Department of Health and Human Services
Health Resources and Services Administration

OMB No. 0915-0184
Expiration Date: 2/28/2029

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.

OPTN Representative

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

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Part 1: General Information

Name of Histocompatibility Laboratory: _____

OPTN Member Code (4 Letters): _____

Office Address

Street: _____ Suite: _____ Phone #: _____

City: _____ State: _____ Zip: _____

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 hospital-based or independent? Check one

- ○ *Hospital-based Histocompatibility Laboratory: A histocompatibility laboratory that is not independent from the transplant hospital it serves. Hospital-based histocompatibility laboratories are held to the same standards and requirements as histocompatibility laboratory members, but do not have a vote on OPTN business separate from the vote granted the transplant hospital member with whom it is associated.*
- ○ *Independent Histocompatibility Laboratory: An independent histocompatibility laboratory is one that has a distinct governing body separate from any transplant hospital or commonly controlled group of transplant hospitals it serves. A histocompatibility laboratory member must be an independent histocompatibility laboratory to have a vote on OPTN business.*

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 OPTN membership requirements and must meet the requirements in the Clinical Laboratory Improvement Amendments (CLIA) at 42 CFR § 493.1278 Standard: Histocompatibility, unless exempt.
Provide a copy of most recent CLIA certification.

If exempt, please check the box below and provide the reason for the exemption.

☐ The Laboratory is exempt, due to

****If the exemption is due to being in a state that is exempt from CLIA, the laboratory must meet the requirements for state licensure including standards for histocompatibility. In that case, provide a copy of state licensure.***

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Part 3: Facilities, Personnel and Resources

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

1. **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:

   HLA Typing Requirements:
   - Sample requirements.
   - Loci and level of resolution typed.
   - Process for reporting of HLA results to the OPTN and verification of results, including verification if changes occur.
   - Expected turnaround time from receipt of sample to reporting results to the transplant program and process of notification if turnaround time is going to be exceeded.
   - Process for resolving discrepancies and errors.

   Crossmatching Requirements:
   - Sample requirements for both donors and recipients.
   - Methodology and criteria for physical crossmatching.
   - Criteria for virtual crossmatching, if performed.
   - Process to obtain sensitization history for each patient.
   - Process for reporting of physical or virtual crossmatching results to the transplant hospital and verification of results, including verification if changes occur.
   - Expected turnaround time from receipt of sample to reporting results to the transplant program and process of notification if turnaround time is going to be exceeded.

   Antibody Screening:
   - Sample requirements.
   - Methodology.
   - Frequency of sample collection.
   - Frequency of antibody screenings.
   - Criteria for determining unacceptable antigens used during organ allocation.
   - Process for reporting unacceptable antigens to the OPTN and verifying unacceptable antigen data at time of registration and if changes occur.
   - Expected turnaround time from receipt of sample to reporting results to the transplant program and process of notification if turnaround time is going to be exceeded.
   - If post-transplant monitoring is performed, include protocol for monitoring donor specific antibodies.

- If desensitization is performed, include protocol for monitoring antibody testing and reporting.

If the laboratory registers candidates for the transplant program, include a process for blood type verification according to OPTN Policy.

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. Please ensure that each agreement is signed by both parties.

2. **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:

HLA Typing Requirements:

- Sample requirements.
- Loci and level of resolution typed.
- Process for verifying and reporting results to the OPO and the OPTN.
- Expected turnaround time from receipt of donor sample to reporting results to the OPO and process of notification if turnaround time is going to be exceeded.
- Process for resolving discrepancies and errors.

Crossmatching Requirements:

- Sample requirements for both donors and recipients.
- If OPO-contracted laboratory performs crossmatching, methodology and criteria for physical crossmatching as well as interpretation and reporting of results.
- Process for reporting of crossmatching results to the OPO or transplant hospital and verification of results, including verification if changes occur.
- Expected turnaround time from receipt of donor sample to reporting results to the OPO and process of notification if turnaround time is going to be exceeded.

The length of time for which donor specimens are to be stored for repeat or future testing.

Provide a list of all OPOs with which the histocompatibility laboratory has written agreements. Provide the written agreements for each OPO the laboratory serves. Please ensure that each agreement is signed by both parties.

3. **Personnel Requirements**

Check to attest to the following:

☐ All personnel are licensed or meet the standards required by federal, state and local regulations.

☐ All laboratory staff are required to complete all continuing education and testing required to maintain accreditation by federal, state, and local regulatory agencies.

4. **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 upon request.

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Part 4: Histocompatibility Laboratory Key Personnel

The laboratory must employ a primary histocompatibility laboratory director, a technical supervisor, a clinical consultant, and a general supervisor. One individual may fill one or more positions. The laboratory may employ additional histocompatibility laboratory directors, but only one may serve as the primary histocompatibility laboratory director of record with the OPTN. If an individual serves as histocompatibility laboratory director for more than one laboratory, that individual cannot serve in the general supervisor position.

Complete the following sections for primary histocompatibility laboratory director, technical supervisor, clinical consultant, general supervisor, and/or additional histocompatibility laboratory directors, 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 role is this individual applying for?

○ This individual is applying as the **primary histocompatibility laboratory director**, a role required by OPTN Management and Membership Policies. A laboratory may appoint additional histocompatibility laboratory directors, but only one histocompatibility laboratory director may serve in the role as primary. The primary histocompatibility laboratory director is the person responsible for ensuring the operation and compliance of the laboratory according to the requirements set forth in OPTN Management and Membership Policies.

○ This individual is applying as an **additional histocompatibility laboratory director**, as only one individual may serve as the primary histocompatibility laboratory director of record with the OPTN. Additional histocompatibility laboratory directors must meet the qualifications to fulfill the responsibilities for histocompatibility laboratory director according to OPTN Management and Membership Policies.

Check to attest to the following:

☐ The histocompatibility laboratory director meets all the qualifications and fulfills the responsibilities for *technical supervisor for histocompatibility* according to CLIA, 42 CFR § 493.1449 (h) and 42 CFR § 493.1451 (a) – (b) respectively.

Provide a copy of the proposed individual's state license (if applicable), diploma, any relevant board or training certifications, transcripts confirming relevant coursework (for Ph.D. applicants), and a summary of any laboratory training or experience the proposed individual has in high complexity testing for the specialty of diagnostic immunology in order to demonstrate fulfillment of CLIA requirements. Complete the table below to demonstrate completion of required experience. Include all current and prior experience.

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

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

○ **Yes (Previously held OPTN laboratory director role)**

Name or OPTN code of lab where director role was held:

_____

○ **No (First time in OPTN laboratory 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 of the Technical Supervisor:

_____

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 histocompatibility technical supervisor according to 42 CFR 493.*

If the individual proposed is not currently approved as an OPTN histocompatibility laboratory director, complete Part 4A of this application to demonstrate that the individual meets OPTN requirements.

Part 4C: Clinical Consultant

Name of the Clinical Consultant:

_____

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 histocompatibility clinical consultant according to 42 CFR 493.*

Provide a copy of the proposed individual's state license (if applicable), diploma, any relevant board or training certifications, transcripts confirming relevant coursework (for Ph.D. applicants), and a summary of any laboratory training or experience the proposed individual has in high complexity testing for the specialty of diagnostic immunology to demonstrate fulfillment of CLIA requirements.

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

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

If the individual proposed is not currently approved as an OPTN histocompatibility laboratory director, complete Part 4A of this application to demonstrate that the individual meets OPTN requirements.

Part 4D: General Supervisor

Name of the General Supervisor:

_____

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.*

Provide a copy of the proposed individual's state license (if applicable), diploma, any relevant board or clinical laboratory training certifications, transcripts confirming required coursework, and resume/CV to demonstrate fulfillment of CLIA requirements.

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

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

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Part 5: Laboratory Coverage Plan

The histocompatibility laboratory director, in conjunction with the technical supervisor, clinical consultant, and general supervisor must submit a detailed Laboratory Coverage Plan to the OPTN. 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 membership requirements.

The laboratory must submit an updated Laboratory Coverage Plan when any key personnel accepts additional responsibilities for more than 30 days at another laboratory. The updated coverage plan must be submitted to the OPTN within 30 days of the key personnel accepting the additional responsibilities.

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, clinical consultant, and general supervisor 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.

Provide the Laboratory Coverage Plan with 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 membership requirements; 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 2/28/2029xThis 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 3.7 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 Information Collection Clearance Officer, 5600 Fishers Lane, Room 13N82, Rockville, Maryland, 20857 or paperwork@hrsa.gov.