Department of Health and Human Services

Health Resources and Services Administration

OMB No. 0915-0184

Expiration Date: xx/xx/201x

APPLICATION FOR

HISTOCOMPATIBILITY LABORATORY MEMBERSHIP

IN THE ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK (OPTN)

UNOS

700 North 4th Street
Richmond, VA 23219
Main Phone: 804-782-4800

Name of Histocompatibility Laboratory:	
Address:	
City, State, & Zip Code:	
Contact Person/Title:	
Phone Number:	**Email:**

PUBLIC BURDEN STATEMENT: 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 project is 0915-0184. Public reporting burden for this collection of information is estimated to average 40 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 10-29, Rockville, Maryland 20857.

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 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.

Date:	Signature:
Print Name:	Title:
Applicant #	

OPTN Histocompatibility Laboratory Membership Application

Part 1: Section A – General Information

1. OPTN Membership Type

Check One	Yes	No
Independent Histocompatibility Laboratory*		
Hospital Based Histocompatibility Laboratory		
Name of member/applicant hospital if hospital based lab applicant:		

** An Independent Laboratory is defined as having a distinct governing body separate from any transplant hospital or commonly controlled group of transplant hospitals.*

2. Upon receipt of your application, these materials will be forwarded to American Society for Histocompatibility and Immunogenetics (ASHI) or the College of American Pathologists (CAP), which have been granted deemed status to perform histocompatibility laboratory inspections for the OPTN. By completion of this application, the applicant hereby grants ASHI and/or CAP the authority to provide all ASHI and CAP accreditation records and information relevant to histocompatibility testing for organ transplantation.

   Indicate whether ASHI or CAP is the agency selected by the laboratory to perform the review for the OPTN.

[Insert detailed response here. Table will expand automatically]

3. Provide the names of the laboratory, director(s), department, and institution, as they should appear in the official OPTN record.

Position	
Histo Lab Director (Primary)	
Other Director(s)	
Director-in-Training	
Technical Supervisor	
Clinical Consultant	
General Supervisor	
Laboratory or Department Name	
Institution/Hospital	
Lab Street Address	
City, State, Zip	
Main Telephone	
Main Fax	
Website Address	http://www.
Accreditation (if applicable)	
CMS ID #	
CLIA ID #	

ASHI ID #	
CAP ID #	

4. Indentify the principal CEO/Administrator(s), and provide contact information (address, phone, e-mail)

[Insert detailed response here. Table will expand automatically]

Part 1: Section B - Areas of Accreditation

1. Check all areas in which lab is seeking accreditation:

Areas of Accreditation	To be Evaluated	Accredited by ASHI or CAP within the last 3 years? Include last certification start and end dates	
		ASHI	CAP
Solid Organ Transplantation: Deceased Donor			
Solid Organ Transplantation: Live Donor			

Part 1: Section C - Operations

1. Describe the Histocompatibility Laboratory Coverage Plan. Plan must address the elements required in the OPTN Bylaws.
   If there is more than one histocompatibility director, indicate all areas in which primary laboratory director will be involved and, if appropriate, in which area they have primary responsibility.

   [Insert detailed response here or reference attachment. Table will expand automatically]

2. Describe current and anticipated procedures for complying with the data submission requirements of OPTN membership:

   a) List the personnel who are/or will be responsible for data collection and submission indicating their background in this area and the percentage of their time that is dedicated to data collection and submission.

Name	Background	% of Time Dedicated to Data Collection & Submission

   b) Describe the methods to be used to collect, verify, and submit data on a timely basis.
   [Insert detailed response here. Table will expand automatically]

   c) Describe the training/orientation for the data coordinator(s) supporting the Lab. Include details regarding competencies measured as part of the training.

   [Insert detailed response here, table will expand automatically.]

3. Is this histocompatibility laboratory insured for professional liability?

Yes	No

If Yes, name the insurer and give the policy limits per person and per occurrence and the expiration date of the current insurance coverage. If No, and the lab has a funded self-insurance program, give the name of the fund administrator and the amount of the self-insurance fund and describe the coverage available to this laboratory.

[Insert detailed response here. Table will expand automatically]

4. Describe in detail the laboratories quality assurance/performance improvement protocol or process and how it will review its performance. Please indicate the method, frequency of reviews, and participants (by title). Expand or duplicate table as needed.

Individuals Involved: (name & title)	
Methods:	
Frequency of reviews:	
Metrics/Data Tracked:	
Detailed response:	

5. Describe the process for ensuring compliance with OPTN obligations. Include who is responsible (name and title/position) and how this process is integrated with other transplant programs and institution wide.

Name/Title:
[Insert detailed response here, table will expand automatically.]

Part 1: Section D - Written Agreements

1. Histocompatibility laboratories must have written agreements with every transplant program and organ procurement organization (OPO) the laboratory serves. List the names and addresses of all clinical transplant hospitals or OPOs this lab will be serving and the type of program(s) at each transplant hospital. Attach written agreements with each clinical transplant program(s) and OPO(s) the laboratory will serve. Written agreements must include all of the elements required in the OPTN Bylaws.

Name & Address	Type of Programs/OPO

Expand rows as needed.

2. Histocompatibility laboratories may refer testing to another laboratory in accordance with the requirements in the OPTN Bylaws. List any subcontracts this laboratory will be implementing.

Lab Name & Location	Type of Testing	Is Lab ASHI or CAP certified?

Part 2: Section A – Personnel Qualifications, Primary Histocompatibility Laboratory Director

The individual identified below as the Primary Histocompatibility Laboratory director must complete this section. If two or more individuals share the histocompatibility laboratory director's responsibilities, one person must be designated as the primary director.

Complete questions below and submit a copy of the following:

- Current certification
- Current licensure if a state requirement
- A current curriculum vitae or resume
- Provide portfolio of cases if required in the OPTN Bylaws
- Letter of reference from histocompatibility laboratories where training obtained if required
- A letter 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.

If the primary histocompatibility laboratory director will not serve as the clinical consultant and technical supervisor, Section 2 of this application must also be completed.

1. Provide the following information:

Name of primary histocompatibility laboratory director	
Degree(s)	
Discipline(s)	
State Licensure in the state/district where the lab is located (provide copy of current license, if applicable)	
Certifications	
Start date at this laboratory (DD/MM/YY)	

2. List all professional positions at any institutions (director, supervisor, consultant, instructor) currently held by the director and estimated time commitment of each (hours/week):

Professional Position (Include Institution)	**Estimated Time Commitment (hours/week)**

3. Post-Doctoral Experience in Human Histocompatibility Testing for solid organ transplantation. List all laboratory specialties in which post-doctoral training was received. Expand rows as needed.

Laboratory Name	Title	Dates	Description of Duties

4. Doctoral training in directing or supervising clinical histocompatibility testing for solid organ transplantation.

   List all laboratory specialties in which post-doctoral training was received, including exact dates and specific training received for each. Add additional sections below as needed.

Institution Name	
Laboratory Name	
Laboratory Specialty	
Instructor Name	
Dates	
Specific Training	
Hours/week	

Institution Name	
Laboratory Name	
Laboratory Specialty	
Instructor Name	
Dates	
Specific Training	
Hours/week	

5. Laboratory Involvement

   a. Detail the report review process for each laboratory report including the histocompatibility laboratory director's role. If the histocompatibility laboratory director does not review all reports, include the percentage that are reviewed and how they are selected.

[Insert detailed response here. Table will expand automatically]

   b. Indicate the approximate number of cases up to 500 (after that just indicate >500) that the proposed laboratory director reviewed in each of the following categories:

Category	# of Cases
Kidney: Deceased donor typing	
Kidney: Deceased donor crossmatch	
Kidney: Living donor typing	
Kidney: Living donor crossmatch	
Other Organs: Deceased donor typing	
Other Organs: Deceased donor crossmatch	
Islet Cell transplantation	
Allele level typing	
HLA antibody screening	
HLA antibody characterization	
Flow cytometry crossmatch	

Part 2: Section B – Personnel Qualifications, Technical Supervisor

The individual identified below as the Primary Technical Supervisor must complete this section if they are not named as the primary histocompatibility laboratory director in Section A of this application. If two or more individuals share the technical supervisor's responsibilities, one person must be designated as the primary.
Complete questions below and submit a copy of the following:

- Current certification
- Current licensure if a state requirement
- A current curriculum vitae or resume
- Provide portfolio of cases if required in the OPTN Bylaws
- Letter of reference from histocompatibility laboratories where training obtained if required
- A letter 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
- A summary of time spent in the laboratory, technologies used, level of responsibility, and specific tasks

1. Provide the following information:

Name of primary technical supervisor	
Degree(s)	
Discipline(s)	
State Licensure in the state/district where the lab is located (provide copy of current, if applicable)	
Certifications	
Start date at this laboratory (DD/MM/YY)	

2. List all professional positions at any institutions (director, supervisor, consultant, instructor) currently held by the technical supervisor and estimated time commitment of each (hours/week):

Professional Position (Include Institution)	**Estimated Time Commitment (hours/week)**

3. Post-Doctoral Experience in Human Histocompatibility Testing for solid organ transplantation. List all laboratory specialties in which post-doctoral training was received. Expand rows as needed

Laboratory Name	Title	Dates	Description of Duties

4. Doctoral Training in directing or supervising clinical histocompatibility testing for solid organ transplantation. Add additional sections below as needed.

   List all laboratory specialties in which post-doctoral training was received, including exact dates and specific training received for each.

Institution Name	
Laboratory Name	
Laboratory Specialty	
Instructor Name	
Dates	
Specific Training	
Hours/week	

Institution Name	
Laboratory Name	
Laboratory Specialty	
Instructor Name	
Dates	
Specific Training	
Hours/week	

5. Histocompatibility Laboratory Involvement
   a. Describe the technical supervisor's role in the report review process for this laboratory. Include the percentage of reports review reviewed and how they are selected.

      [Insert detailed response here. Table will expand automatically]

   b. Indicate the approximate number of cases up to 500 (after that just indicate >500) that that the proposed technical supervisor reviewed in each of the following categories:

Category	**# of Cases**
Kidney: Deceased donor typing	
Kidney: Deceased donor crossmatch	
Kidney: Living donor typing	
Kidney: Living donor crossmatch	
Other Organs: Deceased donor typing	
Other Organs: Deceased donor crossmatch	
Islet Cell transplantation	
Allele level typing	
HLA antibody screening	
HLA antibody characterization	
Flow cytometry crossmatch	

Part 2: Section C – Personnel Qualifications, Clinical Consultant

The individual(s) identified below as the Clinical Consultant must complete this section **if they are not named as the primary histocompatibility laboratory director or technical supervisor in Sections A or B of this application**. If two or more individuals share the Clinical Consultant's responsibilities, one person must be designated as the primary. Complete questions below and submit a copy of the following:

- Current certification
- Current licensure if a state requirement
- A current curriculum vitae or resume
- A letter 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
- A summary of time spent in the laboratory, technologies used, level of responsibility, and specific tasks

1. Provide the following information:

Name of primary clinical consultant	
Degree(s)	
Discipline(s)	
State Licensure in the state/district where the lab is located (provide copy of current license, if applicable)	
Certifications	
Start date at this laboratory (DD/MM/YY)	

2. List all professional positions at any institutions (director, supervisor, consultant, instructor) currently held by the clinical consultant supervisor and estimated time commitment of each (hours/week):

Professional Position (Include Institution)	**Estimated Time Commitment (hours/week)**

3. Describe the clinical consultant's responsibilities in this laboratory:

[Insert detailed response here. Table will expand automatically]

4. Describe the clinical consultant's experience in clinical transplantations:

[Insert detailed response here. Table will expand automatically]

Part 2 : Section D - Personnel Qualifications, General Supervisor

This section of the application must be completed by all personnel with authority to sign out reports and/or function as a general supervisor in the histocompatibility laboratory. Submit curriculum vitae for each person. If the histocompatibility laboratory director serves as general supervisor, indicate this on the cover page and leave the remainder of this section blank.

1. Provide the following information:

Name of General Supervisor	
Does the general supervisor meet the qualifications defined by CLIA (CFR. Sec 493.? (Yes/No)	

2. Provide description of general supervisor's duties in this position

[Insert detailed response here. Table will expand automatically]

3. Describe how the general supervisor meets the qualifications for having at least 3 years experience in human histocompatibility or transplant testing under the supervision of a qualified histocompatibility director or technical supervisor:

[Insert detailed response here. Table will expand automatically]

Part 2: Section E - Personnel List

List all staff involved in histocompatibility testing in this laboratory.

Start Date M/YY	Name	Position	Degrees	Certifications	Yrs HHT	% FTE Clinical HHT	On-Call	Total CE Hours

Expand rows as needed.

Part 2, Section F - Competency Testing

1. The laboratory must have a process for annually testing its staff for competency in performing test procedures. Provide documentation of a plan for competency testing and continuing education of staff.

   [Insert detailed response here. Table will expand automatically]

2. Laboratories must document that proficiency testing and competency requirements in the Bylaws have been met. Provide documentation demonstrating a successful performance in an external proficiency testing program within the last year.