Department of Health and Human Services
Health Resources and Services Administration

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

CHANGE IN KEY PERSONNEL APPLICATION

HISTOCOMPATIBILITY LABORATORY MEMBERSHIP

ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK (OPTN)

UNOS

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

Name of Histocompatibility Laboratory:	
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 2 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 14N-39, 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 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.

Date:	Signature:
Print Name:	Title:
OPTN Member Code:	

OPTN Change in Key Personnel Application - Histocompatibility Laboratory

Part 1: General Information

1. 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 this review for the OPTN.

   [Insert detailed response here. Table will expand automatically]

2. Indicate which change(s) in key personnel is being submitted and complete the relevant section(s) of this application (Section A, B, C, or D).

Check all that apply	Type	Name	Effective Date of Change (MM/DD/YY)
	Primary Laboratory Director		
	Primary Technical Supervisor		
	Primary Clinical Consultant		
	Primary General Supervisor		

3. Describe the histocompatibility laboratory coverage plan. Plan must address in detail the elements required in the OPTN Bylaws and any changes that are occurring as a result of this change in key personnel. If there is more than one histocompatibility director, technical supervisor, clinical consultant, or general supervisor, indicate all areas in which the primary personnel will be involved and, if appropriate, in which area they have primary responsibility. The coverage plan must also explain the role of each additional director, technical supervisor, clinical consultant, general supervisor, as well as the designation of responsibilities to other staff.

   [Insert detailed response here. Table will expand automatically]

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 board certification
- Current licensure if a state requirement
- Current curriculum vitae or resume

If the proposed director has not previously served in the role of primary lab director, the OPTN Bylaws require that the following documents be provided:

- Portfolio of cases
- Letter of reference from histocompatibility laboratories where training obtained
- Proof of active interactions with transplant professionals
- 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
- Documentation demonstrating participation in transplant or clinical laboratory professional conferences or publications in peer-reviewed journals

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

1. Provide the following information:

Name of primary laboratory director			
Start date at this laboratory (DD/MM/YY)			
Degree(s)			
Discipline(s)			
Effective date of appointment (DD/MM/YY)			
State licensure in the state/district where the lab is located (provide copy of current license, if applicable)	Yes	No	Not required
Has this individual served in the role of primary laboratory director previously?	Yes	No	

2. Is this appointment for an interim period, a specific term, or not term limited? If the appointment is interim or for a specific term, indicate term beginning and end dates (MM/DD/YY) and explain the recruitment plan, including timeline.

[Insert detailed response here. Table will expand automatically]

3. List the director's current board certification(s) below. If board certification is pending, indicate the date the exam has been scheduled. If the director has been recertified, use that date. Provide a copy of certification(s). If the director does not possess current American board certification, provide documentation that demonstrates the foreign

education or training is equivalent to that obtained in the United States.

Certification Type	**Certificate Effective Date** (MM/DD/YY)	**Certificate Valid Through Date** (MM/DD/YY)	**Certification Number**

4. List all professional positions (director, technical supervisor, clinical consultant, instructor, etc.) currently held by the director and estimated time commitment (hours/week) of each. Include projected hours for this laboratory. Expand rows as needed.

Professional Position	**Institution**	**Location City/State**	**Estimated Time Commitment (hours/week)**

5. 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**

6. Doctoral training in directing or supervising clinical histocompatibility testing for solid organ transplantation. List all laboratory specialties in which doctoral training was received, including exact dates and specific training received for each. Add additional sections below as necessary.

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	

7. Laboratory Involvement
   a. Detail the 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	Method	# 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, Primary 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 2A 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 board certification
- Current licensure if a state requirement
- Current curriculum vitae or resume

If the proposed primary technical supervisor has not previously served in this role before, the OPTN Bylaws require that the following documents be provided:

- Portfolio of cases
- Letter of reference from histocompatibility laboratories where training obtained
- 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
- Documentation demonstrating participation in transplant or clinical laboratory professional conferences or publications in peer-review journals

1. Provide the following information:

Name of primary technical supervisor			
Start date at this laboratory (DD/MM/YY)			
Effective date of this appointment (DD/MM/YY)			
Degree(s)			
Discipline(s)			
State licensure in the state/district where the lab is located (provide copy of current license if applicable)	Yes	No	Not required
Has this person served in the role of technical supervisor previously?	Yes	No	
Has this person served in the role of primary lab director previously?	Yes	No	
Does the proposed primary technical supervisor meet the qualifications defined in CLIA (42 CFR 493)?	Yes	No	

2. Is this appointment for an interim period, a specific term, or not term limited?
If the appointment is interim or for a specific term, indicate term beginning and end dates (MM/DD/YY) and explain the recruitment plan, including timeline.

[Insert detailed response here. Table will expand automatically]

3. List the technical supervisor's current board certification(s) below. If board certification is pending, indicate the date the exam has been scheduled. If the technical supervisor has been recertified, use that date. Provide a copy of certification(s). If the technical supervisor does not possess current American board certification, provide documentation that demonstrates the foreign education or training is equivalent to that obtained in the United States.

Certification Type	**Certificate Effective Date** (MM/DD/YY)	**Certificate Valid Through Date** (MM/DD/YY)	**Certification Number**

4. List all professional positions (director, technical supervisor, clinical consultant, instructor, etc.) currently held by the technical supervisor and estimated time commitment of each (hours/week). Include projected hours for this laboratory. Expand rows as needed.

Professional Position	**Institution**	**Location (City/State)**	**Estimated Time Commitment (hours/week)**

5. 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**

6. Doctoral Training in directing or supervising clinical histocompatibility testing for solid organ transplantation: List all laboratory specialties in which 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	

7. 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	**Method**	**# of Cases**
Kidney: Deceased donor typing		
Kidney: Deceased donor crossmatch		

Category	Method	# of Cases
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, Primary Clinical Consultant

The individual identified below as the primary clinical consultant must complete this section if they are not named as the primary histocompatibility laboratory director or technical supervisor in Sections 2A or 2B 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
- Current curriculum vitae or resume

If the proposed clinical consultant has not previously served in the role of primary laboratory director or clinical consultant, the following documents must be provided:

- Portfolio of cases
- Letter of reference from histocompatibility laboratories where training was obtained
- Proof of active interactions with transplant professionals
- 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
- Documentation demonstrating participation in transplant or clinical laboratory professional conferences or publications in peer-reviewed journals

1. Provide the following information:

Name of primary clinical consultant		
Degree(s)		
Discipline(s)		
Start date at this laboratory (DD/MM/YY)		
Effective date of this appointment (DD/MM/YY)		
State licensure in the state/district where the lab is located (provide copy of current license, if applicable)		
Has this individual served in the role of clinical consultant previously?	Yes	No
Has this individual served in the role of primary lab director previously?	Yes	No
Does the proposed Clinical Consultant meet the qualifications defined by CLIA (42 CFR 493)?	Yes	No

2. Is this appointment for an interim period, a specific term, or not term limited?
If the appointment is interim or for a specific term, indicate term beginning and end dates (MM/DD/YY) and explain the recruitment plan, including timeline.

[Insert detailed response here. Table will expand automatically]

3. List the clinical consultant's current board certification(s) below. If board certification is

pending, indicate the date the exam has been scheduled. If the applicant has been recertified, use that date. Provide a copy of certification(s). If the applicant does not possess current American board certification, provide documentation that demonstrates the foreign education or training is equivalent to that obtained in the United States.

Certification Type	**Certificate Effective Date** (MM/DD/YY)	**Certificate Valid Through Date** (MM/DD/YY)	**Certification Number**

4. List all professional positions (director, technical supervisor, clinical consultant, instuctor, etc.) currently held by the clinical consultant and estimated time commitment of each (hours/week). Include projected hours for this laboratory. Expand rows as needed.

Professional Position	**Institution**	**Location (City/State)**	**Estimated Time Commitment (hours/week)**

5. Describe the clinical consultant’s responsibilities in this laboratory:

[Insert detailed response here. Table will expand automatically]

6. Describe the clinical consultant’s experience in clinical transplantation:

[Insert detailed response here. Table will expand automatically]

Part 2: Section D - Personnel Qualifications, Primary General Supervisor

This section of the application must be completed for the primary general supervisor. If the histocompatibility laboratory director serves as general supervisor, indicate this in Question 1 below and leave the remainder of this section blank.

If two or more individuals share the general supervisor responsibilities, one person must be designated as the primary. Complete questions below and submit a current curriculum vitae or resume.

1. Provide the following information:

Name of primary general supervisor	
Start date at this laboratory (MM/DD/YY)	
Effective date of this appointment (MM/DD/YY)	
Does the general supervisor meet the qualifications defined by CLIA (42CFR. §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 of experience in human histocompatibility or transplant immunology testing under the supervision of a qualified histocompatibility director or technical supervisor:

[Insert detailed response here. Table will expand automatically]