Histocompatibility Laboratory Agreement Guidance

Histocompatability Lab Agreements must be submitted with any new Histocompatibility Laboratory, OPO, or Transplant Program OPTN membership application. The OPTN also requires a new lab agreement when an existing program wants to affiliate with a new laboratory. Appendix C.2 of the OPTN Bylaw contains information on what must be included in your laboratory agreements.

There are different sets of requirements depending on which organizations are entering into an agreement. Each list can be found in the bylaw and in the tables below.

Please include all of the following information in your lab agreements:

1. An agreement title that includes the names of both of the organizations entering into an agreement.
2. Specify the organ or organs are covered by the agreement, including any details specific to living donors.
3. Signatures from leadership at both organizations.
4. Date your agreement was last updated.
5. Information clearly addressing the transplant program or OPO-specific requirements listed in Appendix C.2 of the OPTN Bylaws and included on the table below.

Transplant Program Affiliation

Appendix C.2.C

Item #	Transplant Program & Histocompatibility Laboratory Agreement MUST include:
1	The sample requirements for typing and crossmatching.
2	The loci and level of resolution typed.
3	A process for requesting extended HLA typing.
4	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.
5	A process for reporting HLA typing results to the OPTN Contractor.
6	A process for resolving HLA typing discrepancies and errors.
7	The maximum turnaround time from receipt of sample to reporting of results to the transplant program.
8	A process to obtain sensitization history for each patient.
9	The frequency of periodic sample collection.

Item #	Transplant Program & Histocompatibility Laboratory Agreement MUST include:
10	The frequency of antibody screenings.
11	The criteria for crossmatching.
12	The assay format that will be used for antibody screening and for crossmatching.
13	The criteria for determining unacceptable antigens used during organ allocation.
14	The duration for which specimens need to be stored for repeat or future testing.
15	If desensitization is performed, then a protocol for monitoring antibody levels.
16	If the laboratory registers candidates for the transplant program, then a process for blood type verification according to *Policy 3.3: Candidate Blood Type Determination before Waiting List Registration*.
17	If post-transplant monitoring is performed, then a protocol for monitoring antibody levels.

OPO Affiliation

Appendix C.2.D

Item #	OPO & Histocompatibility Laboratory Agreement MUST include:
1	The sample requirements for typing and crossmatching.
2	The loci and level of resolution typed.
3	A process for requesting extended HLA typing.
4	A process for verifying and reporting HLA typing results to the OPTN Contractor.
5	A process for resolving HLA typing discrepancies and errors.
6	The maximum turnaround time from receipt of donor sample to reporting of results to the OPO.
7	A process for prioritizing donors for histocompatibility testing.
8	The length of time for which donor specimens are required to be stored for repeat or future testing.
9	If the OPO performs crossmatching, then all methods used for crossmatching and the interpretation and reporting of the results.