

FOR IMMEDIATE RELEASE  
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## **OpenBiome Announces Collaboration with American Gastroenterological Association on Largest Planned Observational Fecal Microbiota Transplantation Study**

SOMERVILLE, Mass. – OpenBiome is pleased to announce a collaboration with the American Gastroenterological Association (AGA) on the Fecal Microbiota Transplantation (FMT) National Registry, planned to be the largest observational FMT study in history.

FMT is a medical procedure in which the stool from a healthy person is processed and then transferred into the intestine of a patient. It is most commonly used to treat recurrent *Clostridium difficile* (*C. diff*) infections that have failed to respond to antibiotic therapy.

The FMT National Registry — funded by the National Institutes of Health (NIH) and administered by the AGA Center for Gut Microbiome Research and Education — will track 4,000 patients for ten years after their FMT procedure, providing a wealth of data about the procedure's effectiveness and both short- and long-term effects of FMT. OpenBiome, a non-profit research institute and the first public stool bank, will collaborate with the AGA and the American Gut Project on the study.

OpenBiome provides clinicians with rigorously screened, ready-to-use stool preparations for FMT procedures. As the only public stool bank in the country, OpenBiome serves as the source of stool for nearly 1,000 clinical partners performing FMT across the United States, and expects to provide a significant portion of the stool preparations used in the study. The organization will also provide screening information and samples to the registry for OpenBiome stool preparations used in the study.

"This study takes aim at some of the biggest questions we have about the burgeoning field of microbiome engineering," said Carolyn Edelstein, Executive Director of OpenBiome. "The repository of information, especially the unprecedented longitudinal data from FMT recipients, will inform physicians, researchers, and patients on the risks, benefits, and most effective ways to use FMT as treatment for *C. diff* infections. It will also help us detect new diseases that might be treatable by changing the microbiome."

The American Gut Project will build and maintain the National Registry's Biobank, which will contain pre- and post-FMT stool samples from approximately 1,000 participants, and will sequence the microbiota present in each sample.

### **How to Participate in the Study**

Patients should reach out to their health care provider to discuss participation in the registry; participating sites will be listed at [ClinicalTrials.gov](https://clinicaltrials.gov). Clinicians may visit [the FMT Registry website](#) for more information, and to register their interest in participating.

### **Registry Information**

The AGA FMT National Registry was initially announced in August 2016 after receiving funding from the National Institute of Allergy and Infectious Diseases (NIAID) of the NIH (award number R24AI118629). The registry is led by principal investigators Colleen Kelly, MD, Loren Laine, MD, AGAF, and Gary D. Wu, MD.

For more information about OpenBiome, please email [media@openbiome.org](mailto:media@openbiome.org). For questions or information on how sites can participate in this registry, please email [FMTRegistry@gastro.org](mailto:FMTRegistry@gastro.org).

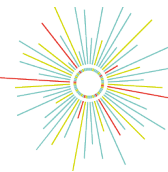
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### **About OpenBiome**

OpenBiome is the first public stool bank, founded to expand safe access to fecal transplantation for patients with recurrent *C. difficile* infection and to catalyze research on the microbiome's role in human health. OpenBiome provides clinicians with rigorously screened, ready-to-use stool preparations and supports researchers with a suite of tools to discover how gut bacteria might treat diseases beyond *C. difficile*. Since 2013, OpenBiome has partnered with nearly 1,000 healthcare institutions across all 50 states and 7 countries to deliver over 30,000 treatments for recurrent *C. difficile*. Its research portfolio includes 49% of all U.S. trials exploring the use of fecal transplants to treat disease. For more information, visit <http://www.openbiome.org>.

### **About the AGA Institute**

The American Gastroenterological Association is the trusted voice of the GI community. Founded in 1897, the AGA has grown to more than 16,000 members from around the globe who are involved in all aspects of the science, practice and advancement of gastroenterology. The AGA Institute administers the practice, research and educational programs of the organization. <http://www.gastro.org>. [Follow AGA on Twitter](#) and [like us on Facebook](#).



The mission of the AGA Center for Gut Microbiome Research and Education is to advance research and education on the gut microbiome with the goal of improving human health. <http://www.gastro.org/microbiome>.

### **About American Gut**

The American Gut Project is a non-profit academic research project based out of the UC San Diego School of Medicine that enables anyone on the planet to participate in exciting cutting-edge microbiome research. The project is predominantly crowd-funded and crowd-sourced, having raised more than \$2M USD since launch in the Fall of 2012. To date, the project has received stool from over 10,000 people, while providing infrastructure for curious individuals, academic driven subprojects, and citizen science endeavors. All of the de-identified data generated, including questionnaire responses, are released for free into the public domain. Learn more at <http://americangut.org>.