

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 [www.ubiome.com](http://www.ubiome.com). If you are an adult (have passed your 18<sup>th</sup> 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 uBiome 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

uBiome provides you access to information about your microbiome, the organisms in and on your body separate from your own cells. We have affiliated 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 uBiome service, you will be collecting samples from your mouth, nose, the surface of your skin, or from inside your gut, or genitals. Make 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 uBiome service. It consists of:

- (i) allowing uBiome investigators to use your biome information for research; and
- (ii) entering data about yourself into uBiome Research features on the uBiome 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 sets out 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 uBiome Research on a continuing basis.

## Data Usage and Sharing

uBiome 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.

uBiome 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. uBiome may release your individual-level data to a third party if we ask for, and receive, your explicit authorization to do so.
2. uBiome'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 uBiome's services.
3. Researchers invited by uBiome to conduct research may access your information (but not your name or contact information) for the purpose of scientific research.
4. uBiome 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. uBiome 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 uBiome 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 uBiome research study:

- Some 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. Such 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 uBiome 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.
- uBiome 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 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 uBiome 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. Should you be uncomfortable handling the collection kit and accepting responsibility for its use, please reconsider your participation in this study.

### **Withdrawing from the Study**

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

Choosing not to give consent or withdrawing from uBiome Research will not affect your access to your information or to microbiome sequencing service. You will still be allowed full access to the microbiome sequencing service, but uBiome will prevent the requested information from being used in new uBiome research occurring after 30 days from 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 uBiome Privacy Statement.

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

- **Transfer of ownership.** If uBiome undergoes a business transition such as an acquisition or merger, the uBiome 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.
- **Bankruptcy.** If uBiome 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:

#### **uBiome Human Protections Administrator**

Email: [privacy@uBiome.com](mailto:privacy@uBiome.com)

Phone: +1 (502) 298-4349

If you have any questions, concerns or complaints about research that you do not wish to discuss with uBiome or would like to offer input or obtain information, you may contact the following independent,

impartial research review board:

**E&I Review Services**

Email: [subject@eandireview.com](mailto:subject@eandireview.com) Phone: 1-800-472-3241

If you have general questions about uBiome's service, please contact:

uBiome Customer Service by email at [privacy@uBiome.com](mailto:privacy@uBiome.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.
- uBiome 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 \_\_\_\_\_  
Type in your name Today's Date

and

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

## uBiome Children's Assent Form

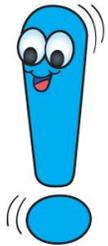
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### What is a research study?

Research studies help us learn new things. We can test new ideas. First, we ask a question. Then we try to find the answer.

This page talks about our research and the choice that you have to take part 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', 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 (very tiny living things) that live inside and outside 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 of the toilet paper after you go to the bathroom.
- Other places: You or your parent or guardian may also use a swab (small piece of cotton) to collect a sample from your mouth, nose, private parts, or your skin. You can choose to do any of these parts, just a few, or none of them.
- 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 visits to the doctor.
- 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. We do hope to learn something from this research for the future.



### **What else should I know about this research?**

If you don't want to be in the study, you don't have to be.

It is also OK to say yes and change your mind later. You can stop being in the research at any time.

Send an email to Human Protections Administrator at [hpa@uBiome.com](mailto:hpa@uBiome.com) to stop your participation at anytime.

You will not be paid to be in the research.

Ask your parents to answer any questions you have. Take the time you need to make your choice. We will give them the information they need to contact us to get the answers. If you would like to call us to answer any questions, please call us at 1+ (502) 298-4349.

If you want to talk to someone who does not work at uBiome about any concerns or complaints, you can call an independent reviewer in charge of participant's rights at 1-800-472-3241 or email them at [subject@eandireview.com](mailto:subject@eandireview.com).



### What are my choices?

\* If you don't want to be in the research, do NOT enter your name below. Select this box instead:  I DO NOT WISH TO PARTICIPATE AT THIS TIME

\* If you want to be in the 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 be a part of this research.

Name of Participant \_\_\_\_\_  
Today's Date \_\_\_\_\_

Name of your Parent / Legal Guardian \_\_\_\_\_

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