OMB No. 0915-0184
Expiration Date: XX/XX/2023

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**

Laboratory Director

_____	_____	_____
Printed Name	**Signature**	**Email Address**

Technical Supervisor

_____	_____	_____
Printed Name	**Signature**	**Email Address**

General Supervisor

_____	_____	_____
Printed Name	**Signature**	**Email Address**

Clinical Consultant

_____	_____	_____
Printed Name	**Signature**	**Email Address**

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Part 1: General Information

Name of Histocompatibility Laboratory:

_____

OPTN Member Code: _____

Office Address
Street: _____ Ste: _____ Phone #: _____

City: _____ ST: _____ Zip: _____ Fax #: _____

OPO Website Address: _____

Mailing Address (if different from Physical Address)
Street/P.O. Box: _____

City: _____ ST: _____ Zip: _____

Name of Person Completing Form: _____ Title: _____

Email Address of Person Completing Form: _____

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: Program Coverage Plan

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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 and Resources

Histocompatibility laboratories must have considerable facilities, equipment, and resources 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.

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.

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

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 transplant program the laboratory serves.

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.

Does the laboratory have the following (check all applicable):

☐ Adequate histocompatibility laboratory staff with training to carry out the volume and variety of tests required to ensure accuracy and prompt completion of tests.

☐ Documentation on file that all personnel are licensed or meet the standards required by federal, state and local regulations.

If the laboratory **provides histocompatibility testing for deceased kidney, kidney-pancreas, or pancreas transplants**, then the laboratory must have:
☐ Personnel to perform required histocompatibility testing 24 hours a day, seven days a week.

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

1. 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).
  If degree is from another country, what country? _____
- 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 by above, and 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 Experience Gained	Start Date	End Date	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).
  If degree is from another country, what country? _____
- 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 Experience Gained	Start Date	End Date	Title/Role

- 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

1. 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, ***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**.**
Attach this portfolio to the application.

- 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.

All documentation that verifies training and experience must be sent directly to the OPTN Contractor from all directors of histocompatibility laboratories where the training was obtained.

2. **Technical Supervisor**

☐ **Check here if the individual proposed as the histocompatibility laboratory director in this application will also be proposed as the technical supervisor. If so, the below section of the application for technical supervisor *does not need to be completed*.**

Complete the section below if the proposed technical supervisor will be a different individual than the histocompatibility laboratory director.

Name of Technical Supervisor:

_____

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

The technical supervisor must meet all the qualifications and fulfill the responsibilities for laboratory director according to OPTN Bylaws for*Histocompatibility Laboratory Director Qualifications*.
***Complete the above* histocompatibility laboratory director section of the application for the proposed technical supervisor.**

3. **General Supervisor**

Name of General Supervisor:

_____

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

The general supervisor must have **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 table

Name of facility experience gained	**Start Date**	**End Date**	**Was the experience gained human histocompatibility, in transplant immunology testing, or both?**	**Name of supervising histocompatibility laboratory director or technical supervisor**

4. **Clinical Consultant**

☐ **Check here if the individual proposed as the histocompatibility laboratory director in this application will also be proposed as the clinical consultant. If so, the below section of the application for clinical consultant *does not need to be completed*.**

Complete the section below if the proposed clinical consultant will be a different individual than the histocompatibility laboratory director.

Name of Clinical Consultant:

_____

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

The clinical consultant must meet all the qualifications for laboratory director as outlined in OPTN Bylaw *C.3.*Histocompatibility Laboratory Director *Qualifications.*

***Complete the above* histocompatibility laboratory director section of the application for the proposed clinical consultant.**

5. **Competency Testing and Continuing Education of Staff**

By checking the boxes below, the organization attests to understanding the OPTN policy and bylaw requirements.

☐ The laboratory must test its staff for competency in performing test procedures. The testing must be done annually, and must be completed for each type of test the staff performs.

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

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 required for a Laboratory Coverage Plan in OPTN Bylaws.

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 XX/XX/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 3 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.