not covered by the transplant program support agreement.

NOTE: The laboratory has records of HLA testing requests which deviate from or are not covered in the existing transplant program support agreement (eg, the use of serum for a final crossmatch that is "too old" or "no final crossmatch" for a patient who would normally require a crossmatch within a previously defined time before transplant).