



## RESEARCH CONSENTS

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If you are a minor, do not use this form; you will need to ask your parent or guardian to sign you up for the study at [Biome360.com](https://Biome360.com). If you are an adult (have passed your 18th birthday), and you have an appointed legal guardian for any purpose, you may not participate in this study. If you are incapacitated or otherwise unable to legally consent, you may not participate in this study.

**This document governs how we conduct our research and how we collect and use data in conjunction with the research. The document outlines the risks and benefits of participating in Biome360 Research.**

**If you have questions relating to parts of this document or do not understand it, please contact us with your questions before signing.**

### **Information about the Study**

Biome360 provides you access to information about your microbiome, the organisms in and on your body separate from your own cells. We have partnered with researchers to study the data we collect from customers like you. In particular, the research seeks to draw links between genetic information from the samples you provide with answers you provide to surveys and questions.

As part of the Biome360 service, you will be collecting samples from inside your gut. Be sure to wash your hands before and after you collect the sample. As part of the research, we will ask you to fill out various surveys about different topics. These topics may include your medical history, your sexual history, your diet, and information about your family members.

Participation in the research will be very similar to normal use of the Biome360 service. It consists of:

- (i) Allowing Biome360 investigators to use your microbiome information for research; and
- (ii) Entering data about yourself into Biome360 Research features on the Biome360 website.

You do not have to participate in this research, and you will still have full access to your microbiome if you choose not to. This document details how we conduct our research, and in particular, how we process, store, and share your data with others. New surveys and features may be added to Biome360 Research on a continual basis.

### **Data Usage and Sharing**

Biome360 uses a range of physical, technical, and administrative procedures to protect the privacy of your personal information and your survey responses.

A key protection is that personally identifying Registration Information (such as name, address, email address, user ID, password, or credit card information) is only available to a small group of people that need access to this information for particular purposes where access to that data is necessary.

Biome360 may collaborate on research with external members of our research consortium or with the public.

External parties will only have access to pooled data stripped of identifying information, with the following exceptions:

1. Biome360 may release your individual-level data to a third party if we ask for and receive your explicit authorization to do so.
2. Biome360's partners or service providers (e.g. credit card processors or our contracted laboratory) may process and/or store your information in order to provide you with Biome360's services.
3. Researchers invited by Biome360 to conduct research may access your information (but not your name or contact information) for the purpose of scientific research.
4. Biome360 may release individual-level information in response to requests from law-enforcement agencies, courts of law, regulatory and government agencies, and if otherwise required to do so by law.
5. The Institutional Review Board and government officials responsible for monitoring our study may inspect the study records.

## Benefits of Participating

Discoveries made as a result of this research could be used to understand the basic causes of disease.

Biome360 does not seek to and does not treat or cure any medical condition, and participation should not be used as a substitute for any medical treatment.

If Biome360 develops intellectual property and/or commercializes products or services, directly or indirectly, based on the results of this study, you will not receive any compensation.

## Risks of Participating

There are some potential risks to participating in the Biome360 research study:

- › Some of the survey questions may make you or your family members uncomfortable.
- › Your data, survey responses, and/or personally identifying information may be compromised in the event of a security breach or failure to follow protocol. These security breaches may include physical compromising of lab and storage facilities, compromising of data storage, as well as failure to adhere to study protocol by employees and contractors. In the event of such a breach, if your data are associated with your identity, they may be made public and it may have social and psychological consequences for you or your loved ones. Furthermore, if a physical sample is stolen or mishandled by an employee or contractor, they may obtain additional information from the sample, such as sequencing data from human DNA in the sample.
- › When Biome360 investigators publish results from this study, your information may be included within pooled summaries that are made public. Identification of your individual-level data from those summaries would be extremely difficult, but it is possible that a third party that has obtained partial data from you could compare their partial data to the published results and indirectly determine some of your survey responses.
- › While the information we keep will not include names, and the microbiome is not uniquely identifiable, human genetic information is unique and can be used to identify people by linking or tracing DNA in public databases. It may also identify your family since your DNA is shared with your family.
- › As with any online service, if you disclose your account password to others, they may be able to access your account and your information. There may be additional risks to participation that are currently unforeseeable.
- › Data that you choose to share with others for any reason could be used against your interests. Biome360 is a private company and the Chief Scientific Officer of the company is also the Primary Investigator (head of research) of this study. There may be a conflict of interest between these two roles; however, the Primary Investigator is obligated to hold the interests of research above those of the company for purposes of the research study.
- › Information that participants choose to share with their physician or other healthcare provider may become part of their medical record and through that route be accessible to other healthcare providers and/or insurance companies in the future. None of the surveys or other procedures used by the investigators in the Biome360 Research study are invasive or experimental. The procedures involved do not include significant risks, and no compensation or treatment is available if injury occurs as a result of participation. Swabs and other materials used for sample collection are sterilized prior to shipment and must be handled with proper care and hygiene.

Should you be uncomfortable handling the collection kit and accepting responsibility for its use, please reassess your involvement in this study.

## Withdrawing from the Study

At any time, you may choose to withdraw all or some of your information from Biome360 Research by sending a request to the Human Protections Administrator at [privacy@Biome360.com](mailto:privacy@Biome360.com), or by changing your consent status within the Biome360 “Settings” page. (Biome360 will notify you if additional ways to withdraw your consent become available.)

Choosing not to give consent or withdrawing from Biome360 Research will not affect your access to your information or to Biome360’s microbiome sequencing service. You will still be granted full access to the microbiome sequencing service, but Biome360 will prevent the requested information from being used in new Biome360 research occurring 30 days after the receipt of your request. Any research on your data that has been performed or published prior to this date will not be reversed, undone, or withdrawn. Your information may still be used for other purposes as described in the Biome360 Privacy Statement.

In addition, the Biome360 Research study may be terminated without your consent. In that case, Biome360 will maintain your information according to the terms of our Privacy Statement.

- › Transfer of ownership. If Biome360 undergoes a business transition such as an acquisition or merger, the Biome360 study may be terminated. We are committed to negotiating that the recipient of the database would remain subject to the terms of any pre-existing Privacy Statement.
- › Bankruptcy. If Biome360 files for bankruptcy or liquidation, a court may impose different terms on the use of your data.

## Contact Information

If you have any questions or concerns about the study, if you suffer a research-related injury, or if you have a question about participants’ rights, please contact the following:

### Biome360 Human Protections Administrator

Email: [support@Biome360.com](mailto:support@Biome360.com)

If you have general questions about Biome360’s service, please contact:

Biome360 Customer Service by email at [support@Biome360.com](mailto:support@Biome360.com)

Agreeing to participate means:

- › You have read this consent and the research study was explained to you.
- › Your rights as a research participant have been provided to you.
- › Biome360 will let you about new information or changes to the study that may affect your health or your willingness to stay in the study.
- › By agreeing, you do not give up any of your legal rights. The researcher(s) or sponsor(s) are not relieved of any liability they may have.
- › You are consenting for yourself to take part in this research study.

**CHOICES**

**I DO NOT WISH TO PARTICIPATE AT THIS TIME**

Or

**I AGREE TO PARTICIPATE**

**Name** \_\_\_\_\_ **Date** \_\_\_\_/\_\_\_\_/\_\_\_\_

Type in your name and today's date.

And

**Biome360 or its affiliates may contact me in the future to invite my participation in additional research.**

**Email** \_\_\_\_\_