Department of Health and Human Services
Health Resources and Services Administration

OMB No. 0915-0184
Expiration Date:
XX/XX/201X

CHANGE IN KEY PERSONNEL APPLICATION

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 8 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 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 the 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 or C).

	Check all that Apply	**Effective Date of Change**
Primary Histocompatibility Laboratory Director		
Technical Supervisor		
Clinical Consultant		

3. Describe the Histocompatibility Laboratory Coverage Plan. Plan must address 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, indicate all areas in which named director, technical supervisor, and clinical consultant will be involved and, if appropriate, in which area they have primary responsibility.

   [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 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.

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 (hours/week) of each. Expand rows as needed.

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.

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	

Add additional sections above as needed.

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 license if applicable)	
Certifications	
Start date at this laboratory (DD/MM/YY)	

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

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. 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 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 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, teacher) 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 transplantation:

[Insert detailed response here. Table will expand automatically]