PART 6: HISTOCOMPATIBILITY TESTING

PART 6, SECTION A: Histocompatibility Testing Arrangements

1. Will you engage one or more laboratories to serve your histocompatibility testing needs that are either:

   a) members of the OPTN (or currently applying for membership); or
   b) controlled by another clinical transplant hospital that is an OPTN member (or is currently applying for membership)?

   Yes: _____ **No**: _____

2. If **Yes**, give name and address of each such histocompatibility laboratory, the contact person, and the functions performed by each laboratory.
   - Include a copy of each agreement your transplant hospital has with a Histocompatibility Laboratory.

   Do not complete Section B & C unless your own laboratory performs one or more histocompatibility testing functions.

Laboratory Name (1)	
Address	
Contact Person	
Functions Performed	

Laboratory Name (2)	
Address	
Contact Person	
Functions Performed	

PART 6: SECTION B –
APPLICATION FOR HOSPITAL BASED HISTOCOMPATIBILITY LABORATORY

Complete this Section if the answer to Question 1 in Part 5, Section A, is **No.**

Name of Applicant Laboratory: _____

CMS #: _____ CLIA # _____

1. In order to qualify for OPTN Institutional Membership as a Clinical Transplant Hospital, each transplant program of the transplant hospital must utilize one or more histocompatibility laboratories that meet the applicable OPTN standards. All histocompatibility laboratories must be accredited in Solid Organ transplantation: Deceased Donor. If the transplant hospital performs living donor organ transplants, the laboratory must be accredited for Solid Organ Transplantation: Living Donor. Does this transplant hospital perform living donor organ transplants?

   Yes___ No ___

2. Upon receipt your application will be forwarded to the American Association for Histocompatibility and Immunogenetics (ASHI) or the College of American Pathologists (CAP), which have been granted deemed status to perform histocompatibility laboratory inspections.

   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.

   a) Has your laboratory been accredited by ASHI or CAP within the last three years?

	ID #	Yes	No	Last Accreditation Date
ASHI Accredited				
CAP Accredited				

   b) If the answer to item "a" above is **Yes**, indicate the categories for which the laboratory was accredited.

Categories	Yes	No
Solid Organ Transplantation: Deceased Donor		
Solid Organ Transplantation: Living Donor		
Islet Cell Transplantation		

3. Identify the laboratory director(s), clinical consultants, technical supervisor, and general supervisor.

Position	Name
Primary Laboratory Director	
Other Laboratory Director (s)	
Clinical Consultant	
Technical supervisor (if other than the laboratory director)	

General supervisor (if other than the laboratory director)	

4. Describe the plan for coverage if the laboratory director is not full time at this laboratory or also serves as a director at another laboratory.

5. 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.

   b) List any regional, national, or international transplant registries to which you are now submitting data. Also, list any registry to which you had previously submitted data, given the years of such submission.

   c) Describe the methods to be used to collect, verify, and submit data on a timely basis. Identify the current status of local data collection and compilation by hard copy and computer. Identify the hardware and software used for any computer files.

6. List the name and address of other transplant hospitals for which you will provide histocompatibility testing services. Attach a copy of your agreement(s).

7. If your histocompatibility laboratory is not presently accredited by ASHI or CAP, do you wish to apply for ASHI or CAP accreditation?

   ASHI: **Yes ____ No ____**
   CAP: **Yes ____ No ____**

If your histocompatibility laboratory is currently accredited or is in the process of being accredited by ASHI or CAP; please stop here.
Attach a copy of the ASHI/CAP application. When available, proof of certification must be provided.

PART 6, SECTION C (1) - OPTN Accreditation Program - Application Instructions

This application form is used for laboratories not currently accredited by ASHI or CAP.

TABLE OF CONTENTS

GLOSSARY OF ABBREVIATIONS

ABB	American Board of Bioanalysis
ABCC	American Board of Clinical Chemistry
ABHI	American Board of Histocompatibility and Immunogenetics
ABMLI	American Board of Medical Laboratory Immunology
ABMM	American Board of Medical Microbiology
ASHI	American Society for Histocompatibility and Immunogenetics
Ab	antibody
Ag	antigen
AHG	antihuman globulin
AP	Accreditation Program
ARB	Accreditation Review Board
CAP	College of American Pathologists
CDC	complement-dependent cytotoxicity
CE	continuing education
CFR	Code of Federal Regulation
CLIA	Clinical Laboratory Improvement Act (Amendments)
DHHS	Department of Health and Human Services
DNA	deoxyribonucleic acid
ELISA	enzyme-linked immuno-sorbent assay
FTE	full time equivalent
HCFA	Health Care Financing Administration
HHT	human histocompatibility testing
HLA	human leukocyte antigen
JC	Joint Commission
MLC	mixed lymphocyte culture
OPTN	Organ Procurement and Transplantation Network
PCR	polymerase chain reaction
PRA	panel reactive antibody
SEOPF	South-Eastern Organ Procurement Foundation
SSOP	sequence specific oligonucleotide probe
SSP	sequence specific primer
TAT	turn around time
TX	transplant
UNOS	United Network for Organ Sharing
XM	crossmatch

GENERAL INSTRUCTIONS

1. **IMMEDIATELY UPON RECEIPT**, record the date of receipt of this application on the Processing Record Form.

2. Before completing the application, read all instructions carefully.

3. All documentation must be in English and typed.

4. Your CLIA provider number, OPTN number (if applicable), and application date must be at the top of each page of the application and at the top of all additional documents submitted (i.e. proficiency reports, etc.).

5. Accreditation in Deceased Donor Solid Organ Transplantation requires that the laboratory provide 24-hour on call coverage.

6. CFR Sec. 493.51 requires that DHHS or its designee be notified within 30 days of any change in ownership, name, location, director, or technical supervisor.

7. The American Society for Histocompatibility and Immunogenetics and the College of American Pathologists have been granted deemed status to carry out its inspections and accreditation process.

8SUBMISSION OF THE APPLICATION

When your application is complete and ready for submission, record the date it is being sent on the Processing Record Form.
Return the original application and one (1) complete copy. Please also return a copy of the application that has been scanned to a CD in PDF format. Label the CD with the Organization name, contact name, and date, and include an table of contents.

Express Mail:
UNOS
Membership Services
700 North 4th Street
Richmond, VA 23219

US Mail:
UNOS
Membership Services
PO Box 2484
Richmond, VA 23218

Main Phone: (804) 782-4800

Processing of the application will not begin if the ASHI or CAP Executive Office has not received payment of the laboratory's accreditation fees.

Retain these instructions, an entire copy of your submission and the Inspector's Checklist to help you prepare for the inspection.

The Accreditation Manager will perform an initial review of the application.

Incomplete applications will not be processed further until they are complete and deadlines cannot be extended.

INSPECTION

Inspectors are appointed on the basis of their expertise, objectivity, integrity, experience, and to minimize expenses born by the applicant, geographical location. If you believe an appointed inspector has a conflict of interest that will interfere with his/her objectivity, please petition in writing for a different inspector. You will have one right of refusal. The commissioner will evaluate the situation and take appropriate action.

The inspection may take one or more days, depending upon the areas in which accreditation is sought and size of the laboratory. To facilitate a thorough evaluation, have all records readily available and, if possible, designate at least one individual to assist the inspector in accessing the necessary information. The manual, or a separate protocol manual, should provide instructions for the appropriate use of each technique and specify testing for the various clinical applications.

At the end of the inspection, an exit interview will be conducted and the inspector will inform you if deficiencies were found. The inspection is only one part of an extensive evaluation process and any comments made by the inspector must not be construed as judgment for or against approval of the laboratory. After the inspection has been performed, complete the inspection questionnaire form that the inspector will leave with you and return it promptly to your commissioner.

RESPONSE TO DEFICIENCIES

Following the inspection, responses to the deficiencies, cited by the inspector and any other deficiencies identified by the commissioner, must be submitted within 30 days of the notification of the deficiency. Responses must include supporting documentation.

COVER PAGE

Provide the names of the laboratory, director(s), and department, as they should appear on the accreditation certificate (+).

CFR 493 requires that the laboratory have a director (493.1441), technical specialist (493.1447), clinical consultant, (493.1453) and general supervisor (493.1459). Provide the appropriate name(s) for each position.

**There must be a name entered for all positions listed above, if left blank, the packet will be returned.

Check all Areas of Accreditation in which you wish to be evaluated for accreditation and record **"NEW"** for those in which your lab is not currently accredited.

A. PERSONNEL: DIRECTOR/TECHNICAL SUPERVISOR QUALIFICATIONS (STANDARD B1.000)

The individual identified as director/technical supervisor must complete this section. If two or more individuals share the director/technical supervisor's responsibilities, use a copy of the forms for each individual. Complete all sections and submit a copy of the curriculum vitae, current certification, and current licensure if a state requirement.
A laboratory director must have sufficient training and experience in each specialty, subspeciality, analyte, test, or procedure for which the laboratory is accredited, to provide adequate management and direction of the laboratory personnel and activities.

(CFR 493.1443) For lab directors, MDs must be licensed to practice medicine in the state in which the lab is located or deemed qualified as of 2-28-92. If not an MD, they must have an earned doctoral degree (not an MD degree) in a biological, chemical, or physical science and, by 12-31-00 be certified by ABHI, ABB, ABCC, ABMLI, ABMM or other board approved by HHS.

The laboratory Technical Supervisor must be qualified by education, training and experience to provide technical supervision for each speciality, subspeciality, analyte, test or procedure for which the laboratory is accredited.

(CFR 493.1449) Technical supervisors must be either an MD licensed to practice medicine in the state in which the lab is located (no grandfather clause) or a PhD (as above) and (for either degree) have 4 years post doctoral training and/or experience in histocompatibility or 2 years training and/or experience in the laboratory specialty of general immunology plus 2 years training and/or experience in histocompatibility.

In most cases, one person fills both positions.

For director/technical supervisors that were previously approved, submit an abridged publication list limited to the last two years, include any updated information on these pages (i.e. additional lab training/experience as required with changing lab activities, change in responsibility, etc.) and a copy of current licensure if a state requirement (required for all MDs).

B. PERSONNEL: CLINICAL CONSULTANT QUALIFICATIONS

If the clinical consultant is not the director or technical supervisor, submit a copy of the current certification and current licensure if a state requirement. The Clinical Consultant must have sufficient training and experience in areas of the laboratory's accreditation to be qualified to consult with and render opinions to the laboratory's clients concerning the appropriateness of human immunogenetics, histocompatibility and /or transplantation immunology testing and the interpretation of these test results in relation to diagnosis, treatment and management of patient care.

(CFR Sec. 493.1455) The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must (a) be qualified as a laboratory director under Sec. 493.1443(b)(1), (2), or (3)(i) or, for the subspecialty of oral pathology, Sec. 493.1443(b)(6); or (b) be a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located.

If the Director/Technical Supervisor serves as the Clinical Consultant, it must be stated on this form.

C. PERSONNEL: GENERAL SUPERVISOR QUALIFICATIONS

This section should be completed by all personnel with authority to sign out reports and/or function as a general supervisor. Submit curriculum vitae for each person. If the director serves as general supervisor, indicate this on the cover page and leave the remainder of this section blank. The general supervisor must have training and experience under the direction of the laboratory director and supervision of the technical supervisor to provide day-to-day supervision of testing personnel and reporting of test results. In the absence of the director and technical supervisor, the general supervisor must be responsible for the proper performance of all laboratory procedures and reporting of test results.

D. PERSONNEL LIST

List all personnel who perform work related to histocompatibility and Immunogenetics activities of the laboratory, including the director(s), co-director(s), associate director(s), scientist(s), fellow(s), supervisor(s), technologist(s), technician(s), lab aide(s) and assistant(s), support staff (clerical, secretarial), administrative personnel (computer, business manager, etc.). Supply the following information either in the following format or on the Personnel List.

Start date in this laboratory
Name
Positions
Degrees
Certifications
Years of working experience in human histocompatibility testing (HHT)
%FTE in clinical HHT
Personnel on-call for deceased donor testing
For non-degreed technical personnel not previously reviewed by the ASHI Accreditation Program, indicate those qualified to work unsupervised, whether or not they take deceased donor call and under which specific standards of CFR 493.1489 and 1491 they qualify.
Copy of the state license for each person required to hold a license.
Copy of the competency quality assurance summary for each of the technical personnel.

E. CONTINUING EDUCATION SUMMARY

For the lab director and each member of the technical staff, submit a summary of

participation in continuing education during the previous year (calendar year or fiscal year). Note programs which are HHT related ASHI approved. Briefly, describe the program content. Include safety training, technical meetings, clinical meetings, technical competency assessment, and review of proficiency testing, quality control and lab manuals. Note the number of hours of actual participation and the level of participation (lecturer, presenter, participant or attendee).

The minimum hours of continuing education will be met if the individual is ABHI certified and has maintained continued certification. For directors/technical supervisors not maintaining continued certification, a minimum of 50 hours/year is required. For general supervisors not maintaining continued certification, a minimum of 27 hours/year is required. For those testing personnel not maintaining continued certification, a minimum of 12 hours/year is required.

Supply the following information either in the following format or on the Continuing Education Summary Form:
Name
Position
Brief job description (i.e. supervises serologic testing and performs molecular testing)
Program
Participation hours
Participation level
Approved by ABHI
Content
Summary of contact hours by type and total

F. LABORATORY ACTIVITIES

In the last year (calendar or fiscal), indicate the approximate percent of the lab's total clinical effort for each Area of Accreditation, the number of cases for each clinical activity listed and the number of tests performed.

G. PROFICIENCY TEST RESULTS

Laboratory accreditation requires successful participation in approved external proficiency testing programs, when available, for all clinical tests performed by the laboratory in the categories being evaluated. Laboratories may use more than one proficiency testing survey provider. Performance of the tests must be rotated among all technologists performing the tests and be processed and tested in the same manner as patient specimens. Satisfactory performance requires at least an 80% success rate for each challenge (send out), of each analyte (CFR 493, subpart H). For a survey report of 5 samples for phenotyping (analyte), a satisfactory performance would be an error of no more than 1 of the 5 phenotypes. Tabulate the results on the Proficiency Result Summary Form, including only those results that reached consensus and submit a copy of corrective actions for any errors in any category submitted. If proficiency testing is not available for a test your laboratory performs, validate accuracy and reproducibility of the test at least twice each year and submit a summary of these results.

Unsuccessful participation in a proficiency testing: failure to attain minimum satisfactory score

Unsuccessful participation in proficiency testing requires remedial action as detailed in CFR 493.1701. Failure to take remedial action can result in CMS imposed sanctions as specified in CFR 493, subpart R.

HLA Class I and II Antigen Typing

Results submitted for any proficiency testing survey provider for each analyte must include all results for a one-year period. Submit the full year's results from the cells/specimens typed for the major A, B and DR antigens, from the twelve (12) month (calendar or fiscal year) period preceding the application date.

Laboratories required to meet the OPTN Standards must be able to type for the World Health Organization (WHO) recognized antigens for which reagents are readily available.

HLA Class I Allele Typing

Results submitted for any proficiency testing survey provider for each analyte must include all results for a one-year period. Submit the full year's results from the cells/specimens typed for HLA Class I alleles, from the twelve (12) month (calendar or fiscal year) period preceding the application date.

HLA Class II Allele Typing

Results submitted for any proficiency testing survey provider for each analyte must include all results for a one-year period. Submit the full year's results from the cells/specimens typed for HLA Class II alleles, from the twelve (12) month (calendar or fiscal year) period preceding the application date.

Antibody Screen Tests and Antibody Identification

Results submitted for any proficiency testing survey provider for each analyte must include all results for a one-year period. Submit the full year's results from the antibody screen tests from the twelve (12) month (calendar or fiscal year) period preceding the application date.

Crossmatch Testing by Cytotoxicity

Results submitted for any proficiency testing survey provider for each analyte must include all results for a one-year period. Submit the full year's results from the crossmatch testing by cytotoxicity from the twelve (12) month (calendar or fiscal year) period preceding the application date.

Crossmatch Testing by Flow Cytometric Methods

Results submitted for any proficiency testing survey provider for each analyte must include all results for a one-year period. Submit the full year's results from the crossmatch testing by flow cytometric methods from the twelve (12) month (calendar or fiscal year) period preceding the application date.

H. VALIDATION REQUIREMENTS FOR USING A NEW PROCEDURE OR TEST

Among the most critical aspects of laboratory evaluation are the assessment of test performance and outcome. This evaluation process includes a review of results of

not only proficiency test surveys but also of tests performed during the various situations found in the laboratory and of internal proficiency tests. These situations include the tests performed on subjects in varying states of health and tests performed using various types of material (blood, lymph nodes, spleen, etc.). The purpose of these guidelines is to describe the minimum data that must be submitted by all laboratories.

Prior to reporting test results of a new procedure or test, the laboratory must establish performance specifications and demonstrate that it can obtain these performance specifications or, for FDA-approved kits, the specifications of the manufacturer. Performance specifications include accuracy, precision, analytical sensitivity and analytical specificity to include interfering substances, reportable range of patient test results, reference range(s) (normal values) and any other performance characteristics required for test performance. Calibration and calibration verification procedures must be performed and documented. Control and quality assurance procedures must be routinely performed. Personnel must be trained, qualified and have appropriate technical supervision available. For further information, refer to CFR 493.1201b, 493.1205a, 493.1205c, 493.1213, 493.1217, 493.1218, 493.1701, 493.1705 and 493.1709.

Minimally, these sections require the lab to do the following:

1. Establish specification requirements for test performance
2. Evaluate the test system to assure that it meets the specification requirements
3. Identify and establish ongoing quality control measures
4. Train personnel and take measures to evaluate and ensure their ongoing competency

Documentation for accreditation should include the following:

1. Protocol and example of a case file. This should include an explanation of how and when the test will be used.

2. Step by step procedure. Include whether this replaces previously used technologies or is an adjunct to technologies in use.

3. Performance requirements. This may be included in the procedure or in a quality control manual. If new equipment is employed, include documentation of validation of the new equipment.

4. Validation summary data, analysis, and conclusions.

5. Limitations and shortcomings, how these will be handled, general troubleshooting. This may be included in the quality control section of the procedure.

6. Training guidelines and documentation of testing personnel competency (for personnel currently authorized to perform this test).

I. SUPPLEMENTARY DOCUMENTATION OF DIRECTOR(S)/TECHNICAL SUPERVISOR(S) QUALIFICATION

Some applicants may fulfill the training/experience requirements for a director of a

histocompatibility laboratory, but lack sufficient documentation of professional competence as delineated in Standard B1.000 ("by external measures such as national proficiency testing, participation in national or international workshops or publications in peer-reviewed journals.") In such cases, the applicant is required to submit the following supplementary documentation to UNOS:

Portfolio of Case Files

The purpose of this portfolio is to provide the OPTN with documentation of the applicant's ability to review and interpret test results obtained in various clinical situations; to provide insight into probable causes of and appropriate solutions for test failure; to recommend additional follow-up tests as needed; and to provide appropriate commentary for use by clinicians. The files, therefore, must include evidence of interpretive comments and review by the applicant. The submitted case files should be consecutive. For example, an applicant wishing to qualify in another area of expertise could visit another accredited lab for specific training and to compile the needed number of cases. The files should include relevant, but anonymous patient information (e.g. race/ethnicity, parity, underlying disease, etc.).

These case files need to reflect the applicant's expertise in three major areas:

Technology
The applicant must have sufficient experience with the technologies employed to know their strengths and limitations. This is necessary in order to be able to select technologies appropriate for each situation, interpret test results, and establish a quality assurance program.

Test Selection
The applicant must be capable of determining what tests are necessary for various clinical applications and of developing new tests and test strategies as dictated by changes in individual patient status.

Interpretation/Consultation
The applicant must have adequate expertise to know what information is needed to evaluate individual clinical cases and be capable of utilizing the collective body of information to assess risk level, identify possible clinical strategies, and make scientific evaluations of the immune state of the patient. Further, the applicant should be capable of supporting clinical studies and of using clinical data in the ongoing development of test strategies.

The most effective way to acquire a case portfolio is through training and experience under the guidance of an ASHI or CAP approved director/technical supervisor. If an individual no longer has access to case files reviewed, it may be possible to visit another laboratory and review files. In this case, the director/technical supervisor must serve as an advisor. The advisor will be required to submit an evaluation of the applicant's expertise in each area in which accreditation is sought. If various test methods are used, the cases submitted should have sufficient numbers of each test method to validate the applicant's expertise/qualifications (e.g. CDC, ELISA and flow cytometry antibody analysis). The case files must be submitted as described below:

1. Fifty (50) family work-ups for living related solid organ transplantation. For renal, living related transplantation, the files must include the recipient's serum screen results. Full HLA phenotypes for all available family members must be included.

2. Fifty (50) recipient work-ups for deceased donor renal and/or non-renal transplantation. This portfolio must include complete HLA phenotypes and serum screens.

3. Fifty (50) deceased donor work-ups. This portfolio must include full HLA phenotypes and other test results as applicable (e.g. ABO if performed in the laboratory).

Continuing Education

Documentation of continuing education during the past 5 years in the areas relevant to their application must be submitted. For non-ASHI or non-CAP approved meetings, information about the program should be submitted in order for the committee to assess the relevance to histocompatibility and Immunogenetics.

In addition, the applicant may submit letters from ASHI or CAP accredited directors if they might help verify training, experience or involvement in the field. In cases of collaborative research or papers, the letter should identify the exact role of the applicant in the project; i.e. did the applicant actually perform or assist with the portions of the project relative to histocompatibility and Immunogenetics.

J. PROCEDURES

Submit a copy of the laboratory procedure manual.

Submit copies of reading/scoring sheets for all tests in use.

HLA Class I and II Antigen Typing

List all HLA antigens your laboratory can identify.

HLA Class I and II Allele Typing

List all HLA alleles for which your laboratory can test and can identify.

Submit a list of probes and primers in use for various tests.

For molecular testing labs, briefly describe or submit protocols for preventing pre-PCR contamination, including description of physical layout.

CFR 493.51 requires that DHHS or the accrediting organization be notified no later than 6 months after any deletions or changes in test methodologies for any test.

K. ANTIBODY SCREENING/ANTIBODY CHARACTERIZATION

Briefly describe or submit your serum screening protocol indicating what serum samples are screened, when, by what technique, etc.

Submit panel phenotypes. If the panel is not the same all the time, submit the phenotypes of the first and last panel of the previous year (calendar or fiscal).

L. QUALITY ASSURANCE

Submit an example of training documentation for new technical personnel.

Submit training documentation for all technical personnel.

List laboratories subcontracted and evidence of their certification.

M. ADDITIONAL DOCUMENTATION, FOR LABORATORIES NOT CURRENTLY ASHI ACCREDITED

Submit a list of all reagents used in clinical tests.

Submit a brief description of quality control testing and monitoring for all reagents.

Submit a floor plan and total square footage for the laboratory.

Submit a list of all laboratory equipment used clinically.

Submit a brief description of the equipment function verification and preventative maintenance procedure.

List the records that are maintained, for how long and what format (paper, electronic). Include worksheets, reports, QC records, etc.

Submit a brief description of the computer validation and back-up system.

3. TEST PROCEDURES AND PROTOCOLS

For each area in which you are seeking accreditation, submit a one-page summary of the testing. Submit a complete case file from the last month for each clinical application.

A case file consists of: A requisition of the orders and a report.

For the application of Solid Organ Transplantation: Deceased Donor, describe the testing process including the procedures (tests) used in the initial patient work-up (typing, antibody screening, auto crossmatching, etc.), deceased donor work-up, pre-TX work-up, specimen selection criteria (i.e. sera used in crossmatch), requirements for specific testing (i.e. flow crossmatch testing on regraft patients), etc.. Accreditation in this area requires that the laboratory provide 24-hour on call coverage and meets the requirements of the OPTN Standards.

For the application of Solid Organ Transplantation: Live Donor, describe the testing process, including the procedures (tests) used in the initial patient work-up (typing, antibody screening, auto crossmatching, etc.), initial donor work-up, all additional pre-TX testing, specimen selection criteria (i.e. sera used in crossmatch), requirements for specific testing (i.e. flow crossmatch testing on regraft patients), etc. Include variations for different organ types. Accreditation in this area requires that the laboratory meet the requirements of the OPTN Standards.

For the application of Islet Cell Transplantation, describe the testing process, including the procedures (tests) used in the initial patient work-up (typing, antibody screening, auto crossmatching, etc.), initial donor work-up, all additional pre-TX testing, specimen selection criteria (i.e. sera used in crossmatch), requirements for specific testing (i.e. flow crossmatch testing on regraft patients), etc.. Accreditation in this area requires that the laboratory meet the requirements of the OPTN Standards.

4. CHECKLIST OF REQUESTED DOCUMENTS

- ❑ Processing Record Form with date of receipt and date of submission (original)
  FIVE copies, each in an accordion file (included):

- ❑ Cover page
- ❑ Director/Technical Supervisor(s) Qualifications
- ❑ Director/Technical Supervisor(s) CV's
- ❑ Director/Technical Supervisor(s) certification(s)
- ❑ Director/Technical Supervisor(s) current state license, if applicable
- ❑ Clinical Consultant(s) Qualifications
- ❑ Clinical Consultant(s) current state license, if applicable
- ❑ General Supervisor(s) Qualifications
- ❑ General Supervisor(s) CV's
- ❑ Personnel List
- ❑ Copy of state license for each of the technical personnel, if applicable
- ❑ Copy of the competency quality assurance summary for each of the technical personnel
- ❑ Continuing Education Summary Form for each member of the technical staff
- ❑ Laboratory Activities
- ❑ Proficiency testing reports
- ❑ Proficiency Result Summary Form
- ❑ Proficiency testing corrective actions, if applicable
- ❑ Validation documentation for new procedures or tests
- ❑ Protocol and example of a case file
- ❑ Step by step procedure
- ❑ Performance requirements
- ❑ Validation summary data, analysis, and conclusions
- ❑ Limitations and shortcomings, how these will be handled, general troubleshooting
- ❑ Training guidelines and documentation of testing personnel competency
- ❑ Supplemental documentation of director/technical supervisor qualifications
- ❑ Copy of the laboratory procedure manual
- ❑ Reading/scoring sheets for all test systems
- ❑ List of all HLA antigens your lab can identify
- ❑ List of all HLA alleles for which your lab can test and can identify
- ❑ List of probes and primers in use for various tests
- ❑ Protocol for preventing pre-PCR contamination
- ❑ Serum screening protocol
- ❑ Panel phenotypes
- ❑ Copy of training documentation for all technical personnel
- ❑ Performance improvement programs initiated
- ❑ List of labs subcontracted and certificates
- ❑ Description of testing process and a complete case file for appropriate application(s):
- ❑ Solid Organ Transplantation: Deceased Donor
- ❑ Solid Organ Transplantation: Live Donor
- ❑ Islet Cell transplantation
- ❑ List of all reagents
- ❑ Description of quality control testing and monitoring for all reagents
- ❑ Floor plan and total square footage of lab
- ❑ List of all laboratory equipment
- ❑ Description of equipment function verification and preventative maintenance procedure
- ❑ List of records maintained
- ❑ Description of computer validation and back-up system

CLIA #_____
OPTN # _____
Date _____

PART6, SECTION C(2)
OPTN ACCREDITATION PROGRAM ACCREDITATION APPLICATION

A. COVER PAGE

Provide the names of the laboratory, director(s), department and institution, as they should appear on the accreditation certificate (+).

Position	Name
+Primary lab Director	
Other lab Director(s)	
Technical Supervisor*	
Clinical Consultant*	
General Supervisor*	
+Laboratory or Department Name	
+Institution	
Street Address	
City, State, Zip	
Contact Person	
Telephone	
Fax	
E-Mail Address	
Website Address	

**As Defined in CFR 493.1441-1467*

AREAS OF ACCREDITATION

Check all areas in which you wish to be evaluated for accreditation and indicate "NEW" for those in which your lab is not currently accredited.

Areas of Accreditation	To be Evaluated	New
Solid Organ Transplantation: Deceased Donor		
Solid Organ Transplantation: Live Donor:		
Islet Cell Transplantation		

Other accreditation/certification held by laboratory (specify):_____
_____

(Print name of director or other authorized individual) _____ does hereby apply for laboratory accreditation in the area(s) of accreditation designated above. I understand that granting of accreditation is dependent on complete compliance with all applicable standards. I certify that all information provided is truthful and accurate.

Signature of authorized individual: _____

Date: _____

CLIA #_____
OPTN # _____
Date _____

B. PERSONNEL QUALIFICATIONS

DIRECTOR/TECHNICAL SUPERVISOR QUALIFICATIONS (Standard B1.000)

The individual identified as director/technical supervisor must complete this section. If two or more individuals share the director/technical supervisor's responsibilities, use a copy of the forms for each individual. Complete all sections and submit a copy of the curriculum vitae, current certification and current licensure if a state requirement.

(CFR 493.1443) For lab directors, MDs must be licensed to practice medicine in the state in which the lab is located or deemed qualified as of 2-28-92. If not an MD, they must have an earned doctoral degree (not an MD degree) in a biological, chemical, or physical science and, by 12-31-00 be certified by ABHI, ABB, ABCC, ABMLI, ABMM or other board approved by HHS.

(CFR 493.1449) Technical supervisors must be either an MD licensed to practice medicine in the state in which the lab is located (no grandfather clause) or a PhD (as above) and (for either degree) have 4 years post doctoral training and/or experience in histocompatibility or 2 years training and/or experience in the laboratory specialty of general immunology plus 2 years training and/or experience in histocompatibility.

In most cases, one person fills both positions.

For directors/technical supervisors that were previously approved

- submit an abridged publication list limited to the last two years, include any updated information on these pages (i.e. additional lab training/experience as required with changing lab activities, change in responsibility, etc.); and
- a copy of current licensure if a state requirement (required for all MDs).

Name	
Discipline(s)	
State Licensure (provide copy of current, if applicable)	
City Licensure (provide copy of current, if applicable)	

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

Professional Position	Estimated Time Commitment (hours/week)

CLIA #_____
OPTN # _____
Date _____

Post-Doctoral Training in Areas of Biology Other Than Human Histocompatibility Testing

List all laboratory specialties in which post-doctoral training was received including exact dates and specific training received for each. Submit a letter from instructor, if possible.

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	

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

Experience in Areas of Biology Other than Human Histocompatibility Testing.

Institution Name	
Name of Director	
Your Title	
Dates	
Hours/week	
Description of Duties	

Institution Name	
Name of Director	
Your Title	
Dates	
Hours/week	
Description of Duties	

Institution Name	
Name of Director	
Your Title	
Dates	
Hours/week	

Description of Duties	

CLIA #_____
OPTN # _____
Date _____

Post-Doctoral Training in Human Histocompatibility Testing

List all laboratory specialties in which post-doctoral training was received including exact dates and specific training received for each. Submit a letter from instructor, if possible.

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	

Laboratory Involvement

Is emergency consultation available during your absence? _____
_____

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

Indicate the approximate number of cases up to 500 (after that just indicate >500) that you have reviewed in each of the following categories:

Category	# of Cases
Renal transplantation, deceased donor typing and crossmatch	
Renal transplantation, living donor, typing and crossmatch	
Non-renal deceased donor typing and crossmatch	
Islet Cell Transplantation	
Allele level typing	
HLA antibody screening	
HLA antibody characterization	
Flow cytometry crossmatch	

CLIA #_____
OPTN # _____
Date _____

In the space below, describe your role in the laboratory, including the

- extent to which you participate in the review, interpretation and reporting of test results,
- development and performance or supervision of test procedures,
- training and evaluation of staff and fellows, and
- establishment of laboratory policy.
- If there is more than one director, indicate all areas in which you are involved and, if appropriate, in which area you have primary responsibility.

CLIA #_____
OPTN # _____
Date _____

Expertise (new director/technical supervisor or when director/technical supervisor add new testing)

Provide below, a description of your professional activities which provide evidence of your expertise in human histocompatibility testing and immunogenetics. Include the following

- participation in relevant national and international scientific societies,
- participation in workshops in human histocompatibility testing,
- formal teaching responsibilities, and
- all other activities that will be helpful in evaluating your qualifications.
- Note, if documentation of expertise is not available, this requirement may be met by submitting a portfolio of cases you have analyzed. Please contact your Commissioner for further information.

C. PERSONNEL QUALIFICATIONS

CLINICAL CONSULTANT QUALIFICATIONS

If the clinical consultant is not the director or technical supervisor, submit a copy of the current certification and current licensure if a state requirement.

(CFR Sec. 493.1455) The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must (a) be qualified as a laboratory director under Sec. 493.1443(b)(1), (2), or (3)(i) or, for the subspecialty of oral pathology, Sec. 493.1443(b)(6); or (b) be a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located.

CLIA #_____
OPTN # _____
Date _____

D. PERSONNEL QUALIFICATIONS

GENERAL SUPERVISOR QUALIFICATIONS

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

If previously submitted, submit an abridged publication list limited to the last two years and include any updated information on these pages.

Name	
Position	
State Licensure (provide copy of current, if applicable)	
City Licensure (provide copy of current, if applicable)	
Provide description of Duties in your present position	

CLIA #__________________
OPTN # ___________________
Date ___________________

Training

List all laboratory training received, beginning with the most recent.

Institution Name	
Laboratory Name	
Instructor Name	
Dates	
Specific Training	

Institution Name	
Laboratory Name	
Instructor Name	
Dates	
Specific Training	

Institution Name	
Laboratory Name	
Instructor Name	
Dates	
Specific Training	

Institution Name	
Laboratory Name	
Instructor Name	
Dates	
Specific Training	

Institution Name	
Laboratory Name	
Instructor Name	
Dates	
Specific Training	

Institution Name	
Laboratory Name	
Instructor Name	
Dates	
Specific Training	

CLIA # ___________________
OPTN # ___________________
Date ___________________

Experience

List all laboratory working experience, beginning with the most recent prior to your present position.

Institution Name	
Name of Director	
Your Title	
Dates	
Hours/Week	
Description of duties	

Institution Name	
Name of Director	
Your Title	
Dates	
Hours/Week	
Description of duties	

Institution Name	
Name of Director	
Your Title	
Dates	
Hours/Week	
Description of duties	

Institution Name	
Name of Director	
Your Title	
Dates	
Hours/Week	
Description of duties	

Institution Name	
Name of Director	
Your Title	
Dates	
Hours/Week	
Description of duties	

CLIA #_____
OPTN # _____
Date _____

E. PERSONNEL LIST

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

CLIA #_____
OPTN # _____
Date _____

E. PERSONNEL LIST (continued)

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

CLIA #_____
OPTN # _____
Date _____

E. PERSONNEL LIST (continued)

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

CLIA #_____
OPTN # _____
Date _____

F. CONTINUING EDUCATION SUMMARY FORM

The minimum hours of continuing education will be met if the individual is ABHI certified and has maintained continued certification. For directors/technical supervisors not maintaining continued certification, a minimum of 50 hours/year is required. For general supervisors not maintaining continued certification, a minimum of 27 hours/year is required. For those testing personnel not maintaining continued certification, a minimum of 12 hours/year is required.

Name	
Position	
Brief job description	
Period (12) month period preceding the application date)	

Name	
Position	
Brief job description	
Period (12) month period preceding the application date)	

Name	
Position	
Brief job description	
Period (12) month period preceding the application date)	

Name	
Position	
Brief job description	
Period (12) month period preceding the application date)	

Summary of contact hours by type:	Hours
Lecturer	
Presenter	
Participant	
Attendant	
Total	

CLIA #_____
OPTN # _____
Date _____

G. LABORATORY ACTIVITIES

Period (twelve (12) month period preceding the application date)_____to_____
_____

In the past twelve (12) month period preceding the application date, indicate the approximate percent of the lab's total clinical effort for each Area of Accreditation:

Area of Accreditation	%
Solid Organ TX: Deceased Donor	
Solid Organ TX: Living Donor	
Islet Cell Transplantation	
All Other (e.g., HSC/BMT)	

In the past twelve (12) month period preceding the application date, complete the following indicating the number of cases for which your laboratory provided services:

	# of Cases
Deceased donor renal transplants	
Deceased donors: local	
Deceased donors: imports	
Average number of patients on the deceased donor renal waiting list	
Non-renal solid organ transplants	
Living donor transplants	
Islet Cell transplantation	

In the past twelve (12) month period preceding the application date, indicate the number of tests performed.

	# of tests performed
Class l serologic	
Class l SSP	
Class l SSOP	
Class l sequencing	
Class ll serologic	
Class ll SSP	
Class ll SSOP	
Class ll sequencing	
Single Ag	
PRA-CDC	
PRA-ELISA	
PRA-Flow Cytometry	
Ab-CDC	
Ab-ELISA	
Ab-Flow Cytometry	
XM-CDC	
XM-ELISA	
XM-Flow Cytometry	
MLC	

Others	

CLIA #_____
OPTN # _____

H. *PROFICIENCY RESULTS SUMMARY FORM*

Period (twelve [12] month period preceding the application date)_____

_____

Typing Survey	*Technology*	*No. of specimens with errors*	*No. specimens tested*	*Concordance(%)*	*Successful*	*Unsuccessful*
	Class I Serologic					
	Class I DNA-Low Resolution					
	Class I DNA-High Resolution					
	Class II Serologic					
	Class II DNA-Low Resolution					
	Class II DNA-High Resolution					
	ABO/Rh Typing					

Crossmatch Survey	Technology	No. of specimens with errors	No. specimens tested	Concordance(%)	Successful	Unsuccessful
	T Cell CDC					
	T Cell AHG					
	T Cell Flow					
	B Cell CDC					
	B Cell AHG					
	B Cell Flow					

Ab Screen Survey	Technology	No. of specimens with errors	No. specimens tested	Concordance(%)	Successful	Unsuccessful
	Class I CDC					
	Class I AHG					
	Class I ELISA					
	Class I Flow					
	Class II CDC					
	Class II AHG					
	Class II ELISA					
	Class II Flow					

Include corrective action documentation for each error