

OPTN Membership Application for Histocompatibility Laboratories

CERTIFICATION

The undersigned, a duly authorized representative of the applicant, does hereby certify that the answers and attachments to this application are true, correct and complete, to the best of his or her knowledge after investigation. I understand that the intentional submission of false data to the OPTN may result in action by the Secretary of the Department of Health and Human Services, and/or civil or criminal penalties. By submitting this application to the OPTN, the applicant agrees: (i) to be bound by OPTN Obligations, including amendments thereto, if the applicant is granted membership and (ii) to be bound by the terms, thereof, including amendments thereto, in all matters relating to consideration of the application without regard to whether or not the applicant is granted membership.

If you have any questions, please call the UNOS Membership Team at 833-577-9469 or email MembershipRequests@unos.org.

OPTN Representative

| Printed Name | Signature | Email Address |
|--------------|-----------|---------------|
|--------------|-----------|---------------|

Part 1: General Information

Name of Histocompatibility Laboratory: _____

OPTN Member Code: _____

Office Address

Street: _____ Suite: _____ Phone #: _____

City: _____ State: _____ Zip: _____ Fax #: _____

Lab Website Address: _____

Name of Person Completing Form: _____ Title: _____

Email Address of Person Completing Form: _____

Date Form is submitted to OPTN Contractor: _____

Is the histocompatibility laboratory part of a hospital or independent? Check one

- Part of a Hospital
- Independent

What is the purpose of this application? Check one

- New Histocompatibility Lab
Complete the entire application
- Key Personnel Change
Complete Part 4: Histocompatibility Laboratory Key Personnel (for applicable primary personnel changes) and Part 5: Laboratory Coverage Plan

Part 2: Histocompatibility Laboratory Compliance

Each histocompatibility laboratory member must comply with all OPTN Obligations according to *Article 1.1.E: Member Compliance* and *both* of the following:

1. The requirements in the Clinical Laboratory Improvement Amendments (CLIA) at 42 CFR § 493.1278, unless exempt.
Provide a copy of most recent CLIA certification.
2. The requirements, as they apply to solid organ and islet transplantation, of the American Society for Histocompatibility and Immunogenetics (ASHI) 2013 Revised Standards for Accredited Laboratories, or the College of American Pathologists (CAP) Histocompatibility Checklist, Laboratory General Checklist, Flow Cytometry Checklist, and Team Leader Assessment of Director and Quality Checklist as of April 21, 2014. This requirement does not mandate membership in either ASHI or CAP.
Provide a copy of certification with the application if the Lab is a member of either ASHI or CAP.

Part 3: Facilities, Resources, and General Staffing

Histocompatibility laboratories must have considerable facilities, equipment, resources and staffing to ensure accurate, reliable and efficient testing.

1. Facilities & Medical Records

The laboratory must have enough space and equipment so that procedures and tests can be performed accurately and efficiently.

The laboratory must have adequate facilities to store medical and test records for candidates, recipients, and donors.

Records for active candidates must be immediately accessible onsite. Records for recipients and donors must be accessible as necessary to meet the clinical practice needs of any associated transplant hospital or OPO.

Explain how the laboratory meets the facilities and medical records requirements indicated above.

2. Transplant Program Affiliation

Histocompatibility laboratories must have written agreements with every transplant program the laboratory serves, unless clinical urgency prevents such an agreement.

Each written agreement *must* include all of the following:

- 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.
- 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, then a protocol for monitoring antibody levels.
 - 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.
 - If post-transplant monitoring is performed, then a protocol for monitoring antibody levels.
- Provide a list of all transplant programs with which the histocompatibility laboratory has written agreements. Provide the written agreements for each transplant program the laboratory serves.***

3. OPO Affiliation

Histocompatibility laboratories must have written agreements with every OPO member the laboratory serves, unless clinical urgency prevents such an agreement.

Each written agreement must include all of the following:

- The sample requirements for typing and crossmatching.
- The loci and level of resolution typed.
- A process for requesting extended HLA typing.
- A process for verifying and reporting HLA typing results to the OPTN Contractor.
- A process for resolving HLA typing discrepancies and errors.
- The maximum turnaround time from receipt of donor sample to reporting of results to the OPO.
- A process for prioritizing donors for histocompatibility testing.
- The length of time for which donor specimens are required to be stored for repeat or future testing.
- If the OPO performs crossmatching, then all methods used for crossmatching and the interpretation and reporting of the results.

Provide a list of all OPOs with which the histocompatibility laboratory has written agreements. Provide the written agreements for each OPO the laboratory serves.

4. Histocompatibility Laboratory Staffing

Check to attest to the following

- The laboratory has adequate staff with training to carry out the volume and variety of tests required to ensure accuracy and prompt completion of tests.*
- The laboratory has documentation on file that all personnel are licensed or meet the standards required by federal, state and local regulations.*
- The laboratory provides histocompatibility testing for deceased kidney, kidney-pancreas, or pancreas transplants and has personnel to perform required histocompatibility testing 24 hours a day, seven days a week.***

- The laboratory tests its staff for competency in performing test procedures. The testing is done annually and is completed for each type of test the staff performs.*

- The director, technical supervisor, and all technical staff participate in continuing education in histocompatibility, immunogenetics or clinical transplantation as required for accreditation by national, state, and local regulatory agencies.*

5. Submission Requirements for New Laboratories

If this laboratory has not previously been approved as an OPTN histocompatibility laboratory member, then the laboratory must be able to submit procedures and test validation data for all categories and methods of testing performed to the OPTN Contractor upon request.

Part 4: Histocompatibility Laboratory Key Personnel

The laboratory must employ a histocompatibility laboratory director, a technical supervisor, a general supervisor, and a clinical consultant. One person may fill one or more positions.

Complete the following sections for laboratory director, technical supervisor, general supervisor, and/or clinical consultant as applicable.

Part 4A: Histocompatibility Laboratory Director

The histocompatibility laboratory director ensures that the laboratory provides high quality and comprehensive histocompatibility and immunogenetics testing.

Name of Histocompatibility Laboratory Director:

Include this individual's resume/CV with the application.

Which pathway will the histocompatibility laboratory director be applying under? (Check one):

Pathway 1

- Have a M.D. or D.O. from an accredited institution, or equivalent degree from another country

Provide a copy of certification(s).

- Have a license to practice medicine in the state where the laboratory is located

Provide a copy of state license.

- Be certified in anatomic and clinical or clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology, or possess qualifications of those equivalent to those required for such certification

Provide a copy of certification(s).

If not board certified as specified above but qualifications are equivalent, provide an explanation.

- Have at least two years full-time experience directing or supervising clinical histocompatibility testing for solid organ transplantation

Complete table

| Name of Facility (where experience was gained) | Start | End | Title/Role |
|---|-------|-----|------------|
| | | | |
| | | | |
| | | | |

Pathway 2

- Have a doctoral degree in a medical, chemical, physical, biological, or clinical laboratory science from an accredited institution, or equivalent degree from another country
Provide a copy of certification(s).
- Have at least two years full-time, post-doctoral experience or four years pre-doctoral experience in immunology, histocompatibility, or immunogenetics, and two years post-doctoral training in directing or supervising clinical histocompatibility testing for solid organ transplantation

Complete table

| Name of Facility (where experience was gained) | Start | End | Title/Role |
|---|-------|-----|------------|
| | | | |
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| | | | |

- Certification as a Diplomate by the American Board of Histocompatibility and Immunogenetics, a high complexity laboratory director by the American Board of Bioanalysis, or a Diplomate by the American Board of Medical Laboratory Immunology.

Provide a copy of certification(s).

Check only if applicable:

- A professional who holds an earned doctoral degree but who does not hold one of these certifications may qualify if they were serving as director of an accredited laboratory performing human histocompatibility and immunogenetics testing before February 24, 2003

Has the proposed individual previously served in the role of laboratory director at an OPTN approved histocompatibility laboratory?

- Yes (Previously held Director role)**

Name of lab where director role was held:

- No (First Time in Director role)**

If the proposed individual is a professional being considered for the position of histocompatibility laboratory director, and has not served in the role of laboratory director prior to the date of application, ***in addition to the above all of the following must be provided:***

- A portfolio of 50 cases, covered during the five years prior to the date of application that demonstrates the professional's analytical skills, ability to recognize and resolve testing and interpretation issues, and instances when the applicant made recommendations for additional testing or clinical care.
Provide portfolio documentation, such as a log or table summarizing cases.
- Proof of active interaction with transplant professionals.

Provide a list of transplant professionals that could be contacted to confirm interaction.

- A letter from the applicant that describes all experience in immunology and clinical histocompatibility testing, including a summary of time spent in the laboratory, technologies used, level of responsibility, and specific tasks performed.

Attach this letter to the application.

- Demonstrated participation in transplant or clinical laboratory professional conferences or publications in peer-reviewed journals.

Describe participation if not included in resume/CV.

Part 4B: Technical Supervisor

Name:

Check to attest to the following

- The proposed individual meets all qualifications for histocompatibility lab director as outlined in Part 4A of this application.*
- The proposed individual meets all qualifications for technical supervisor according to 42 CFR 493.*

If the individual proposed is not a current histocompatibility laboratory director, complete Part 4A of this application to demonstrate that the individual meets bylaw requirements.

Part 4C: General Supervisor

Name:

Check to attest to the following:

- The proposed individual meets all qualifications for general supervisor according to 42 CFR 493.*
- The proposed individual has at least three years of experience in human histocompatibility or transplant immunology testing under the supervision of a qualified histocompatibility laboratory director or technical supervisor.*

Complete the below table to demonstrate completion of the required experience. Include all current and prior experience.

| Name of Facility (where experience was gained) | Start | End | Director or Technical Supervisor |
|---|--------------|------------|---|
| | | | |
| | | | |
| | | | |

Include this individual's resume/CV with the application.

Part 4D: Clinical Consultant

Name:

Check to attest to the following:

- The proposed individual meets all qualifications for histocompatibility lab director as outlined in Part 4, Question 1 of this application.*
- The proposed individual meets all qualifications for clinical consultant according to 42 CFR 493.*

If the individual proposed is not a current histocompatibility laboratory director, complete Part 4A of this application to demonstrate that the individual meets bylaw requirements.

Part 5: Laboratory Coverage Plan

The histocompatibility laboratory director, technical supervisor, general supervisor, and clinical consultant, must submit a detailed Laboratory Coverage Plan to the OPTN Contractor. The Laboratory Coverage Plan must describe how continuous coverage is provided by all laboratory personnel and meet all requirements for a Laboratory Coverage Plan in OPTN Bylaws.

The Laboratory Coverage Plan must address *all* of the following:

1. The laboratory must document that qualified key personnel are providing coverage at all times, including during the entire application process for changes in key personnel, regardless of the status of the application.
2. The laboratory must document that the laboratory director, technical supervisor, general supervisor, and clinical consultant are available to provide onsite, telephone, or electronic consultation to facilitate organ acceptance and transplantation.
3. The laboratory must document if any of the responsibilities designated to the laboratory director, technical supervisor, or clinical consultant will be performed by other laboratory staff. This documentation must include a list of the duties delegated, the times when the duties will be delegated, the qualifications of the staff that will perform the delegated duties, and the quality systems in place to ensure the duties are correctly performed.
4. If the laboratory is engaged in histocompatibility testing for deceased kidney, kidney-pancreas, or pancreas donor transplants, then the laboratory must document that key personnel and qualified testing personnel are available 24 hours a day, 7 days a week to provide laboratory coverage, unless a written explanation is provided that justifies the current level of coverage to the satisfaction of the MPSC.
5. If any key personnel serves more than one histocompatibility laboratory, then the Laboratory Coverage Plan must specify how continuous coverage will be provided at each histocompatibility laboratory served.

Attach the Laboratory Coverage Plan to the application.

PUBLIC BURDEN STATEMENT

The private, non-profit Organ Procurement and Transplantation Network (OPTN) collects this information in order to perform the following OPTN functions: to assess whether applicants meet OPTN Bylaw requirements for membership in the OPTN; and to monitor compliance of member organizations with OPTN Obligations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0915-0184 and it is valid until 08/31/2023. This information collection is required to obtain or retain a benefit per 42 CFR §121.11(b)(2). All data collected will be subject to Privacy Act protection (Privacy Act System of Records #09-15-0055). Data collected by the private non-profit OPTN also are well protected by a number of the Contractor's security features. The Contractor's security system meets or exceeds the requirements as prescribed by OMB Circular A-130, Appendix III, Security of Federal Automated Information Systems, and the Departments Automated Information Systems Security Program Handbook. The public reporting burden for this collection of information is estimated to average 2.5 hours per response, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Reports Clearance Officer, 5600 Fishers Lane, Room 14N136B, Rockville, Maryland, 20857 or paperwork@hrsa.gov.