

OPTN Membership Application for Intestine Transplant Programs

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.

If you have any questions, please call the UNOS Membership Team at 833-577-9469 or email MembershipRequests@unos.org.

OPTN Representative

Printed Name	Signature	Email Address
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Part 1: General Information

Name of Transplant Hospital: _____

OPTN Member Code (4 Letters): _____

Transplant Hospital Address (where transplants occur)

Street: _____ Suite: _____

City: _____ State: _____ Zip: _____

Intestine Transplant Program Phone #: _____

Intestine Transplant Program Fax #: _____

Name of Person Completing Form: _____ Title: _____

Email Address of Person Completing Form: _____

Date Form is submitted to OPTN Contractor: _____

Part 2: Certificate of Assessment

The hospital must conduct an assessment of all transplant program surgeons and physicians for any involvement in prior transgressions of OPTN obligations and plans to ensure compliance.

The **primary surgeon** and **primary physician** are responsible for ensuring the operation and compliance of the program according to the requirements set forth in these Bylaws. The transplant hospital must notify the OPTN Contractor immediately if at any time the program does not meet these requirements. The individuals reported to the OPTN Contractor as the program's primary surgeon and primary physician should be the same as those reported to the Center for Medicaid and Medicare Services (CMS).

Additional Transplant Surgeons must be credentialed by the transplant hospital to provide transplant services and be able to independently manage the care of transplant patients, including performing the transplant operations and organ procurement procedures.

Additional Transplant Physicians must be credentialed by the transplant hospital to provide transplant services and be able to independently manage the care of transplant patients.

A surgeon or physician employed by the transplant hospital that does not independently manage the care of transplant patients may be listed as **other**.

This information is subject to medical peer review confidentiality requirements and must be submitted according to the guidelines provided in the application.

Instructions:

On the next page, list all surgeons and physicians involved in the transplant program.

- *For any surgeon or physician indicated as 'Primary' that isn't already the approved primary surgeon or primary physician for the program, complete the relevant sections of the application below.*
- *For each surgeon or physician that is newly designated as 'Additional', provide a credentialing letter with this application.*
- *For each surgeon or physician listed as 'Other', no further action is needed.*
- *If you have answered 'yes' to any surgeon or physician having prior transgressions with the OPTN, please explain in the blank space provided below the table.*

The program director, along with the primary surgeon and physician, must submit a detailed **Program Coverage Plan** to the OPTN Contactor. The Program Coverage Plan must describe how continuous medical and surgical coverage is provided by transplant surgeons and physicians who have been credentialed by the transplant hospital to provide transplant services to the program.

A transplant program must inform its patients if it is staffed by a single surgeon or physician and acknowledge the potential unavailability of these individuals, which could affect patient care, including the ability to accept organ offers, procurement, and transplantation.

Instructions:

Complete the questions below and provide documentation where applicable.

Transplant Surgeon and Physician Coverage

Surgeons

Yes No

- Is this a single surgeon program?
If yes, provide a copy of the patient notice or protocol for providing patient notification.*
- Does the transplant program have transplant surgeons available 365 days a year, 24 hours a day, 7 days a week to provide program coverage?
If the answer is no, provide a written explanation in the Program Coverage Plan that justifies the current level of coverage.*
- Is a transplant surgeon readily available in a timely manner to facilitate organ acceptance, procurement, and transplantation?*
- Will any of the transplant surgeons be on call simultaneously at two transplant programs more than 30 miles apart?
If the answer is yes, the program must request an exemption from the MPSC to operate as a transplant program sharing primary personnel with another transplant hospital, without additional transplant staff.*
- Is the **primary** transplant surgeon designated as the primary transplant surgeon at more than one transplant hospital?
If yes, answer the question below.*

Yes No

Do you have additional surgeons listed with the program? **If the answer is no, the program must request an exemption from the MPSC to operate as a transplant program sharing primary personnel with another transplant hospital, without additional transplant staff.**

Is the **primary** transplant surgeon **onsite** full-time at this transplant hospital?
If the answer is no, please describe in detail the onsite arrangements:

Does the **primary** transplant surgeon have **on-call responsibilities** at more than one transplant hospital at the same time? **If the answer is yes, please explain below:**

Physicians

Yes No

Is this a single physician program?

If yes, provide a copy of the patient notice or protocol for providing patient notification.

Does the transplant program have transplant physicians available 365 days a year, 24 hours a day, 7 days a week to provide program coverage?

If the answer is no, provide a written explanation that justifies the current level of coverage.

Will any of the transplant physicians be on call simultaneously for two transplant programs more than 30 miles apart?

If the answer is yes, the program must request an exemption from the MPSC to operate as a transplant program sharing primary personnel with another transplant hospital, without additional transplant staff.

Is the primary transplant physician designated as the primary transplant physician at more than one transplant hospital?

If yes, answer the question below.

Yes No

Do you have additional physicians listed with the program?

If the answer is no, the program must request an exemption from the MPSC to operate as a transplant program sharing primary personnel with another transplant hospital, without additional transplant staff.

Is the **primary** transplant physician **onsite** full-time at this transplant hospital?

If the answer is no, please describe in detail the onsite arrangements:

- Does the **primary** transplant physician have **on-call responsibilities** at more than one transplant hospital at the same time?

If the answer is yes, please explain below:

Patient Notification

Check the box below to attest to the following:

- The transplant program provides patients with a written summary of the Program Coverage Plan when placed on the waiting list and when there are any substantial changes in the program or its personnel.

Attach a copy of the Program Coverage Plan to the application.

Part 4: Program Director(s)

An intestine transplant program must identify at least one designated staff member to act as the transplant program director. The director must be a surgeon or physician who is a member of the transplant hospital staff.

Program Director(s) (list all):

Name	Credentials
Name	Credentials
Name	Credentials
Name	Credentials

Part 5: Primary Intestine Transplant Surgeon Requirements

1. Name of Proposed Primary Intestine Transplant Surgeon (as indicated in Part 2: Certificate of Assessment):

Name	NPI # (optional)
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2. Check to attest to each of the following. Provide documentation where applicable:

- The surgeon has an M.D., D.O., or equivalent degree from another country with a current license to practice medicine in the hospital's state or jurisdiction.

Provide a copy of the surgeon's medical license or resume/CV to show proof of this requirement.

- The surgeon been accepted onto the hospital's medical staff and is practicing on site at this hospital.

Provide documentation from the hospital credentialing committee that it has verified the surgeon's state license, board certification, training, and transplant continuing medical education, and that the surgeon is currently a member in good standing of the hospital's medical staff.

3. Certification. Check one and provide corresponding documentation:

- The surgeon is currently certified by the American Board of Surgery, the American Board of Osteopathic Surgery, or the Royal College of Physicians and Surgeons of Canada.

Provide a copy of the surgeon's current board certification.

- The surgeon is without certification by the American Board of Surgery, the American Board of Osteopathic Surgery, or the Royal College of Physicians and Surgeons of Canada.

If this option is selected:

- **The surgeon must be ineligible for American board certification. Provide an explanation why the individual is ineligible:**

- **Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that:**

- o **the surgeon obtains 60 hours of Category I continuing medical education (CME) credits.**
- o **the surgeon performs a self-assessment that is relevant to the surgeon's practice every three years, with a score of 75% or higher. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program.**
- o **the transplant hospital document completion of this continuing education.**

- **Provide at least 2 two letters of recommendation from directors of designated transplant programs not employed by the applying hospital that address:**
 - o **why an exception is reasonable.**
 - o **the surgeon’s overall qualifications to act as a primary intestine transplant surgeon.**
 - o **the surgeon’s personal integrity and honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.**
 - o **any other matters judged appropriate.**

4. Summarize the surgeon’s training and experience in transplant:

Training and Experience	Date (MM/DD/YY)		Transplant Hospital	Program Director
	Start	End		
Fellowship				
Experience Post Fellowship				

5. Which of the following pathways is the proposed primary surgeon applying (check one, and complete the corresponding pathway section below):

- The **full approval pathway**, as described in *Section 5* Error: Reference source not found below.
- The **conditional pathway**, as described in *Section 5B: Conditional Intestine Surgeon Approval Pathway* below.

5A: Full Intestine Surgeon Approval Pathway

Surgeons can be fully approved as a primary intestine transplant surgeon by completing a formal surgical transplant fellowship or by completing clinical experience at an intestine transplant program if *all* of the following conditions are met:

1. *The surgeon performed 7 or more intestine transplants at a designated intestine transplant program, to include the isolated bowel and composite grafts, as primary surgeon or first assistant within the last 10 years.*
This experience must be documented on a log that includes the date of transplant, the role of the surgeon, medical record number or other unique identifier that can be verified by the OPTN. This log must be signed by the program director, division chief, or department chair from the program where the experience or training was gained.
2. *The surgeon performed 3 or more intestine procurements as primary surgeon or first assistant. These procurements must include 1 or more organ recovery that includes a liver.*
This experience must be documented on a log that includes the date of procurement and Donor ID. This log must be signed by the program director, division chief, or department chair from the program where the experience or training was gained.
3. *The surgeon must maintain a current working knowledge of intestine transplantation, defined as direct involvement in intestine transplant patient care within the last 5 years.*
Check to attest to the following
 - The surgeon has experience managing patients with short bowel syndrome or intestinal failure.*
 - The surgeon has experience with recipient selection.*
 - The surgeon has experience with donor selection.*
 - The surgeon has experience with histocompatibility and tissue typing.*
 - The surgeon has experience with performing the transplant operation.*
 - The surgeon has experience with immediate postoperative and continuing inpatient care.*
 - The surgeon has experience with the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression.*
 - The surgeon has experience with differential diagnosis of intestine allograft dysfunction.*
 - The surgeon has experience with histologic interpretation of allograft biopsies.*
 - The surgeon has experience with interpretation of ancillary tests for intestine dysfunction.*
 - The surgeon has experience with long term outpatient care.*
4. *The training was completed at a hospital with an intestinal transplant training program approved by the American Society of Transplant Surgeons or the Royal College of Physicians and Surgeons of Canada, or another recognized fellowship training program accepted by the OPTN. **This program must meet all of the below criteria. Check to attest to the following***
 - The program is at a transplant hospital that transplants two or more organs, including liver and intestines.*
 - The program is at an institution that has ACGME approved training in general surgery.*
 - The program performs at least 10 intestine transplants during each year of the fellowship training.*

5. ***Provide the following letters with the application:***

- A letter from the qualified intestine transplant physician and surgeon who have been directly involved with the surgeon documenting the surgeon's experience and competence.
- A letter of recommendation from the primary surgeon and transplant program director at the fellowship training program or transplant program last served by the surgeon outlining:
 - the surgeon's overall qualifications to act as a primary transplant surgeon.
 - the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations.
 - any other matters judged appropriate.

The MPSC may request additional recommendation letters from the primary surgeon, primary physician surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.

- A letter from the surgeon that details the training and experience the surgeon gained in intestine transplantation.

5B: Conditional Intestine Surgeon Approval Pathway

Surgeons can meet the requirements for conditional approval as primary intestine transplant surgeon through experience gained during or post-fellowship, if *all* of the following conditions are met:

1. *The surgeon has performed **at least 4** intestine transplants that include the isolated bowel and composite grafts and must perform **3 or more** intestine transplants over the next 3 consecutive years as primary surgeon or first assistant at a designated intestine transplant program.*

This experience must be documented on a log that includes the date of transplant, the role of the surgeon, medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair from the program where the experience or training was gained.

Note: Each year of the surgeon's experience must be substantive and relevant and include pre-operative assessment of intestine transplant candidates, transplants performed as primary surgeon or first assistant and post-operative management of intestine recipients.

2. *The surgeon has performed **at least 3** intestine procurements as primary surgeon or first assistant. These procurements must include **at least 1** procurement of a graft that includes a liver.*

This experience must be documented on a log that includes the date of procurement and Donor ID.

3. *The surgeon has maintained a current working knowledge of intestine transplantation, defined as direct involvement in intestine transplant patient care within the last 5 years.*

Check to attest to the following

- The surgeon has experience with managing patients with short bowel syndrome.*
 - The surgeon has experience with managing patients with intestinal failure.*
 - The surgeon has experience with the selection of appropriate recipients for transplantation.*
 - The surgeon has experience with donor selection.*
 - The surgeon has experience with histocompatibility and tissue typing.*
 - The surgeon has experience with performing the transplant operation.*
 - The surgeon has experience with immediate postoperative and continuing inpatient care.*
 - The surgeon has experience with the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression.*
 - The surgeon has experience with differential diagnosis of intestine dysfunction in the allograft recipient.*
 - The surgeon has experience with histologic interpretation of allograft biopsies.*
 - The surgeon has experience with interpretation of ancillary tests for intestine dysfunction.*
 - The surgeon has experience with long term outpatient care.*
4. *The surgeon develops a formal mentor relationship with a primary intestine transplant surgeon at another approved intestine transplant program. The mentor will discuss program*

requirements, patient and donor selection, recipient management, and be available for consultation as required until full approval conditions are all met.

Check to attest to the following:

- The surgeon has developed a formal mentor relationship with a primary intestine transplant surgeon at another approved intestine transplant program.*

5. *Provide the following letters with the application:*

- A letter from the director of the transplant program and chair of the department or hospital credentialing committee verifying that the surgeon has met the above requirements and is qualified to direct an intestine transplant program.
- A letter of recommendation from the primary surgeon and transplant program director at the transplant program last served by the surgeon, outlining:
 - the surgeon's overall qualifications to act as primary transplant surgeon.
 - the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations.
 - any other matters judged appropriate.The MPSC may request additional recommendation letters from the primary surgeon, primary physician, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
- A letter from the surgeon that details the training and experience the surgeon gained in intestine transplantation as well as detailing the plan for obtaining full approval within the 3-year conditional approval period.
- A letter of commitment from the surgeon's mentor supporting the detailed plan developed by the surgeon to obtain full approval.

Part 6: Primary Intestine Transplant Physician Requirements

1. **Name of Proposed Primary Intestine Transplant Physician (as indicated in Part 2: Certificate of Assessment):**

Name	NPI # (optional)
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2. **Check to attest to each of the following. Provide documentation where applicable:**

The physician has an M.D., D.O., or equivalent degree from another country with a current license to practice medicine in the hospital's state or jurisdiction
Provide a copy of the physician's medical license or resume/CV to show proof of this requirement.

The physician has been accepted onto the hospital's medical staff and is practicing on site at this hospital.
Provide documentation from the hospital credentialing committee that it has verified the physician's state license, board certification, training, and transplant continuing medical education, and that the physician is currently a member in good standing of the hospital's medical staff.

3. **Certification. Check one and provide corresponding documentation:**

The physician is currently certified in gastroenterology by the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada.
Provide a copy of the physician's current board certification.

The physician is without certification in gastroenterology by the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada.

If this option is selected:

- **The physician must be ineligible for American board certification. Provide an explanation why the individual is ineligible:**

- **Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that:**

- o **the physician obtains 60 hours of Category I continuing medical education (CME) credits.**
- o **the physician performs a self-assessment that is relevant to the individual's practice every three years, with a score of 75% or higher. Self-assessment is**

defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program.

- o *the transplant hospital document completion of this continuing education.*
- **Provide at least 2 two letters of recommendation from directors of designated transplant programs not employed by the applying hospital that address:**
 - o *why an exception is reasonable.*
 - o *the physician’s overall qualifications to act as a primary intestine transplant physician.*
 - o *The physician’s personal integrity and honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.*
 - o *any other matters judged appropriate.*

4. Summarize the physician’s training and experience in transplant:

Training and Experience	Date (MM/DD/YY)		Transplant Hospital	Program Director
	Start	End		
Fellowship				
Experience Post Fellowship				

5. Pediatric-specific physician requirement for programs that serve predominantly pediatric patients:

Any physician who meets the criteria as a primary intestine transplant physician can function as the primary intestine transplant physician for a program that serves predominantly pediatric patients, if a pediatric gastroenterologist is also involved in the care of the transplant recipients.

Check yes or no

Yes No

- Does this program serve predominantly pediatric patients?*

If yes, check to attest to the following

- There is a pediatric gastroenterologist involved in the care of the pediatric transplant recipients at this intestine program.*

6. Which of the following pathways is the proposed primary physician applying (check one, and complete the corresponding pathway section below):

- The primary intestine transplant physician **full approval** pathway, as described in *Section 6A: Full Intestine Physician Approval Pathway* below.
- The primary intestine transplant physician **conditional** pathway, as described in *Section 6B: Conditional Intestine Physician Approval Pathway* below.

6A. Full Intestine Physician Approval Pathway

Physicians can meet the requirements for a primary intestine transplant physician during the physician's adult gastroenterology fellowship, pediatric gastroenterology fellowship, or through acquired clinical experience (including accumulated training during any fellowships) if all of the following conditions are met:

1. *The physician has been directly involved within the last 10 years in the primary care of **7 or more** newly transplanted intestine recipients and continued to follow these recipients for a minimum of 3 months from the time of transplant.* This clinical experience must be gained as the primary intestine transplant physician or under the direct supervision of an intestine transplant physician and in conjunction with an intestine transplant surgeon at a designated intestine transplant program.
This experience must be documented on a log that includes the date of transplant, medical record number or other unique identifier that can be verified by the OPTN. This log must be signed by the program director, division chief, or department chair from the program where the experience or training was gained.
2. *The physician has maintained a current working knowledge of intestine transplantation, defined as direct involvement in intestine transplant patient care within the last 5 years.*
Check to attest to the following
 - The physician has experience with managing patients with intestinal failure.*
 - The physician has experience with the selection of appropriate recipients for transplantation.*
 - The physician has experience with donor selection.*
 - The physician has experience with histocompatibility and tissue typing.*
 - The physician has experience with immediate postoperative patient care.*
 - The physician has experience with the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression.*
 - The physician has experience with differential diagnosis of intestine allograft dysfunction.*
 - The physician has experience with histologic interpretation of allograft biopsies.*
 - The physician has experience with interpretation of ancillary tests for intestine dysfunction.*
 - The physician has experience with long term outpatient care.*
3. *The physician has observed **at least 1** isolated intestine transplant and **at least 1** combined liver-intestine or multi-visceral transplant.*
This experience must be documented either on a log or the table in Part 6, Question 4 above.
4. ***Provide the following letters with the application:***
 - A letter from the transplant program director documenting the physician's experience and training.
 - A letter of recommendation from the primary physician and transplant program director at the fellowship training program or transplant program last served by the physician outlining:
 - o the physician's overall qualifications to act as a primary transplant physician.

- o the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations.
- o any other matters judged appropriate.

The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.

- A letter from the physician that details the training and experience the physician gained in intestine transplantation.

6B. Conditional Intestine Physician Approval Pathway

Physicians can meet the requirements for approval as primary intestine transplant physician through a conditional approval pathway if *all* of the following conditions are met:

1. *The physician has been involved in the primary care of **at least 4** newly transplanted intestine recipients, and has followed these patients for at least 3 months from the time of their transplant. Additionally, the physician must become involved in the care of **3 or more** intestine recipients over the next 3 consecutive years. This clinical experience must be gained as the primary intestine transplant physician or under the direct supervision of an intestine transplant physician and in conjunction with an intestine transplant surgeon at a designated intestine transplant program.*

This experience must be documented on a log that includes the date of transplant, medical record number or other unique identifier that can be verified by the OPTN. This log must be signed by the program director, division chief, or department chair from the program where the experience or training was gained.

2. *The physician has maintained a current working knowledge of intestine transplantation, defined as direct involvement in intestine transplant patient care within the last 5 years.*
Check to attest to the following

- The physician has experience with managing patients with intestinal failure.*
- The physician has experience with the selection of appropriate recipients for transplantation.*
- The physician has experience with donor selection.*
- The physician has experience with histocompatibility and tissue typing.*
- The physician has experience with immediate postoperative patient care.*
- The physician has experience with the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression.*
- The physician has experience with differential diagnosis of intestine allograft dysfunction.*
- The physician has experience with histologic interpretation of allograft biopsies.*
- The physician has experience with interpretation of ancillary tests for intestine dysfunction.*
- The physician has experience with long term outpatient care.*

3. *The physician developed a formal mentor relationship with a primary intestine transplant physician at another approved designated intestine transplant program. The mentor will discuss program requirements, patient and donor selection, recipient management, and be available for consultation as required.*

Check to attest to the following:

- The physician has developed a formal mentor relationship with a primary intestine transplant physician at another approved intestine transplant program.*

4. **Provide the following letters along with your application:**

- A letter from the qualified intestine transplant physician and surgeon who were directly involved with the physician verifying that the physician has satisfactorily met the above requirements to become the primary transplant physician of an intestine transplant program.

- A letter of recommendation from the primary physician and transplant program director at the transplant program last served by the physician outlining:
 - the physician's overall qualifications to act as a primary transplant physician.
 - the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations.
 - any other matters judged appropriate.The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
- A letter from the physician that details the training and experience the physician gained in intestine transplantation as well as a detailed plan for obtaining full approval.
- A letter of commitment from the physician's mentor supporting the detailed plan developed by the physician to obtain full approval.

PUBLIC BURDEN STATEMENT

The private, non-profit Organ Procurement and Transplantation Network (OPTN) collects this information in order to perform the following OPTN functions: to assess whether applicants meet OPTN Bylaw requirements for membership in the OPTN; and to monitor compliance of member organizations with OPTN Obligations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0915-0184 and it is valid until 08/31/2023. This information collection is required to obtain or retain a benefit per 42 CFR §121.11(b)(2). All data collected will be subject to Privacy Act protection (Privacy Act System of Records #09-15-0055). Data collected by the private non-profit OPTN also are well protected by a number of the Contractor's security features. The Contractor's security system meets or exceeds the requirements as prescribed by OMB Circular A-130, Appendix III, Security of Federal Automated Information Systems, and the Departments Automated Information Systems Security Program Handbook. The public reporting burden for this collection of information is estimated to average 11 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 14N136B, Rockville, Maryland, 20857 or paperwork@hrsa.gov.