CONSENT TO PARTICIPATE IN A PROJECT TO DEVELOP A RESEARCH RESOURCE FOR FUTURE STUDIES OF [SPECIFY BODY SITE OR LIST TYPES OF DISEASES]

1. Introduction

We invite you to participate in a research project that will develop an important research resource for future studies of many diseases of the [specify body site or list types of diseases]. This project is part of the **Human Microbiome Project (HMP**). The HMP is sponsored by the National Institutes of Health (NIH), the main U.S. agency that funds biomedical research, and is part of an international network. Many different institutions, scientists, and people around the world are participating in the HMP and related projects.

This research will involve approximately [specify number of participants] at [specify institution]. You are being asked to participate as a [healthy volunteer]. We are looking for men and women who:

- are between the ages of [specify age range];
- are willing to give us information about their general health history and their history of diseases of [specify body site];
- are willing to give us some samples from [specify body site] that can be collected quite simply and painlessly [if this is accurate];
- are willing to give us a blood sample [if collecting blood];
- are willing to have many researchers in many institutions around the world (not just at [specify institution]) study the samples they give us for a long time [if sharing of samples is planned];
- are willing to have the results of many studies that will use the samples placed in scientific databases that will be available over the Internet (with special precautions in place to protect privacy); and
- are willing to be asked to participate in follow-up studies in the future [alternatively, give participants an opportunity to state later whether or not they agree to such recontact].

If you think you might want to participate, please read the rest of this form. Please take as much time as you need to decide whether to participate. Ask us to explain anything you do not understand. You may also want to talk about the research with family, friends, or a health care provider.

The alternative to participating is not to participate, and the decision about whether to participate is completely up to you. If you decide not to sign this form, it will not affect:

- the treatment or care your health care providers give you;
- your insurance payments or enrollment in any health plans; or
- any benefits to which you are entitled.

However, if you do not sign the form, you will not be able to participate in this research.

2. What is the purpose of this research?

Our bodies carry around trillions of microbes--bacteria, viruses, and other living things so tiny that we need a powerful microscope to see them. These microbes live in groups in many places on and inside our bodies, such as the skin, the mouth, nose, gut and (in women) vagina. While we still don't know how they do it, many of these microbes help to keep us healthy, while others contribute to disease. Similarly, changes in our health can affect our microbes. So can things like where we live or work, our age, ancestry, health status, and diet—and probably many other things that we don't know about yet.

People and microbes both have DNA, the material that contains genetic instructions. The microbes' DNA affects how they live with each other and how they act in our bodies. Our own DNA also affects how we react to our microbes. All of the different kinds of microbes that live on and inside us, taken together, are called the "human microbiome." **The purpose of the HMP is to learn about the human microbiome** by studying the microbes' DNA, other chemicals that the microbes produce, human DNA, and how microbes interact with each other and with their human host to contribute to health and disease.

In this particular study (which is just one part of the HMP), we will focus just on the microbes that live in [on] one part of the body: [specify body site]. We will collect samples from the [specify body site]--both from people who have certain diseases of the [specify body site] and from people who do not. By comparing the microbes that we find in these two sets of samples, and by making the information that we learn available to other research scientists all around the world, we will gradually begin to understand more about the complicated relationships between the microbes that live in [on] the [specify body site] and these diseases. Future studies that build on this research will help us to understand even more about how the human microbiome affects human health more generally. We hope that all of this research will eventually transform the very way we think about health and the way we prevent, diagnose, and treat many diseases—not only those related specifically to the [specify body site], but others as well.

This is a research project, not medical care. You should still see your health care provider for any scheduled visits or if you have a health problem or medical question.

3. What will I be asked to do?

[Note: this section may need to be modified substantially, depending on the specific study procedures for the demonstration project.]

If you are interested in participating, we will first ask you to complete a **screening visit.** During this visit we will first ask you to give informed consent. We will then ask you about your background and general health history, and any [specify body site] diseases you may have had. We may also ask you about whether you have recently taken any antibiotics, and about [specify other relevant areas]. We realize that some of the questions we ask are sensitive, but we have to ask them in order to see whether you are eligible to participate and to make sure that we are including people from many different backgrounds in the research.

If you are found eligible to continue, we will ask you to come in again for a **clinic visit** to give us some samples. Before the clinic visit, we will ask you to **refrain from** [specify any particular activities participants should refrain from before they come in to give samples, and for what period of time].

During your **clinic visit,** which will take about [specify length of time], we will:

- ask you some more detailed health questions;
- [describe specific sampling procedures]; and
- draw about [specify amount] of blood from your arm.

4. What will you do with the information and samples I give you?

[Note: this section may need to be modified substantially, depending on the specific study procedures for the demonstration project.]

We will do this with the **information** you give us:

- remove your name and any other traditional identifying information from the clinical interview sheets, and label the information with a code number;
- place the coded information in a *controlled access* scientific database so that it can be correlated with the data we get from analyzing the samples (see below) and so that it can be used by scientists in many future studies; to make the information most useful for research, the database will be available to qualified scientists over the Internet.

We will do this with the **microbe samples** you give us:

- remove your name and any other traditional identifying information, and label the samples with code numbers;
- process and extract DNA from the coded microbe samples.
- analyze the DNA from the coded microbe samples by a process called "sequencing," which means reading out the complete genetic "code" in the sample;
- remove any human DNA sequence information from the microbe DNA sequence information (this will make it very difficult for anyone who looks at the information about your microbe DNA to tell anything about your human DNA;

- compare the DNA in the coded microbe samples you give us with the DNA in the coded microbe samples we collect from the other participants in this study and with DNA of known microbes;
- store the remaining portion of the samples you give us, so that they will be available later if we decide we want to extract other chemicals from them and study them to answer other questions relating to the human microbiome;
- place all the information we learn identified only by code numbers, in an *open access* (public) scientific database available over the Internet, so that it can be used by scientists in many future studies.

We will do this with the **blood sample** you give us:

- remove your name and any other traditional identifying information, and label the sample with a code number;
- store the coded blood sample, so that it will be available later if we decide we want to process and extract DNA from it;
- make a "cell line" from the coded blood sample, which is a way to make it possible for us to make more DNA than we can get from the original sample, so that it can be used in many future studies;
- if we decide it would be important to study the DNA from the coded cell line, we will sequence it (similar to what we will do with the microbe samples);
- compare the DNA in the coded blood sample you give us with the DNA in the coded blood samples we collect from the other participants in this study;
- perhaps later, extract other chemicals from the coded blood sample and study them to answer other questions relating to the human microbiome;
- combine the data we get from studying the coded blood samples we collect from *all of the participants*, and place the aggregated information in an *open access* (public) scientific database available over the Internet, so that it can be used by scientists in many future studies (because any data obtained from your blood sample will be mixed with data from all of the other blood samples, no one should be able to identify which of the data came from you);
- place any information we learn from studying the coded blood sample that relates to you *individually* in a *controlled access* scientific database available over the Internet, so that it is not available to just anyone who can use the Internet, but can still be used by scientists in many future studies.

See #10, *"How will you protect my privacy?"* for more information about how we will handle the information and samples you give us.

5. What will happen with the information and samples I give you after this project is over?

This project is one of the first components of the HMP. Its purpose is to create a resource, which will be a set of data and materials that will be maintained indefinitely and that will form the foundation of the HMP. Researchers around the world working in

many different settings--in universities, hospitals, non-profit groups, companies, and government laboratories--will later use this resource, by studying the information in the databases, and compare the information with the results of their own experiments. Thus, the information and samples you give us will be used in studies of many diseases related to the [specify body site]. The information and the samples may also be used in general human microbiome studies related to other aspects of health and disease.

[If applicable:**]** **Material from both the microbe samples and the blood samples will be kept and used for many years, by both researchers at [institution] and other researchers around the world.** These samples may be used for studies related to [specify body site] or, in the future, other studies related to the human microbiome more generally. **The sample you give us will never be used to make a clone (genetic copy) of you.** [Indicate here how access to samples by other researchers will be controlled and monitored.

In the unlikely event that [institution] can no longer maintain the samples, they will be [archived/destroyed – choose one].

6. How long will I be involved in the project?

While the information and samples you give us to create the resource will be used for many years, developing the resource will only take a couple of years. You will need to be actively involved for only about [specify length of time] (depending on scheduling). [If participants will be asked to return at a later date to provide more samples or information, this should be described here; investigators should also consider giving participants the option to state whether or not they agree to be recontacted.]

7. What are the costs and payments?

It will not cost you anything to participate.

We will reimburse you [specify amount] for your time and inconvenience when you come in for your screening visit. If you continue in the project and give samples, we will reimburse you [specify amount] after you have given us all the samples.

The samples and information you give us will be used only for research purposes and will not be sold. Some of the research may someday lead to the development of new predictive or diagnostic tests, medicines, or other commercial products. If this happens, you will not receive any of the profits generated from those products.

8. What are the risks of participating?

We believe that the risks to you from participating are minimal, but we must describe them fully to you so that you will understand them in order to decide whether or not to take part.

If you give samples, you may be exposed to the following **physical risks:**

Samples from [specify body site]: [Describe physical risks here.]

Blood sample: You may have some brief discomfort or pain and bruising where the needle goes in your vein. There is also a small chance that you may get an infection, have excess bleeding, become dizzy, or faint from the blood draw.

You may also be exposed to some **non-physical risks:**

- Some questions that we ask in the interviews may make you feel uncomfortable. You can refuse to answer any question you want to (but in some cases, this may mean that we will not be able to use your samples for the study).
- While we will take every precaution we can to keep the information obtained in these studies confidential, there is a small risk that some of the information we collect from you or learn from studying the DNA in your microbes or in your blood could be disclosed to someone outside the project. This might happen by mistake or if someone hacked into the database. Also, even though there are no methods that people can use now to figure out information about you from the aggregated information in the database, we cannot guarantee that there will not be new techniques developed in the future that could do this. If any of these things happened, someone might try to use that information to try to learn more about you or your family members and then to try to use it against you or your family members in some way. ***See #10, "How will you protect my privacy?".***

We cannot always foresee the results of research, so **new risks may come up in the future that we cannot predict now.** It is our belief that the benefits of learning more about the [specify body site] microbiome and how it relates to [specify body site] health and disease, as well as to health and disease more generally, greatly outweigh the current and potential future risks. However, this is something you must judge for yourself.

[Institution] investigators and their staffs will do whatever they can to reduce, control, and treat any complications from this research. If you believe you have been injured because of this research, please contact [specify contact person]. Decisions about payment for medical treatment for injuries relating to your participation in research will be made by [institution].

9. Are there any benefits to taking part in the study?

You will probably not get any direct personal benefits from participating in this project because it is likely that this research will take a long time to produce medically useful results. However, your participation will help researchers around the world understand more about the human [specify body site] microbiome and how it relates to health and disease. Many research participants get great satisfaction from making such a contribution to human health research.

10. How will you protect my privacy?

We will take many measures to protect your privacy:

- We will follow all applicable federal and state laws to protect your privacy.

- We will obtain a Certificate of Confidentiality (see below).

- We will remove any standard or traditionally used identifying information (such as your name, address, telephone number, Social Security number) from the information and samples you give us. We will label everything only with code numbers, which will be used in all further studies with the samples. Only a few members of the study team at [name of institution], who have specifically agreed to protect your privacy, will have access to the codes. [Provide additional detail here, as relevant, regarding plans for data encryption, password protection, etc.].

- We will store your signed consent form, and the clinical interview sheets that contain your name and other identifying information, in a locked file. Only a few members of the study team at [name of institution], who have specifically agreed to protect your privacy, will have access to this file.

- As described in #4 *"What will you do with the information and samples I give you?,"* we will place the information we learn from studying the coded microbe samples you give us in an open-access (public) scientific database. We will also place coded *aggregate* information we learn from studying the *entire set* of coded blood samples collected from *all the participants together* (i.e., *information that does not relate to you individually*) in an open access database. "Open access" means that anyone who can use the Internet will be able to look at this information. However, *it will not be possible for anyone to identify you personally from looking at any of this information.* Furthermore, all human DNA sequence information will be removed from the microbe DNA sequence information before the coded information is put into the open-access database,so it will be very difficult for anyone to tell anything about your human DNA from looking at the information about your microbe DNA sample.

- As described in #4, *"What will you do with the information and samples I give you?,"* we will place the coded information from your clinical interview sheet, and any information we learn from studying the coded blood sample that relates to you *individually,* in a controlled access scientific database. The information in this database, if combined with information someone obtained about you from outside the database, could potentially be used to identify you. However, "controlled access" means that *only qualified researchers who have received prior approval from an NIH Data Access Committee will be able to look at this information.*

- The databases developed for this project will use state-of-the-art methods for protection from hacking and unauthorized access.

Because of the steps we are taking to protect your privacy, **it will be very hard for anyone who looks at any of the Internet databases to know which information came from you, or even that any information came from you.** Also, when scientists publish research results in papers or books or discuss them at scientific meetings, nobody should be able to tell that you were a participant.

While we will try as hard as we can to protect your privacy, **there is a small risk that some information about you could be disclosed to someone outside the project.** This could happen if:

- A hacker violated the security of the computer that will store the codes linking your information to your name, or if a researcher accidentally disclosed the codes linking your information to your name.
- We were required by law to disclose your information to someone outside the study.
- Somebody someday figured out how to link some of the information about you or the samples we collect from you in the databases back to you. For example, someone who compared information in the databases with information from you (or a family member) in some other database might be able to identify you (or your family member). Although this risk is now small, it may grow in the future. Also, as technology advances, there may be new ways that we cannot now foresee of tracing information back to you.

If someone did figure out how to link information back to you, there is a risk that they might try to use it in a way that would cause you or your family distress. For example, since some genetic information can help predict future health or illness, this information could be of interest to employers, insurers, or others, who might try to use it in making decisions about you or family members regarding employment, insurance, or other benefits. While there are some state laws that protect against genetic discrimination, there is currently no federal law that prohibits this.

If law enforcement officials thought that genetic information from the study of samples collected from you might be included in the databases, they might try to learn more about you or your family members and use that information in an investigation. This risk is very low, however, because anyone seeking access to the information in the controlled access databases will need prior approval of the NIH Data Access Committee. Because the information in the databases is intended only for research use, the NIH Data Access Committee will not approve such a use, or any other non-research uses.

Also, we have obtained a **Certificate of Confidentiality** from the Department of Health and Human Services. The Certificate is designed to prevent us from being forced to disclose identifying information for use in any federal, state, or local civil, criminal, administrative, legislative, or other court proceeding, even if faced with a court subpoena.

You should understand, however, that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. We may not withhold information if you give your insurer or employer or a law enforcement agency permission to receive information about your participation in this project. This means that you and your family must also actively protect your own privacy.

The Certificate does not prevent us from taking steps, including reporting to authorities, to prevent serious harm to yourself or others. Such disclosures will be made as described below.

The research team may share your information with:

- The Department of Health and Human Services (HHS), to complete federal responsibilities for audit or evaluation of this project;
- Public health agencies, to complete public health reporting requirements;
- Hospital or university representatives, to complete hospital or university responsibilities for oversight of this study;
- Your primary care physician if a medical condition that needs urgent attention is discovered;
- Appropriate authorities to the extent necessary to prevent serious harm to yourself or others.
- [Insert any additional necessary language related to any applicable state mandatory reporting requirements (e.g., findings of STDs ,TB, etc.]

[Insert here, or below, the institutionally-required language for the Notice of Privacy Practices under the Health Insurance Protection and Accountability Act (HIPAA).]

11. Can I change my mind after I decide to participate?

If you want to withdraw any of the materials you give us from use in this research, you may contact [name of PI] at [institution and contact number], and we will attempt to destroy any samples, cell lines, or DNA that have not already been distributed to research laboratories. If materials have already been distributed, we will make a good faith effort to have them returned or destroyed, but this may not be possible in every case. Also, once information from the study of the samples you give us has been placed in the databases, we will not be able to withdraw that information--only any remaining portions of the samples or DNA.

If you decide to withdraw the samples you give us from the research, your decision will not affect:

- your treatment or the care given by your health provider;
- your insurance payment or enrollment in any health plans; or
- any benefits to which you are entitled.

12. How can I find out about the results of the research?

In general, we will not give you any individual results from the study of the samples you give us. This is because it will probably take a long time for this project to produce health-related information that we will know how to interpret accurately. However, we will tell you if we find that you have a communicable disease that we are required by law to report. We will also periodically summarize [on a project website, through a newsletter, etc.] interesting *general* findings from this project and how they are contributing to our understanding of health and disease.

13. Who do I call if I have questions or problems?

If you have any questions, concerns, or complaints about the project, or feel that you have been injured because of the study, contact [name and contact information]. If you wish to talk to someone else, or have questions or concerns about your rights as a research participant, contact [name and contact information].

[Add any other required boilerplate here.]

AGREEMENT TO PARTICIPATE

I have read this consent form and have been given the chance to ask questions. I will also be given a signed copy of this consent form for my records. I give my permission to participate in the project described above, the Human Microbiome Project (HMP) and related studies. [Investigators may choose to include additional detail here.]

_____ _____

Participant's Signature or legally Authorized Representative

Date

Thank you for your important contribution to biomedical research.