

# BioMe® News

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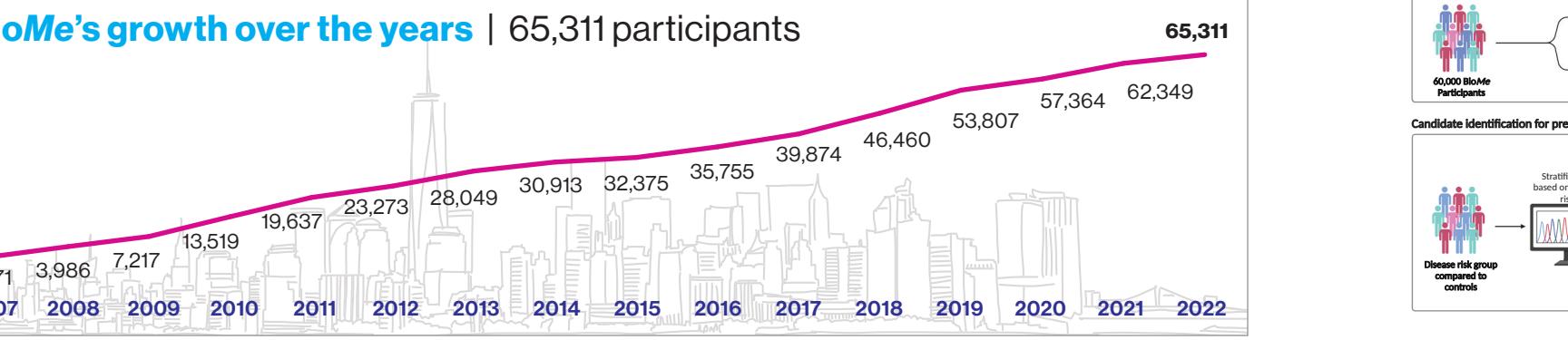


## Happy 15th Birthday, BioMe!

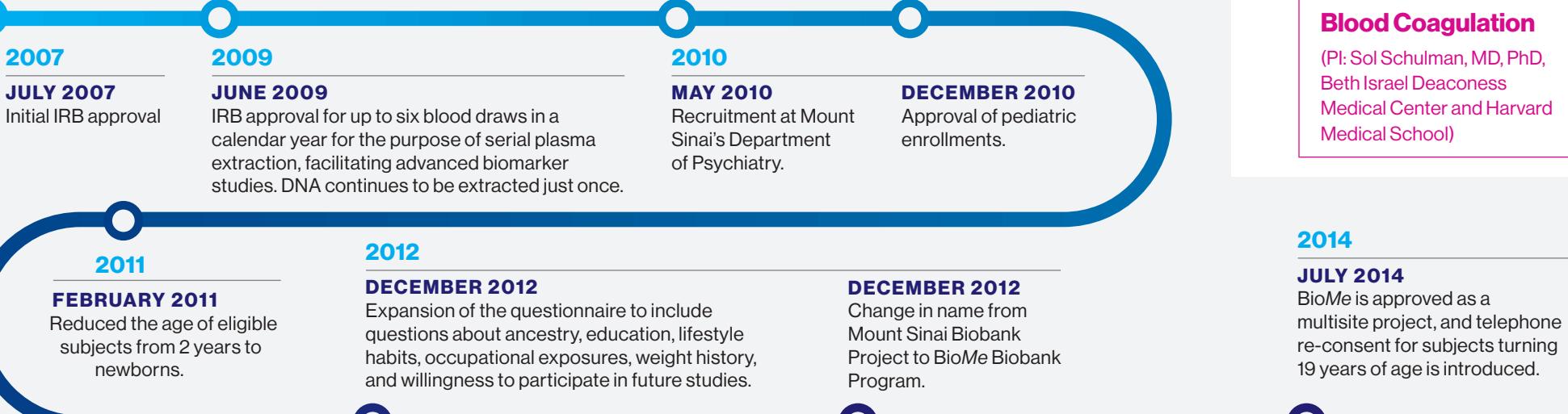
July 2022 marks the 15-year anniversary of BioMe's initial approval by Mount Sinai's Institutional Review Board. An institutional review board (IRB) is a group that has been formally designated to review and monitor biomedical research involving human subjects. This group review serves an important role in the protection of the rights and welfare of human research subjects. As of June 10, 2022, BioMe has enrolled **65,311** Mount

Sinai patients and has banked 608,412 DNA samples and 705,453 plasma samples, de-identified and available for future research studies. Major amendments (changes) to the BioMe protocol have occurred in the last 15 years, and we are proud to share these milestones with **you**, our participants, to show you how your contribution to the program has driven advancements in research, thus revolutionizing the future of medicine.

### BioMe's growth over the years | 65,311 participants



### Key IRB-Approved Amendments by Year

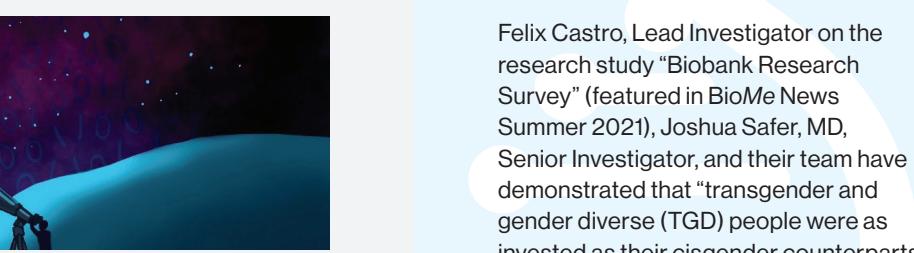


## Research Studies Using BioMe Samples/Data

### Characterizing Severe Mental Illness in a Diverse Patient Population

(PI: Alexander W. Charney, MD, PhD)

Severe mental illnesses are some of the most debilitating in the medical field and rank as one of the leading causes of disease burden worldwide, affecting millions of Americans every year. The new Mount Sinai Blau Center serves as a clinical and research platform that aims to increase our understanding of mental illness and develop new interventions for those suffering from and at increased risk of developing mental illness. The Blau Center will primarily focus on schizophrenia and related psychotic disorders. This protocol is the center's first research initiative that we hope will ultimately help future patients live happier, healthier lives. The objective of this study is to better understand severe psychiatric illness and its current available treatments,



particularly in vulnerable patient populations that are disproportionately affected by mental illness requiring hospitalization. The study team hypothesizes that neuropsychiatric traits in humans are largely governed by genetic variation via the effect on downstream levels of molecular biology (e.g., RNA, proteins), which in turn regulate the structure and activity of the brain. A subset of BioMe participants will be recalled by BioMe and asked to consider prospective participation in this project that could include questionnaires, clinical interviews, and biospecimen collections. The study team will conduct an observational cohort study that utilizes diverse tools in the clinical neuroscience toolkit to profile the neurobiology, structure, and function of the brain in living human subjects.

### Center for Inborn Errors of Immunity (CIEI)

(PI: Dusan Bogunovic, PhD, Study lead: Mike Espino, MD/PhD candidate, Precision Immunology Institute, Mindich Child Health and Development Institute, Center for Inborn Errors of Immunity)

A dysfunctional immune system can cause a number of diseases. These include cardiovascular, rheumatologic, infectious, and neoplastic diseases, to name a few. For this reason, it becomes extremely important to identify patients where genetic variation in their immune system can help with either diagnosis of their constellation of symptoms or classify such patients early, as disease risk prone. In our previous study conducted here at Mount Sinai, we identified a patient with a genetic variation in the immune system gene. This patient was then successfully treated with a targeted therapy stemming from this genetic finding. In the present study, we would like to evaluate genetics of more than 60,000 BioMe participants for variations in their immune system genes. The overall goal of this study is to develop genetic risk scores when we compare those BioMe participants with and without specific genetic variations, with the idea of eventually offering tailored drug treatments based on each individual's genetic composition.

### Human Genetic Variation Regulating the Activation of Blood Coagulation

(PI: Sol Schulman, MD, PhD, Beth Israel Deaconess Medical Center and Harvard Medical School, and BioMe Co-Investigator Ernest Turro, PhD, at Mount Sinai, will use the BioMe Biobank to investigate the

dysfunction in the clotting cascade can lead to severe clotting or bleeding, which have major health complications like deep vein thrombosis or pulmonary embolism and bleeding in the joints or brain. Sol Schulman, MD, PhD, and Marisa Brake, PhD, at Beth Israel Deaconess Medical Center and Harvard Medical School in Boston, and BioMe Co-Investigator Ernest Turro, PhD, at Mount Sinai, will use the BioMe Biobank to investigate the consequences of rare human genetic variation on coagulation activation. Whereas genome-wide association studies have linked many loci to pertinent traits (loci are the specific physical locations of a gene or other DNA sequence on a chromosome, like a genetic street address), these studies fail to capture rare genetic variation and generally enable very superficial phenotyping. The team will integrate human genetic data with advanced biochemical phenotyping (data analysis) to dissect blood coagulation (clotting) in humans. De-identified, frozen plasma and some relevant, de-identified clinical data from BioMe participants (such as age, sex, smoking status) will be sent to the study team for investigation of the protein levels of coagulation factors.

### High Research Interest Observed Among Transgender and Gender Diverse Patients

Felix Castro, Lead Investigator on the research study "Biobank Research Survey" (featured in BioMe News Summer 2021), Joshua Safer, MD, Senior Investigator, and their team have demonstrated that "transgender and gender diverse (TGD) people were as invested as cisgender counterparts in participating in research and furthering the collective knowledge base regarding their care." This was also true across racial groups. BioMe's own Clinical Research Coordinator Michell Yee, who enrolled more than 150 patients from the Center for Transgender Medicine and Surgery (CTMS) into BioMe between 2019 and 2021, worked closely with Mr. Castro and Dr. Safer to gather and analyze data she collected from interactions with the patients while recruiting for BioMe at this practice. Ms. Yee has learned through her time at CTMS that "these patients are willing and are looking for opportunities to participate in research but are turned down most of the time."

BioMe is an important resource to further understand the TGD population. To quote Dr. Safer, the data collected through participation in the program is helpful "and because it includes gender identity in its demographic data, BioMe is well positioned to stratify data by gender identity. Such stratification is not possible in most other bio repositories."

### ImmuneID Collaborates With BioMe to Study and Compare Antibody Reactivity

ImmuneID, a biopharmaceutical company that uses existing antibody responses to understand disease drivers and reveal pathways leading to precise therapies, is collaborating with BioMe's Principal Investigator, Judy Cho, MD. The immune response is how your body recognizes and defends itself against bacteria, viruses, and substances that appear foreign and harmful. Antibodies are protein components of the immune system that circulate in the blood, recognize foreign substances like bacteria and viruses, and neutralize them. After exposure to a foreign substance, called an antigen, antibodies continue to circulate in the blood, providing protection against future exposures to that antigen. Together, BioMe and ImmuneID are working to conduct an expansive study comparing antibody reactivity profiles

across a large patient population, involving the analysis of thousands of de-identified BioMe participants' plasma and clinical data. As described in ImmuneID's press release on March 31, 2022, "this study aims to generate a global profile of antibody binding specificities in patients with various autoimmune conditions, including Sjogren's syndrome, systemic lupus erythematosus (SLE), lupus nephritis (LN), and scleroderma," challenging conditions in autoimmunity. Thanks to BioMe, and to you for sharing your broad range of clinical, demographic, ancestral, and environmental information as part of your participation in BioMe, ImmuneID will seek to "conduct research and generate critical data used to analyze and study comparative long-term health outcomes."

### Unprecedented 'Discard Specimen' Workflow to Boost BioMe Numbers, Reduce Patient Burden, and Increase Research

On March 4, 2022, BioMe received approval from Mount Sinai's IRB to turn "discard" or "leftover" blood specimens, for which clinical analyses are complete, into de-identified BioMe samples, provided the patient who gave the blood consents to participate in BioMe. This new, transformative initiative is expected to pilot in summer 2022.

Clinical blood specimens that are now considered "leftover" or "discard" from a patient's most recent provider visit that would otherwise have become biohazard waste after storage, according

to Mount Sinai Laboratory policy, may now be processed and banked for patients who want to participate in BioMe. The purpose is to process those valuable specimens in accordance with the BioMe research and laboratory protocols, upon patient consent to BioMe, thus negating the need for a separate "research visit" by the patient, negating a separate blood draw, and upholding stringent ambulatory care and research guidelines by reducing patients' time spent in the practices. With more than 100,000 blood samples being sent for clinical evaluation at the Mount Sinai laboratories each year, this approval represents a significant opportunity to increase BioMe's sample collection, paving the way for more research studies and potentially contributing to more personalized approaches to diagnoses, treatments, and medications for all unique populations on a molecular, individualized level.

Please email us at [biomebiobank@mssm.edu](mailto:biomebiobank@mssm.edu) to find out more about updating your BioMe consent to potentially receive genetic results of high medical importance.

[icahn.mssm.edu/research/imp](http://icahn.mssm.edu/research/imp)

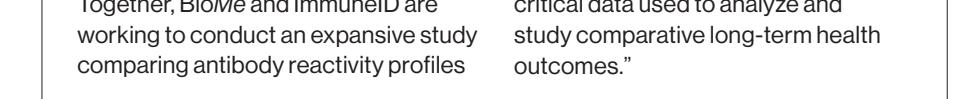
[@biomebiobank](https://www.instagram.com/@biomebiobank)

[linkedin.com/in/ipmsina](https://www.linkedin.com/in/ipmsina)

### Update Your Consent Form Online Today!

As of October 2018, BioMe Biobank is approved to offer return of genetic results to its participants. You may be eligible to update your informed consent form and potentially receive valuable health information.

If you are interested in updating your initial consent form, please email us at [biomebiobank@mssm.edu](mailto:biomebiobank@mssm.edu). Updating your consent form is quick, easy, and can be completed in the comfort of your own home!



### New BioMe Patient Recruitment Locations Opened in 2022!

Mount Sinai Doctors Stuyvesant Town

17 East 102nd Street

70 participants

as of June 10, 2022

First Avenue

East 14th Street

Fifth Avenue

Madison Avenue

Park Avenue

Non-Profit Org.  
U.S. Postage Paid  
New York, NY  
Permit No. 8876

The Charles Bronfman Institute for Personalized Medicine

Icahn School of Medicine at Mount Sinai

One Gustave L. Levy Place

Box 1003

New York, NY 10029-6574

