Introduction: The OpenBiome Dual Mission

Safe Access | Catalyzing Research

Since its founding in 2012, OpenBiome has reached significant milestones in our commitment to expand safe access to fecal microbiota transplantation (FMT) and has provided fecal microbiota preparations for more than 50,000 C. difficile treatments with over 1,200 clinical partners in 50 states and 7 countries.

In addition to our commitment to provide safe access to FMT, we are here to partner with investigators to uncover the role of the gut microbiome in health and discover how engineering the microbiome might drive better health outcomes. OpenBiome seeks to catalyze academic and commercial microbiome research with our expertise in the microbiome and by providing access to standardized microbiota research materials.

Fecal Microbiota Preparation for Research (FMP-R) Packs: FMP-R packs contain 25 1ml aliquots of prepared stool material sourced from a single rigorously screened stool donor, and is designed to support non-clinical science researchers that are interested in harnessing the microbiome to develop biological tools, including humanized animal models and biomarker screening methods.

In the sections below, you can learn more about the resources we can bring to your research program, and the process for working with us. To begin a conversation about how we may work together, please complete our short Non-Clinical Research Request Form and submit it to science@openbiome.org.

If you have any further questions, please feel free to contact our research team at science@openbiome.org.
FMT Microbiota Preparation for Research (FMP-R)

Quality & Safety | In Vivo/Vitro

For researchers looking for standard methods to humanize animal models, develop diagnostics, or harness universal biological standards for microbiome analysis, we have designed the Fecal Microbiota Preparation for Research applications (FMP-R) pack.

Each FMP-R pack contains 25 1ml aliquots of concentrated fecal microbiota sourced from one qualified OpenBiome donor. These samples can be used for in-vitro assays and in-vivo applications (i.e. humanization, colonization, and competition experiments) in pre-clinical animal models.

Please refer to the product specifications below and to our Quality Metrics reference at www.openbiome.org/safety for a description of our donor screening and quality procedures.

For information regarding the use of other types of microbiota preparations meant for use in clinical trials, please visit our Clinical Research page.
After receiving your research request, our research team will contact you to affirm your study requirements and material need. We tailor our involvement in investigations on an individual basis, usually providing the tools and services listed below.

**IRB-supervised Donor Recruitment:** We have recruited a registry of over 8,000 prospective donors to enter our screening and collection program and have screened over 1,300 candidates under IRB supervision. This large pool of prospective donors is a critical resource that enables exceptional selectivity as we seek to identify healthy participants.

**Clinical Assessment:** Each donor undergoes a 200-point clinical assessment for a wide range of risk factors for chronic and infectious diseases ranging from behavioral traits like travel and sexual health histories to a careful review of medical history and direct measurement of BMI and vital signs.

**Laboratory Screening:** Donors that pass the clinical assessment provide blood and stool samples that are evaluated for a broad range of over 30 viral, bacterial and parasitic infectious agents, including multi-drug resistant organisms, using FDA-cleared laboratory tests conducted at a CLIA-certified testing facility. Less than 3% of prospective donors pass both the clinical and laboratory assessments and enter our program as qualified donors.

**Material Processing and Monitoring:** Material is processed in a sterile 12.5% glycerol and 0.9% saline buffer at 2.5 ml of buffer per gram of stool. This buffer acts as a cryo-protectant for long-term storage. Each sample is passed through a 330 µm filter to remove large particulate matter and facilitate liquid handling for gavage and molecular analysis. We deliver material by overnight courier on dry ice with temperature monitoring and verification.

To speak with a member of our team about our resources and how we may support your research, please email us at science@openbiome.org.
Purchase of FMP-R Packs for Non-Clinical Research

Material Details | Non-Clinical Research Request Form | Material Transfer Agreement

To submit a request for FMP-R Packs for research usage, please fill out our short Non-Clinical Research Request Form and submit it to science@openbiome.org. OpenBiome’s Research Review Panel reviews requests on a quarterly basis.

If your proposed study is (1) funded or sponsored by commercial entities or (2) investigating Inflammatory Bowel Disease (IBD) or C. difficile Infection (CDI), there will be an additional review process. We have a collaboration with Finch Therapeutics, who holds intellectual property on some of the material that we provide (learn more here). Due to the terms of our agreement, research that meets the above criteria will need to be reviewed by Finch prior to our engagement with you. We are happy to answer any questions you may have about this process – please do not hesitate to reach out to us at science@openbiome.org.

All investigators’ institutions must execute a material transfer agreement with OpenBiome prior to shipment of FMP-R packs to sites.

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<th>Item</th>
<th>Description</th>
<th>Price</th>
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<tr>
<td>FMP-R</td>
<td>25 x 1mL aliquots</td>
<td>$2,500 per pack</td>
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Academic Users

As we seek to catalyze non-clinical science research of the microbiome, OpenBiome is often able to offer FMP-R Packs at a discount to academic users with limited funding. Please indicate your request for OpenBiome financial support or contact our team at science@openbiome.org to discuss your goals and financial considerations.

Delivery

Material will be delivered on dry ice via overnight courier with temperature verification.

Handling Precautions

When handling fecal microbiota preparation (FMP-R) packaging and the aliquots contained within, always wear appropriate personal protective equipment. Researchers should work with FMP-R Pack materials only in a certified biosafety cabinet within a BL2-rated facility. Upon delivery, always examine packaging integrity and shipping temperature indicator. Contact OpenBiome immediately if package or product integrity has been compromised.
**Animal Use**

All users who indicate that will be using FMP-R Pack materials in mouse models or other animal testing must provide OpenBiome with a current approval from their Institutional Animal Care and Use Committee (IACUC) approval for the proposed research prior to shipment.
Frequently Asked Questions

1. **How are laboratory assays of donor health and product safety performed?** Our [Quality Metrics](#) guide contains a full description of our donor screening and quality procedures.

2. **How do I confirm that the samples have been tested for pathogens of interest?** Donors undergo a series of stool-based and serological assays by a third-party Clinical Laboratory Improvement Amendments (CLIA) certified testing facilities to assess for infectious pathogens, including multi-drug resistant organisms, and general health metrics. For stool preparations, we currently use a combination of microbiological culturing, enzyme immunoassays and PCR technologies to detect potential infectious agents in a CLIA-certified laboratory. These diagnostics were developed through the review of best clinical practices published in the literature\(^1\)\(^2\)\(^3\) coupled with the consensus guidance from our clinical advisory board.

3. **Do I have to work with FMP material in any particular setting?**
   Yes. Researchers should work with FMP-R Pack materials only in a certified biosafety cabinet within a BL2-rated facility.

4. **How much do these research products cost?**
   The price for an FMP-R Pack starts at $2,500. For academic and non-profit partners, requests for discounted materials can be discussed directly with an OpenBiome representative.

5. **What is OpenBiome’s relationship with Finch Therapeutics Group?**
   OpenBiome collaborated with Finch to develop CP101, a freeze-dried oral FMT capsule, for treatment of recurrent *C. difficile*. Finch is running a clinical trial to test CP101, and trial sites around the U.S. and Canada are now enrolling patients. You can read more about the relationship between OpenBiome and Finch, and our commitment to integrity, [here](#).

6. **Was OpenBiome impacted by the safety alert from FDA in June 2019? Does OpenBiome screen for multi-drug resistant organisms (MDROs) and meet the updated screening guidelines from FDA?**
   OpenBiome material was not involved with, nor impacted by, FDA’s safety alert from June 2019. We have been screening for MDROs, including Extended-Spectrum Beta Lactamase (ESBL) since 2016, and meet all updated guidelines from FDA. Trials using OpenBiome material were not halted, and OpenBiome material may continue to be used under FDA’s latest guidance.
References

