

## **BIOME360 PARENTAL PERMISSION FORM**

This document governs how we perform 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. Please read it carefully for facts concerning the risks of participation and how we use our data.

You have the option of having your child or teen take part in a research study. This is a parental permission form. The goals of this form are to give you information about what would happen in the study if you choose to have your child take part and to help you decide if you want your child to be in the study. It provides a summary of the information the research team will discuss with you. If you decide that your child can take part in this study, you would check the appropriate box at the end of this form to confirm your permission.

If the prospective research participant is a foster child or a ward of the state, there are special rules about participation. Please email us at [support@BioMe360.com](mailto:support@BioMe360.com) for instructions on how to proceed.

## **BACKGROUND**

Biome360's mission is to make meaningful scientific contributions by enabling its customers to participate directly in research. Biome360 offers each of its users the opportunity to participate in research. Biome360 seeks your child's voluntary participation in Biome360 Research, an ongoing research study conducted by Biome360 that concerns the microbiome, "the organisms in and on your body separate from your own cells." Biome360's research aims to:

- › Discover environmental factors behind symptoms and diseases
- › Correlate metagenomic data with self-reported data
- › Understand how people react to their personal survey information

Biome360 Research is aimed at learning things that increase scientific knowledge and are substantive enough to merit publication in peer-reviewed journals and to apply for research grants funded by the federal government and other organizations.

As part of getting started, Biome360 is asking all recipients and their children to participate in our research.

This document describes what involvement in our research study means:

1. What you are agreeing to if you give your child permission to participate
2. How your child can participate
3. How your child's data will be used
4. How we protect your child's data and keep it secure
5. The benefits and risks of involvement
6. Your child's choices and how to withdraw
7. Whom to contact if you have queries

## 1. WHAT AM I AGREEING TO?

Giving consent by checking the appropriate box below means that you agree to let Biome360 investigators use your child's Phenotypic & Self-Reported Information for Biome360 research.

“Phenotypic & Self-Reported Information” refers to:

- › Your child's Phenotypic data
- › Information you or your child enter into surveys and forms
- › Information you or your child enter via features labeled with the Biome360 Research logo
- › Data you authorize us to import for research
- › Your child's age, ethnicity, and other demographic or psychographic data

Phenotypic data refers to any genetic data, including data resulting from sequencing your child's microbiome, or other matter, such as the human cells making up your child's body. You can see a sample of some phenotypic data from sequencing a microbiome here: <http://www.Biome360.com/consent>. Other phenotypic data may look different, and include much more data.

Self-Reported Information includes, but is not limited to, any information you submitted prior to giving consent. We may also use the results of further analysis of your child's sample in Biome360 Research.

## 2. HOW DOES MY CHILD PARTICIPATE?

Participation consists of

- › Allowing Biome360 investigators to use your child's Phenotypic & Self-Reported
- › Information for research, and
- › Entering data about your child into Biome360 Research features on the Biome360 website.

These features include surveys, individual questions, and other features where you or your child enters information.

If you and/or your child do not feel comfortable providing a piece of information, you may choose not to answer that question. You or your child may choose to take all, some, or none of the surveys. You and your child should carefully consider what you want to share with others and what the consequences might be of doing so.

The Biome360 Research study is open-ended: new surveys and features may be added to Biome360 Research on a continual basis. If new surveys or features are added, you may receive an email update or see a notification when you or your child sign in to your child's account. We might ask you or your child to participate in a specific study if your child's Phenotypic & Self-Reported Information matches the area of interest.

## 3. HOW WILL MY CHILD'S DATA BE USED IN BIOME360 RESEARCH?

Your child's Phenotypic & Self-Reported Information will be used in conjunction with other research data to discover possible links between Phenotypic and non-Phenotypic markers and a variety of traits, diseases, behaviors and other characteristics, to study population history, or to assess how people respond to personal Phenotypic information.

These questions may cover potentially sensitive topics such as sexual orientation, illicit drug use or other illegal behavior, or HIV/AIDS status. When Biome360 conducts studies on these topics, you and your child will be provided additional information to help you decide whether you want to participate in research on these topics. Neither you nor your child will be required to answer any of these questions to participate in the study or to keep access to the Biome360 website.

#### **4. HOW DO YOU KEEP MY CHILD'S DATA PROTECTED AND PRIVATE?**

Biome360 uses a range of physical, technical, and administrative procedures to protect the privacy of your child's personal information, your child's Phenotypic data, and your child's 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, such as customer service and website testing. Other measures for protecting your child's privacy are described in more detail in the Biome360 Privacy Statement.

Biome360 may collaborate on research with external members of our research consortium or with the public. As outlined in the Privacy Statement, external parties will only have access to pooled data stripped of identifying information, with the following exceptions:

- › Biome360 may release your child's individual-level data to a third party if we ask for, and receive, your explicit authorization to do so.
- › Biome360's partners or service providers (e.g. credit card processors or our contracted laboratory) may process and/or store your child's information in order to provide you with Biome360's services.
- › Researchers invited by Biome360 to conduct research may access your child's individual-level Phenotypic & Self-Reported Information (but not your child's name or contact information) for the purpose of scientific research.
- › 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. WHAT ARE THE BENEFITS AND RISKS OF PARTICIPATING?**

##### **Benefits:**

Discoveries made as a result of this research could be used to understand the basic causes of disease, develop drugs or other treatments and/or preventive measures, or predict a person's risk of disease. The topics to be studied span a wide range of traits and conditions, from common to rare.

One of Biome360's missions is to make meaningful scientific contributions by enabling its customers to participate directly in Phenotypic research. If Biome360 publishes study results in peer-reviewed journals, there may be an indirect benefit to you and your child as scientific knowledge increases and/or new drugs or tests are developed.

You and your child may also have the opportunity to acquire one or more of the following, in return for some level of participation in the research:

- › Comparison of your child's personal survey responses to those of all responders.
- › Electronic, graphical "badges" that signify that your child has contributed to one or more research projects.

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. 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.

**Risks:**

There are some potential risks to participating in the Biome360 Research study, as described below:

- › Some survey questions may make you, your child or your child's family members uncomfortable.
- › Your child's Phenotypic data, survey responses, and/or personally identifying information may be stolen in the event of a security breach. In the event of such a breach, if your child's data are associated with your child's identity, they may be made public and it may have social and psychological consequences for you, your child or your child's loved ones.
- › When Biome360 investigators publish results from this study, your child's Phenotypic & Self-Reported Information may be included within pooled summaries that are made public. Identification of your child's individual-level data from those summaries would be extremely difficult, but it is possible that a third party that has obtained partial Phenotypic data from you or your child could compare their partial data to the published results and indirectly determine some of your child's survey responses.
- › As with any online service, if you disclose your child's account password to others, they may be able to access your child's account and your child's Phenotypic & Self-Reported Information.
- › There may be additional risks to participation that are currently unforeseeable.
- › Data that you or your child choose to share with others for any reason could be used against your child's interests.
- › Information that participants choose to share with their physician or other health care provider may become part of their medical record and through that route be accessible to other health care 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 involve 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. Make sure that your child washes his or her hands before and after collecting each sample. Should you be uncomfortable handling the collection kit and accepting responsibility for its use, please reconsider your child's participation in this study.

## 6. ARE THERE ANY OTHER ALTERNATIVES? CAN WE WITHDRAW FROM THIS STUDY?

You can still receive your child's microbiome results if you choose not to participate in the Biome360 Research study. Even if you do give consent to participate in this study, we will not force you to participate in any surveys, and you are free to terminate your child's participation in the study at any time. If you choose not to give consent for Biome360 Research, your child's Phenotypic & Self-Reported Information may still be used for other purposes, as described in our Privacy Statement.

At any time, you or your child may choose to withdraw all or some of your child's Phenotypic & Self-Reported Information from Biome360 Research by sending a request to the Human Protections Administrator at [support@BioMe360.com](mailto:support@BioMe360.com), or by changing your child's consent status within the Biome360 "Settings" page. (Biome360 will notify you if additional ways to withdraw consent become available.)

Choosing not to give permission or withdrawing from Biome360 Research will not result in penalty or loss of benefits to which you or your child are otherwise entitled to and it will not affect your child's access to your child's Phenotypic Information or to microbiome sequencing service. You will still be allowed full access to the microbiome sequencing service, but Biome360 will prevent the requested information from being used in new Biome360 research occurring after 30 days from receipt of your or your child's request.

Any research on your child's data that has been performed or published prior to this date will not be reversed, undone, or withdrawn. Your child's Phenotypic & Self-Reported 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 or your child's consent. In the following cases, Biome360 will maintain your child's Phenotypic & Self-Reported 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 Research 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.
- › **Bankrupt.** If Biome360 files for bankruptcy or liquidation, a court may impose different terms on the use of your child's data.

## 7. WHOM DO I CONTACT IF I HAVE QUESTIONS?

**If you or your child have any concerns or questions 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**

**Email:** [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 and your child's rights as a research participant have been provided to you.
- › Biome360 will tell you about new information or changes to the study that may affect your child's health or your or your child's willingness to have him or her stay in the study.
- › By signing this parental permission form, you do not give up any of your or your child's legal rights. The researcher(s) or sponsor(s) are not relieved of any liability they may have.
- › You are the child's legal guardian and you agree to have the child named above take part in this research study.
- › Your child still has the right to decline to participate even if you consent to their participation.
- › If your child is of reading age, they need to complete the "Child Assent Form" to participate in this research.

**CHOICES**

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

Or

**I AGREE TO PARTICIPATE**

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

Type in your child's name and today's date.

And

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

Type in your name and today's date.

And

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

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

## **BIOME360 CHILDREN'S ASSENT FORM**

What is a research study?

Research studies help us learn new things and test new ideas. First, we ask a question. Then we try to find the answer. This page talks about our research and the choice you have to participate in it.

### **IMPORTANT THINGS TO KNOW...**

You get to decide if you want to take part in this research.

You can say 'No' or you can say 'Yes.'

If you say 'Yes' now, you can always say 'No' later.

You can say 'No' at any time.

No one will be upset if you say 'No.'

### **WHY ARE WE DOING THIS RESEARCH?**

We are doing this research to find out more about the bacteria (tiny living things) that live inside and outside of your body.

### **WHAT WOULD HAPPEN IF I JOIN THIS RESEARCH?**

If you decide to be in the research, we would ask you to do the following:

**Bathroom:** You or your parent or guardian may collect some of your feces (poop) off the toilet paper after you go to the bathroom.

**Questions:** You or your parent or guardian may answer some questions about your eating habits, sleeping habits, and other habits, as well as questions about your doctor visits.

Always wash your hands before and after you collect the sample.

### **COULD BAD THINGS HAPPEN IF I JOIN THIS RESEARCH?**

Some of the tests might make you uncomfortable or the questions might be hard to answer. We will try to make sure that no bad things happen. You can say "no" to the research at any time.

### **COULD THE RESEARCH HELP ME?**

This research will not help you. However, Biome360 does hope to learn something from this research for the future.

### **WHAT ELSE SHOULD I KNOW ABOUT THIS RESEARCH?**

If you do not want to be in the study, you do not have to be. It is also OK to say yes now and change your mind later. You can stop participating in the research at any time.

## WHAT ARE MY CHOICES?

**\* If you do not wish to participate in Biome360's research, do NOT enter your name below. Select this box instead:**

I DO NOT WISH TO PARTICIPATE AT THIS TIME

**\* If you wish to participate in Biome360's research after reading this, please enter your name below. This shows that you read this form or had it read to you and you want to participate in this research.**

Your Name \_\_\_\_\_ Date \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Name of your Parent / Legal Guardian

**Your parent also needs to complete a "Parental Permission form." Make sure your parent has completed this form or you will not be able to participate in this research.**