

CLINICAL PARTNER REGISTRATION FORM FOR PARTNERS USING INVESTIGATIONAL FMT PREPARATIONS MANUFACTURED BY THE UNIVERSITY OF MINNESOTA

RETURN THIS FORM ALONG WITH ANY NEW VENDOR FORMS TO INFO@OPENBIOME.ORG OR BY FAX TO **617-575-2201**.
IF YOU ARE PART OF A HEALTH SYSTEM OR NETWORK AND WOULD LIKE TO INQUIRE IF YOUR NETWORK IS ON CONTRACT WITH US PRIOR TO FILLING OUT THIS FORM, PLEASE REACH OUT TO INFO@OPENBIOME.ORG.

NOTE: WE MUST RECEIVE THIS FORM COMPLETED IN FULL BEFORE YOUR FIRST ORDER. THIS IS NOT AN ORDER FORM. YOU WILL RECEIVE AN EMAIL CONFIRMATION ONCE YOUR REGISTRATION HAS BEEN PROCESSED AND YOU ARE ELIGIBLE TO ORDER.

Institution Information

A. HOSPITAL / CLINIC / PRACTICE INFORMATION	
Name of hospital, clinic, or practice	
Department(s) using material	
Has your facility previously performed a fecal transplant (FMT)? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Type of hospital, clinic, or practice: <input type="checkbox"/> Academic <input type="checkbox"/> Community <input type="checkbox"/> Government <input type="checkbox"/> Private Practice <input type="checkbox"/> Other:	
Health System or Network: <input type="checkbox"/> Facility does not belong to a Health System or Network	

Shipping Information

Provide your facility's shipping address and a contact to be notified in the event of shipping disruptions.

B. SHIPPING INFORMATION		
ATTN:		
Address Line 1		
Address Line 2		
City	State	Zip
Shipping contact name	Shipping contact title	
Shipping contact phone	Shipping contact email	

Billing Information

Provide your billing address and an accounts payable (A/P) contact (an individual with whom we can discuss invoices and payment).

C. BILLING INFORMATION		
Please indicate your institution's tax status: <input type="checkbox"/> Non-Exempt <input type="checkbox"/> Exempt (Please submit certificate of exemption with your registration)		
ATTN:		
Address		
City	State	Zip
Email to receive PDF invoices		
<input type="checkbox"/> Check if your facility requires purchase order numbers to pay invoices		
A/P contact name	A/P contact title	
A/P contact phone	A/P contact email	

Supervising Physician(s) Information

Provide information for the licensed physician (MD/DO) who will be our primary clinical contact for the investigational FMT program at your facility. The Supervising Physician must be a Board-Certified Gastroenterologist or Infectious Disease specialist. Exceptions are rare and must be approved by OpenBiome clinical staff.

D. SUPERVISING PHYSICIAN INFORMATION	
Name	Specialty
Phone	Email

Administering Physician(s) Information

Provide information for all physicians who will be administering OpenBiome investigational FMT at your facility in addition to the Supervising Physician(Section D). Supervising physicians will be added automatically.

E. SUPERVISING PHYSICIAN INFORMATION	
Administering Physician	
Name	Specialty
Phone	Email
Administering Physician	
Name	Specialty
Phone	Email
<i>See Appendix A to list additional physicians.</i>	

Adverse Event Contact

Provide information for the contact with a medical role (e.g. doctor, nurse) who is able to investigate and help resolve reported adverse events.

F. ADVERSE EVENT CONTACT	
Name	Title
Phone	Email

Patient Resource Contact

Provide information for the contact who will serve as a resource for patients reaching out to the facility. OpenBiome may provide the name and phone number to patients requesting assistance. The email address is collected for our internal records only.

G. PATIENT RESOURCE CONTACT	
Name	Title
Phone	Email

Material Tracking Logs Contact

Provide the contact responsible for the submission of Material Tracking Logs; see Information & Policies section for guidance.

H. MATERIAL TRACKING LOGS CONTACT	
Name	Title
Phone	Email

General Information and Policies (Initial and Sign)

A. Terms and Conditions

Subject to the terms and conditions set forth in this Clinical Partner Registration Form ("CPRF"), the University of Minnesota ("UMN") will manufacture and OpenBiome will store and supply you with the type and quantity of Fecal Microbiota Preparations ("Product") requested on one or more Order Forms or Purchase Orders at the pricing described herein and solely to the extent that such Product is not available for purchase from a commercial seller. The term of this CPRF will begin on the date of your signature below and continue for a period of two (2) years therefrom, at which time this CPRF will expire and you will be required to fill out and execute a new CPRF prior to purchasing additional Product. If you breach any provision of this CPRF and fail to cure such breach within thirty (30) days of OpenBiome's notice to you of such breach, OpenBiome may terminate this CPRF and your registration as a clinical partner of OpenBiome.

Initials

B. Price List

Any price adjustments to the below will be forwarded to your listed billing contact no later than 30 days prior to the effective date of the price adjustment. **These prices are effective as of August 1, 2022.**

Initials

<u>ITEM</u>	<u>DESCRIPTION</u>	<u>UNIT PRICE</u>
MTP-101LR	Liquid preparation for recurrent <i>C. difficile</i> infection (standard dose)	\$1,695.00
MTP-101LF	Liquid preparation for fulminant <i>C. difficile</i> infection (high dose)	\$1,695.00

C. Ordering

Submit OpenBiome Order Form or Purchase Order by email to orders@openbiome.org (preferred) or by fax to 617-575-2201. All Order Forms or Purchase Orders will be governed by the terms and conditions set forth in this CPRF.

Initials

D. U.S. Shipping

Standard S&H Flat \$150 fee per shipment.

- Orders placed Monday-Wednesday will be delivered in 2 business days.
- Orders placed on Thursday or Friday will be scheduled for delivery the following Tuesday.
- Product arrives on dry ice in a temperature-monitored container.
- Shipped using UPS Next Day Air (10:30AM delivery for most locations).

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Optional Next-Day Delivery \$50 additional fee

- Same-day shipping, for delivery the following morning.
- Order must be received before 3PM ET Monday-Thursday.
- Availability not guaranteed.
- Confirmation of additional fee must be included with order.

Optional UPS Early AM Delivery \$100 additional fee

- Confirmation of additional fee must be included with order.

Weather Notice

OpenBiome will make every effort to process and ship your order for delivery within the estimated delivery date. However, some events beyond OpenBiome's control can occasionally delay a shipment, even an expedited shipment. When forces of nature delay a carrier's delivery of an order, OpenBiome cannot guarantee the arrival date of your order. To reduce any issues caused by a late arrival of treatments, especially during the winter months where weather delays are more frequent, please place your order early to allow extra time for delivery.

E. Billing Policy

Electronic Invoicing: All invoices will be sent via e-mail by default to the e-invoice e-mail address provided in the Billing Information section above.

Payment Terms: OpenBiome's payment terms are **Net 30**, and you agree that you shall pay all invoices for Product within thirty (30) days from receipt of such invoices.

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Late Payment Penalties: OpenBiome reserves the right to assess late payment penalties for invoices not fully paid on-time, including but not limited to recouping the cost of any collection agencies employed.

Payment Options: OpenBiome accepts the following payment methods:

1. Electric Funds Transfer: Via "Pay Now" button on e-invoices or any other method of e-payment.
 2. Checks: Made payable to Microbiome Health Research Institute. Our remit-to address is:
ATTN: Accounts Receivable
Microbiome Health Research Institute
2067 Massachusetts Avenue, Cambridge, MA 02140
 3. Credit card: Via phone by calling 617-575-2201 x5
- If you require any registration or credentialing services, please contact info@openbiome.org.

F. Safety Policy

All clinicians using Product will review our introduction to the Quality and Safety Program available online at <https://openbiome.org/fmt-access/report-an-adverse-event/>. Should an adverse event occur, a clinician will notify OpenBiome within 24 hours using our online reporting tool at www.openbiome.org/adverse-events or by phone to 617-575-2201, option 1. You agree to complete and return a Material Tracking Log to OpenBiome prior to placing any new orders and to submit patient investigational FMT Follow-Up data through a digital REDCap survey, which will be managed by UMN, for all product supplied. If your site participates in the American Gastroenterological Association FMT National Registry ("FMT National Registry"), you are not required to submit patient investigational FMT Follow-Up data directly to OpenBiome and UMN. You are required to communicate any change in your choice of reporting mechanism to the Clinical Outreach Team at info@openbiome.org. If you do not submit Material Tracking Log information, and/or you do not submit patient investigational FMT Follow Up data or provide confirmation that you have supplied patient outcome data to the FMT National Registry, OpenBiome will place a shipping hold on your account until all information is submitted. Information obtained from logs and forms submitted to OpenBiome and UMN may be used for any purpose by OpenBiome and UMN, which may include quality assurance and/or commercial purposes. These forms will not include any patient-identifiable information. For more on this requirement, read our primer found at <https://openbiome.org/fmt-access/report-an-adverse-event/>.

Initials

G. Usage Policy

Fecal Microbiota Transplantation is intended for clinical use under medical supervision only. Fecal Microbiota Transplantation is an investigational therapy that is not approved by the FDA. You shall only use the Product to treat *C. difficile* infection that is not responsive to standard therapies. You shall obtain adequate informed consent from each patient who is to receive the Product or a legal representative. Informed consent shall include at minimum a statement that the use of the Product to treat *C. difficile* infection is investigational, and a discussion of the therapy's potential risks and treatment alternatives, consistent with the Investigator's Brochure available at <https://openbiome.org/fmt-access/forms-and-guides/>, and applicable law (including any required Institutional Review Board approval). Use of this Product is part of the practice of medicine as exercised by appropriately licensed individual practitioners. UMN provides quality and manufacturing assurances that the Product meets the specifications and quality assurance guidelines outlined in UMN's Quality Metrics found at <https://openbiome.org/fmt-access/treatment-guide/>. OpenBiome provides assurances of appropriate storage and shipment of the Product to you. You understand and agree that there are considerable risks associated with use of the Product, including, but not limited to, the potential for the presence of infectious agents. Such agents could include both agents not included in UMN's screening panel or agents that were not detected by the assays employed by UMN. You acknowledge the inherent risks associated with the clinical use of the Product and accept these risks as a condition of use.

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UMN provides a summary of its donor screening, and you may request raw results to review directly and make an informed medical decision about the use of the Product. Responsibility for medical interpretation of these results lies with the medical practitioner and not with OpenBiome or UMN. Furthermore, you accept the ethical and legal responsibility to inform patients of the risks associated with this procedure and provide treatment under informed consent. You agree that you will maintain true and accurate records regarding the handling, storage, and use of the Product, and will provide such records to UMN or OpenBiome upon request. In handling, storing, utilizing, and disposing of Product, you shall at all times comply with all applicable laws, regulations and generally accepted industry practices, and will follow all instructions provided by OpenBiome. You further agree that your purchase of the Product is for the treatment of your own patients only, and that you will not transfer, distribute or release the Product to any other person or entity.

H. No Warranty

Products are understood to be experimental in nature and may have hazardous properties that are not known or fully appreciated. THE PRODUCT IS PROVIDED WITHOUT ANY WARRANTY, EITHER EXPRESS OR IMPLIED,

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AS TO ITS SAFETY OR FITNESS FOR ANY PARTICULAR PURPOSE OR USE. Acceptance by you of the Product will constitute your acceptance of liability for any damages or injuries resulting from your possession, use, or disposal of the Product. OpenBiome and UMN make no representation that the use of the Product will not infringe on any patent or other proprietary rights of third parties.

I. Intellectual Property and Confidentiality

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Nothing in this CPRF shall grant or may be construed as granting to you any rights in or to any intellectual property rights of OpenBiome or UMN, whether by implication, estoppel or otherwise. For purposes of this CPRF, "Confidential Information" means any and all information of a confidential, secret, and/or proprietary nature provided by or on behalf of Supplier or its agents to Customer in connection with this Agreement. Confidential Information includes, but is not limited to, the Product specifications and quality assurance information provided at the link in Section F above.

- (a) You agree that you will maintain OpenBiome's Confidential Information in strict confidence and shall disclose OpenBiome's Confidential Information only to those of your employees, officers, and agents who have a need to know and who are obligated to keep such information confidential. The obligations of this section do not apply to information that you can demonstrate: (i) was generally known to the public prior to disclosure or being generated under CPRF or later becomes generally known to the public through no fault of yours; (ii) was already known to you prior to disclosure or generation under this CPRF; (iii) was obtained by you from a third party in lawful possession of such information and with the right to disclose the same; and (iv) was independently developed by you without reference to OpenBiome's Confidential Information.
- (b) You agree that you will maintain UMN's Confidential Information in strict confidence and shall disclose UMN's Confidential Information only to those of your employees, officers, and agents who have a need to know and who are obligated to keep such information confidential. The obligations of this section do not apply to information that you can demonstrate: (i) was generally known to the public prior to disclosure or being generated under CPRF or later becomes generally known to the public through no fault of yours; (ii) was already known to you prior to disclosure or generation under this CPRF; (iii) was obtained by you from a third party in lawful possession of such information and with the right to disclose the same; and (iv) was independently developed by you without reference to UMN's Confidential Information.

The provisions of this paragraph shall survive the expiration or termination of this CPRF or any Order Forms or Purchase Orders hereunder.

J. Insurance

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You agree that you shall, for as long as you possess or make use of Product under any Purchase Order or Order Form issued hereunder, at your own cost and expense, obtain and maintain in force: (1) general liability insurance with minimum limits of \$3 million per occurrence or claim, \$5 million annual aggregate, and (2) worker's compensation insurance that meets statutory requirements in the state in which you are located. You shall provide a certificate of insurance verifying such coverage upon request by OpenBiome. If the form of insurance is claims made, you agree to maintain appropriate tail coverage for claims, demands, or actions reported in future years for acts or omissions during the term of your use or possession of Product. Your failure to maintain coverage according to this paragraph shall be grounds for termination of your registration as a Clinical Partner of OpenBiome.

K. Indemnification

Initials

- (a) You hereby agree to indemnify, protect, and save harmless OpenBiome and its agents, officers, and employees, from and against that portion of any and all losses, claims, demands, actions, or judgments, joint or several, for which OpenBiome may become liable arising out of or in connection with this CPRF or the Product that result from the gross negligence, willful misconduct or wrongful acts or omissions of you or any of your agents, officers, or employees, or from any medical services provided by you or any of your agents, officers, or employees, whether utilizing the Product or otherwise.
- (b) You hereby agree to indemnify, protect, and save harmless UMN and its agents, officers, and employees from and against any that portion of any and all third-party losses, claims, demands, actions or judgments joint or several, for which UMN may become liable arising out of or in connection with this CPRF or the Product except to the extent resulting from the gross negligence, willful misconduct, or wrongful acts or omissions of UMN.
- (c) You hereby release UMN from any liability arising out of or in connection with this CPRF or the Product except to the extent resulting from the gross negligence or willful misconduct of UMN.

L. Miscellaneous

Initials

This CPRF contains the entire agreement between you, UMN, and OpenBiome regarding the subject matter

hereof, and there are no other promises or conditions in any other agreement whether oral or written. This CPRF supersedes any prior written or oral agreements between you and OpenBiome. This CPRF may be modified or amended only if the amendment is made in writing and agreed by both you and OpenBiome. If any provision of this CPRF shall be held to be invalid or unenforceable for any reason, the remaining provisions shall continue to be valid and enforceable. If a court finds that any provision of this CPRF is invalid or unenforceable, but that by limiting such provision it would become valid and enforceable, then such provision shall be deemed to be written, construed, and enforced as so limited. The failure of OpenBiome to enforce any provision of this CPRF shall not be construed as a waiver or limitation of OpenBiome's right to subsequently enforce and compel strict compliance with every provision of this CPRF. You may not assign this CPRF or any Order Form or Purchase Order without the prior written consent of OpenBiome. This CPRF will be governed by the laws of the Commonwealth of Massachusetts, without giving effect to its conflicts of laws principles, except that liability, if any, of UMN is subject to the limits and provisions of the Minnesota Tort Claims Act, Minnesota Statutes, Section 3.736. You represent and warrant that your signatory to this CPRF is duly authorized to execute this CPRF on your behalf, and that no consents (which have not already been obtained) are required in order for this CPRF to be effective and enforceable against you in accordance with its terms. UMN and OpenBiome shall not be liable in damages for failure to comply with its obligations to the extent that its performance is prevented by causes beyond its reasonable control including acts of God or of the public enemy, acts of any governmental authority, fires, war, riots, terrorist acts, unavailability or shortages of electricity or other utilities, floods, unusually severe weather, epidemics, quarantine restrictions, strikes, labor disputes or shortages of labor, freight embargoes, or inability to secure necessary parts and materials. Any action by you brought against the UMN will be brought in the courts of Hennepin County, Minnesota.

By your signature below, you agree to purchase Product subject to, and abide by, the terms and conditions contained in this CPRF, and that the terms and conditions hereof will be binding on you, your successors and permitted assigns.

CLINICAL PARTNER

Signature of authorized hospital / clinic / practice representative

Date

Printed name

Title

Additional Administering Physician(s)

Provide information for all physicians who will be administering investigational FMT provided by OpenBiome at your facility in addition to the Supervising Physician(Section D). Supervising physicians will be added automatically. Leave blank if not needed.

E. SUPERVISING PHYSICIAN INFORMATION	
Administering Physician	
Name	Specialty
Phone	Email
Administering Physician	
Name	Specialty
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