

Human Microbiome Sample Collection Pamphlet

WHAT WILL HAPPEN TO YOUR SAMPLES, THE INFORMATION WE LEARN FROM YOU, AND THE INFORMATION FROM YOUR SAMPLES

This is what will happen to the *information we learn from your screening interview and physical examinations*:

- We will remove your name and any other traditional identifiers from the sheets we use to record the information, and label the information with code numbers so that it can be linked to the information we get from studying the samples (see below).
- We will place the coded information in controlled access scientific databases accessible over the Internet (the information will be available only to qualified researchers and will be used in many future studies).

This is what will happen to the *body site (microbe) samples* you give us:

- We will label the samples with code numbers so that they can be linked to the information you give us and to your blood sample.
- We will extract genetic material (DNA and possibly RNA) from the samples.
- We will send the genetic material to special laboratories, where project researchers will study the DNA by “sequencing” it (reading out the complete genetic code in each sample).
- Project researchers will make every effort to remove any bits of human DNA data from the microbe DNA data, to make it very hard for anyone who looks at the data about your microbe DNA to tell anything about your human DNA.
- Project researchers will compare the genetic material they find in the samples with the DNA of known microbes that have already been studied.
- Project researchers will place all the data (identified only by code numbers) in *open access (public)* scientific databases available over the Internet so that the data can be used by researchers in many future studies.
- After the project is over, any portions of the samples that remain will be destroyed, but Washington University will store the genetic material from the samples and distribute it to future researchers in other institutions, to study other questions related to the human microbiome (all such researchers will need to apply to Washington University with a written description of the proposed research, which will be reviewed to make sure that it is consistent with the uses described in this consent form).
- All of the information from this research, combined with the information from the study of the human DNA from the blood samples, will help researchers understand what microbes are on and inside people, how they interact with each other, and how they interact with human DNA.

This is what will happen to the sample you give us when you come for your *screening visit*:

- We will test the sample to see whether you have an active infection caused by hepatitis B, hepatitis C, or HIV (if you do, you will not be able to participate).
- We will tell you the results of these tests, and if you have an active infection, we will refer you to a doctor.
- We will report the results of these tests to the health department, as required by law.

This is what will happen to the sample you give us when you come for your *first sampling visit*:

- We will label the sample with a code number so that it can be linked to the information you give us and to your microbe samples.
- We will send the coded sample (without a link to the code or any identifying information) to the not-for-profit Coriell Institute for Medical Research in Camden, New Jersey (“Coriell”).
- Coriell will extract DNA, and later make a “cell line” from the sample, this cell line will last for a very long time and will make it possible to get an unlimited supply of DNA.
- Coriell will send DNA from the sample or the cell line to project researchers, who will study the DNA by “sequencing” it.
- Project researchers will combine the data they get from studying the blood sample with the data they get from studying all of the blood samples from all of the participants, and place the *combined data* in *open access (public)* scientific databases available over the Internet so that it can be used by researchers in many future studies (but without anyone being able to tell which data came from you).
- Project researchers will place the coded data from the blood sample that relates to *you* *individually* in *controlled access* scientific databases accessible over the Internet (these data will be available only to qualified researchers but will be used in many future studies).
- After the project is over, Coriell will continue to store the DNA and cell line and distribute these materials to future researchers in other institutions, to study other questions related to the human microbiome; these may include studies of the products that DNA and genes make (such as RNA and proteins) and how they are controlled (such as how genes are expressed). All such researchers will need to apply to Coriell with a written description of the proposed research, which will be reviewed to make sure that it is consistent with uses described in this consent form.
- All of the information from this research, combined with the information from the research on the microbes, will help us understand how genetic differences among people affect which microbes they have.

GLOSSARY OF TERMS

Cell – the basic unit of any living organism that can reproduce itself exactly. Humans are made from millions of cells that are adapted to carry out particular functions.

Clinical information – includes medical history, diagnosis, treatment, and outcome.

Coded data – means that collected samples or data are unidentified for research purposes by use of a random or arbitrary alphanumeric code, but the samples may still be linked to their sources through use of a key to the code available to an investigator or collaborator.

Controlled Access Database – storage of data on a computer in a systematic manner. Only researchers given permission can see the data.

DNA (deoxyribonucleic acid) – the substance of heredity; a large molecule that carries the genetic information present in each cell. The other type of nucleic acid found in the body is RNA (ribonucleic acid).

Human subject – a person who participates in a research study.

Proteins – substances composed of amino acids that are essential to body structure and proper functioning.

Human Microbiome Project – a large investigation that studies the small microorganisms that live in and on the human body.

Microbes – small organisms such as bacteria, virus particles and other single-celled organisms.

Open Access Scientific Databases – storage of data on a computer that anyone is able to access.

Results – scientific or medical findings.

RNA (ribonucleic acid) – one of the two nucleic acids found in all cells. In the cell, RNA transfers genetic information from DNA to proteins. RNA is transcribed off DNA and then translated to produce protein.

Serum – the liquid part of blood after coagulation and removal of the fibrin clot and blood cells.

Specimen – a small part or sample of any substance or material obtained for testing. A human specimen specifically represents a bodily material such as tissue, cells, blood, serum, plasma or urine collected for testing.

Studies – a systematic investigation designed to develop or contribute to general knowledge, to discover new information, revise conventional wisdom, and develop new treatments.

Swabs – material used to collect specimens.