Important note: *This language was developed for the NIH Common Fund Human Microbiome Project (HMP). It is included here only as an example of how to describe a sequencing project to potential research participants.*

[**x**] Adult [] Minor

INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Participant Name:_____

HRPO Approval Number: xx-xxxx

Principal Investigator: xxxxx xxxxxxxxx, MD
PI's Phone Number: (xxx) xxx-xxxx
Title of Project: **Human Microbiome Project (HMP): CORE MICROBIOME SAMPLING**

You are invited to take part in a research study by Dr. xxxxxx and/or colleagues as a healthy volunteer.

Please ask for an explanation of any words you do not understand.

You may want to talk about this study with your family or friends before you decide to be in it.

This study is part of a project called the Human Microbiome Project (HMP) and is sponsored by the National Institutes of Health (NIH), the main U.S. agency that funds biomedical research. Washington University is one of many institutions involved in the HMP.

General information about the HMP, including major findings resulting from this research, will be summarized on the project website, http://hmp.nih.gov/donor.htm.

1. Why is this study being done?

Our bodies carry around trillions of microbes--bacteria, viruses, and other living things so tiny that we need a microscope to see them. These microbes live on our skin and in places like our mouth, nose, gut and (in women) vagina. The groups of microbes that live on or inside our bodies can affect our health. Changes in our health can also affect these groups of microbes. Which microbes live on or inside us can also be affected by 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 - material that provides genetic instructions that affect how the microbes act in our bodies, how they live with each other, and how we react to them. All of the different kinds of microbes that live on and inside us, combined, are called the "human microbiome."

In the Human Microbiome Project (HMP), we hope to learn about the human microbiome and to put all the information that we discover in scientific databases available over the Internet, so that researchers around the world can use it in future studies related to health and disease.

Being in a research study does not take the place of routine exams or visits to your own doctor and should not be relied on to diagnose or treat medical problems.

2. What am I being asked to do?

Step 1: If you are interested in participating, we will first ask you to complete a **screening visit.** This visit will take about 3-4 hours.

- You will be asked for your consent, which involves learning the purpose of the research and the risks, benefits and requirements of participation. You will be given adequate time to review this consent form, express concerns, or ask questions; these will be answered to your satisfaction before you sign this document.
- You will be asked about:
    - your background, general health history and any medications you may take;
    - your dental health history and any digestive, respiratory, or skin diseases you may have had;
    - If you are a woman, your gynecological health, sexual practices, and sexual history.
- We will record your vital signs, including temperature, height and weight.
- We will draw no more than two tablespoons of blood from your arm to test for HIV, Hepatitis B and Hepatitis C.
- You will have a dental exam by a periodontist to examine your mouth and teeth.
- You will have an examination of your skin and nose.
- If you are a woman, you will have a vaginal exam.
- If you are a woman who is able to get pregnant, you will have a urine pregnancy test. Since you must not be pregnant while you participate in this study, you should not plan to participate if you plan to get pregnant within the next year.
- You will be given a kit with instructions for collecting a stool sample, to be brought in at your next visit.

You might consider that some of the questions we ask during the screening visit are very personal, but this is necessary in order to see whether you are eligible to continue to take part and to make sure that we choose people from a variety of backgrounds.

Step 2: We will contact you within one week after your screening visit to let you know whether you are eligible to give samples. If we find that you are eligible and you still want to participate, we will schedule a time for you to return for your **first sampling visit** to obtain the samples**.** We will ask you to avoid certain activities and avoid using certain products that could alter the microbes on and in your body for a certain period of time just before your visit. The activities and products you must avoid, and how long you must avoid them, are explained on the accompanying Information Sheet.

During the **first sampling visit,** which will take 3-4 hours we will:

- Ask you some more detailed health questions;
- Take the stool sample that you have collected and brought in with you;
- Record your vital signs, including temperature, height and weight;
- Repeat a urine pregnancy test if you are a woman who is able to get pregnant;
- Draw no more than 2 tablespoons of blood from your arm. This blood sample will be used to isolate and study your DNA.
- Take 2 swabs from your nose;
- Take several samples with a swab from your skin;
- Take several saliva samples and scrapings from your oral cavity (mouth and teeth) by a periodontist;
- If you are a woman, give you a vaginal exam to measure your vaginal pH, and take several samples with a swab.

Step 3: You will be asked to return to the clinic for a **second sampling visit** within one year to repeat the same sampling (except that we will not take an additional blood sample).

All of the procedures and tests described above will be used for research purposes only.

In this study, you will be tested for HIV (the virus that causes AIDS), Hepatitis B, and Hepatitis C. If you test positive, you may be infected HIV, Hepatitis B, or Hepatitis C. The study doctor and other doctors will talk to you about what these tests mean and possible treatments for the virus(es). They will refer you to the Infectious Disease Clinic at Washington University for further help. Since this is a research study, the results of your tests will not become part of your medical record. However, if you require treatment, your physician will be told the results of the test.

What will happen to my samples?
The samples collected from you will be used for research purposes as described in the accompanying information sheet that you will receive, "Human Microbiome Sample Collection Pamphlet".

The samples and information will be used only for research. We will not give you any *individual* results from the study of your samples. 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.

How long will I be in the study?
You will be in the study for approximately 1 year, depending on scheduling and your willingness to return for repeat sampling. However, the specimens that are collected from you (such as the DNA from your microbes) may be used until they are physically depleted, even after this one year period, and your blood sample may be studied for many years.

How many other participants will be in the study?
This study will involve approximately 300 healthy adults participants at 2 medical centers in the U.S. – approximately 150 participants will be recruited at Washington University and 150 participants at Baylor College of Medicine in Houston, TX.

3. What are the costs for participating?
It will not cost you anything to take part in this project.

Some research based on the samples or information collected in this study may someday lead to the development of new predictive or diagnostic tests, medicines, or other commercial products. If this happens, however, there are no plans to provide you with any of the profits generated from those products.

Will I be reimbursed for my participation? For their time and inconvenience, men will receive $100 for the screening visit if all procedures are completed and a blood sample is collected for hepatitis B, hepatitis C, and HIV testing. Men will receive an additional $200 when all samples have been collected at the first sampling visit and an additional $200 when all samples have been collected at the second sampling visit

For their time and inconvenience, women will receive $150 for the screening visit if all procedures are completed and a blood sample is collected for hepatitis B, hepatitis C, and HIV testing. Women will receive an additional $250 when all samples have been collected at the first clinic sampling visit and

an additional $250 when all samples have been collected at the second sampling visit. You should understand that if you receive more than $600 as a result of participating in this study, this will be considered income, Washington University will send you an IRS Tax Form 1099, and you will be required to report this income to the IRS for tax purposes.

4. What are the risks?

You may be exposed to the following risks related to this research:

- **Blood sample collection:** Brief discomfort or pain and bruising where the needle goes in your vein; a small chance that you may get an infection, have excess bleeding, become dizzy, or faint.

- **Stool sample:** Possible skin contamination with feces from the collection container.

- **Mouth sample:** Possible dry area in the mouth at the sampling (swab) sites for a short period of time (less than 5 minutes); slight tenderness in the gums surrounding the teeth where the samples are collected.

- **Skin sample:** Possible irritation or temporary redness at the sampling (scraping) sites; slight chance of bleeding or infection at the sampling sites.

- **Nasal sample:** Possible irritation or dryness at the sampling sites for a short time (less than 5 minutes).

- **Vaginal sample (women only):** Possible discomfort during the sample collection; slight irritation at the sampling sites; possible embarrassment at having the procedure.

- **Interviews/Questionnaires:** Some questions may make you uncomfortable; however, you may refuse to answer any question for any reason.

- **Screening Tests:** As part of the screening procedure, you will have testing performed to determine whether you have HIV, Hepatitis B, or Hepatitis C. If appropriate, you will also have a pregnancy test. You will also have a general health exam. An unexpected positive result from any of these tests or screenings may be new information to you and, depending upon the result, could cause you emotional distress.

- **Loss of confidentiality and/or privacy**: One potential risk of participating in this study is that personal and confidential information about you may be accidentally disclosed to people who should not have this information. There is a small risk that someone outside of this research project could learn some personal information about you. For example, this could happen if any of the following were to occur:
    - An individual violated the security of the computer that will store the codes that link your research information to your name, or if a researcher accidentally disclosed the codes.
    - Someone using your research data figured out how to link some of the information in the databases back to your name.
    - The study team was required by law to disclose your information to someone outside of the project.

If the health information or medical screening test results collected in this study become known outside of the research (for example, if your participation were to be noted in your medical record) you (and possibly your family members) may be unable to obtain health, life, or disability insurance. You might also be refused employment or be terminated from your current employment. If information regarding your test results is noted in your medical record, this may allow insurance providers to access this information.

When we study the DNA from your blood samples, we will also generate data about your entire genetic code. Despite the measures we take to protect this data and its link to your identity, and although there is now a federal law that prohibits genetic discrimination in health insurance and employment, there is a small risk that somebody could learn some genetic information about you from this study and then try to use it to discriminate against you or your family members in some way. For example, genetic data from this study could possibly be used by a disability, life, or long term care insurance company to deny you coverage, or by law enforcement officials to learn more about you or your family members for the purpose of a criminal investigation. The risk of this happening is currently very small, but as technology advances, there may be new ways to do this that we cannot foresee now.

We cannot always foresee the results of research, so new risks may come up in the future that we cannot predict now. However, we believe that the benefits of learning more about the human microbiome and how it relates to health and disease outweigh the current and potential future risks.

What happens if I am injured because I took part in this study?
Washington University investigators and their staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the Investigator, Dr. xxxxx at (xxx) xxx-xxxx or the Human Research Protection Office Chairperson, Dr. xxxx at (xxx) xxx-xxxx.

Decisions about payment for medical treatment for injuries relating to your participation in research will be made by Washington University. If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

5. Are there benefits to taking part in the study?
You will not benefit personally from giving samples for this project because 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 microbiome and how it relates to health and disease. Also, as part of your screening visit, you will receive certain types of physical examinations by health care professionals. These examinations will give you a free evaluation of some aspects of your health status, and we will encourage you to consult with your usual health care provider, where appropriate.

6. What other options are there?
Taking part in this research study is voluntary. You may choose not to take part in this research study or you may withdraw your consent at any time. You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found at http://hrpo.wustl.edu under Information for Research Participants. Your choice will not at any time affect the commitment of your health care providers to administer care. There will be no penalty or loss of benefits to which you are otherwise entitled.

7**. What about privacy and confidentiality?**
Protected Health Information (PHI) is health information that identifies you. For this study, PHI will include the information you provide about your health status, the results of the research screening lab tests performed, and the biological specimens that you donate for research purposes. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study explained in this consent form.

The samples that you give us will not be labeled with your name or any other traditional identifying information (for example, address, telephone number, Social Security number). Your samples will be labeled only with code numbers (de-identified), and the link between these codes and your identity will be stored in a locked file and password protected computer. Only Dr. Watson and a small number of authorized people at Washington University who are directly involved in this project and who have specifically agreed to protect your identity will have access to the link between sample code numbers and your identity.

The research team will only use and share your information as discussed in the accompanying information sheet that you will receive, "Human Microbiome Sample Collection Pamphlet". The research team will make sure information cannot be linked to you (this is referred to as de-identified information). However, once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 1-866-747-4975.

A Certificate of Confidentiality has been requested from the Department of Health and Human Services. This will help further protect information that may identify you. The Certificate prevents the investigator from being forced to disclose identifying information for use in court without your permission. The investigator may not even be forced by court subpoena. Courts that may be prevented from getting your information include any federal, state, local civil, criminal, administrative, legislative, or other court proceeding.

You should understand 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. The investigator may not withhold information if you give your insurer or employer permission to receive information about your participation in this research. This means that you and your family must also actively protect your own privacy.

The Certificate also does not prevent the researchers 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 also be required to share your information and identity with:

- The Department of Health and Human Services (HHS) to complete federal responsibilities for audit or evaluation of this study.
- The National Institutes of Health (NIH). Representatives of the NIH will have access to your research and/or medical records for monitoring the study. The research team will also send study results to the NIH. Information sent to the NIH will contain a linked code. The NIH is not required to abide by the HIPAA regulations, but agrees to protect the confidentiality of your information.
- 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.

Once your health information is shared with someone outside of the research team (for example, other investigators who want to study your data to learn more about the human microbiome), it may no longer be protected by HIPAA.

The research team will only use and share your information as discussed in the accompanying information sheet that you will receive, 'Human Microbiome Sample Collection Pamphlet". When possible, the research team will make sure information cannot be linked to you (this is referred to as de-identified information). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions about your privacy and the use of your PHI, please contact the University's Privacy Officer at (xxx) xxx-xxxx.

Representatives of the NIH will have access to your research and/or medical records for monitoring the study. The research team will also send study results to the NIH. Information sent to the NIH will contain a linked code. The NIH is not required to abide by the HIPAA regulations, but agrees to protect the confidentiality of your information.

Results from this research study will be kept separately from your medical record. Unlike your medical record, you will not have access to these research results.

If you decide not to sign this form, it will not affect

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

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research.
- Your signature and this form will not expire as long as you wish to participate.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
    - To revoke your authorization, complete the withdrawal letter found in the Participant section of the Human Research Protection Office website at http://hrpo.wustl.edu or you may request that the Investigator send you a copy of the letter.
        - **If you revoke your authorization:**
            - The research team may only use and share information already collected for the study.
            - Your information may still be used and shared if necessary for safety reasons.
            - You will not be allowed to continue to participate in the study.

Please specify any contact restrictions you want to request for this study only.
(Example – no calls at home, no messages left for you, no emails, etc.)

_____

_____

Notice of Privacy Practices

The Notice of Privacy Practices is a separate document. It describes the procedures used by WU to protect your information. If you have not already received the Notice of Provacy Practices, the research team will make one available to you.

_____ I have been offered a copy of the Notice of Privacy Practices.
Initial

8. Whom do I call if I have Questions or Problems?

Please contact the researcher listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Report an illness, injury or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Dr. xxxxxx
Mailing Address: xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx. St. Louis, MO 63110
Telephone: (xxx) xxx-xxxx

If you wish to talk to someone else, or have questions or concerns about your rights as a research subject, call Dr. xxxxx, Chairman of the University's Human Research Protection Office, at (xxx) xxx-xxxx.

We will periodically summarize on the HMP project website interesting general findings from this project and how they are contributing to our understanding of health and disease. See http://nihroadmap.nih.gov/hmp/.

Additional Permissions:

1. May we contact you for future studies conducted as part of the HMP? ___Yes ___No

If Yes, we will need to look at your Protected Health Information (PHI) to check for your study eligibility.

2. May other Washington University physicians conducting research on the human microbiome contact you? ___Yes ___No

If Yes, your PHI will be shared with other Washington University physicians.

3. May other physicians from outside Washington University conducting research on the human microbiome contact you? ___Yes ___No

If yes, your PHI will be shared with other outside physicians.

Taking part in future studies is optional. You can ask us any time to take you off our contact list.

Washington University would also like your permission to keep the portion of the blood sample that is not needed for this project. This portion of the sample would be used in future research studies--*including research unrelated to the human microbiome*--such as research that involves testing for antibodies against other viruses, bacteria or other microbes. This left over portion of the sample would be coded and stored at Washington University. It would not be sold or used directly for production of any commercial product. Reports about future research done with this sample would NOT be kept in your health records, but the sample would be kept with the study records or in other secure areas. *You can decide if you want the left over portion of the blood sample to be used for future research of this type.* Your decision can be changed at any time by notifying the study doctors or nurses in writing. If you withdraw this permission, any remaining blood samples that have not already been used for research will be destroyed. Your decision will not affect your participation in this project or in other studies.

Please indicate your decision about permission for possible future research use of the left over portion of the blood sample below -

4. May we store the left over portion of your coded blood sample for future research unrelated to the human microbiome? If you indicate 'No' your remaining blood sample will be destroyed after the end of this study.

Yes No Initial:_____

9. Withdrawal:

You may withdraw your consent to participate at any time. If you want to withdraw your microbe samples, your blood samples, or both from use in the project or in other studies, you may contact Dr. xxxx at Washington University, (xxx) xxx-xxxx and we will ask the facilities where your samples are to destroy any samples, cells, or DNA that have not already been distributed to research laboratories. If cells or DNA have already been distributed, the facilities where your samples are stored will make a good faith effort to have the samples returned or destroyed; however, this may not be possible in every case. **Also, once information from the study of your samples has been placed in the databases, you will not be able to withdraw that information, only to stop any additional information from being put in the databases. If you withdraw your consent:**

10. You will be given a signed copy of this consent form for your records

Please mark all that apply. This section is optional.
[] Not Hispanic or Latino [] Hispanic or Latino [] Unknown
[] Asian [] Black or African-American [] Caucasian [] Native American or Alaskan Native
[] Native Hawaiian or Pacific Islander [] Other [] Unknown

The Office of Management and Budget has declared that Hispanic/Latino is an ethnicity. National Institutes of Health, in an effort to ensure diversity in research, requests that you report your ethnicity. (http://grants.nih.gov/grants/funding/women_min/women_min.htm)

I have read this consent form and the accompanying information sheet, “Human Microbiome Sample Collection.” I have been given the chance to ask questions. I agree to participate in this research described above, titled: Human Microbiome Project (HMP): CORE MICROBIOME SAMPLING.

HRPO does not require participants to re-sign the consent form unless a change is made; the investigator, however, may choose to re-consent participants at any time.

Signature: _____

Printed Name: _____ Date of Signature: _____

Principal Investigator (or designee)

I have given this research participant information about this study that I believe is accurate and complete. The participant has indicated that he or she understands the nature of the study and the risks and benefits of participating.

Signature: _____ Title: _____

Printed Name: _____ Date of Signature: _____

Washington University in St. Louis

Human Microbiome Sample Collection Pamphlet

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

1. This is what will happen to the information we collect 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 that are accessible over the Internet. This information will be available only to qualified researchers but will be used in many future studies.

2. This is what will happen to the blood 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 any positive results of these tests to the health department, as required by law. However, when a positive result is reported, it will not include any information that can specifically identify you. That is, the report will be anonymous.

3. This is what will happen to the **body site (microbe) samples** you give us when you come for your ***first and second and third (if applicable) sampling visits***:
    - 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 (i.e. your own) 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 your body 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.

4. This is what will happen to the **blood 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 from some of your blood cells, 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 your DNA for research.
- 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 your 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. This may include studies of the products that DNA and genes make, such as RNA and proteins, and how they are controlled. 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.

All of the information learned from studying the DNA in the microbe samples from your mouth, nose, skin, gut, and (in women) vagina, and some very general information learned from studying the DNA in the *entire set of blood samples combined* (not from your individual sample), will be placed in *public access databases* on the Internet (accessible to anyone who uses the Internet); however, this information will be coded and will not contain your name or any other traditional identifying information. It will be very hard for anyone to tell anything about *your* DNA from looking at the information about the microbe DNA because we will try to remove any bits of information from your DNA that are in the microbe samples. Also, only researchers with special expertise will know how to interpret the information in the databases.

The information from your screening visit and physical examination, and the information learned from studying the DNA from your blood sample, will be placed in *controlled access* databases on the Internet (accessible only to researchers who have received prior approval to look at the information); this information will be coded and will not contain your name or any other traditional identifying information.

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

Because of the measures we are taking to protect your privacy, it will be very difficult for anyone who looks at any of the databases on the Internet 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.

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 – data that protects the identity of the person by referring to the person only by a set of numbers or letters, unrelated to the person's identity.

Communicable Disease – a disease that can be passed from one person to another

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 **Human subjects** – 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

Swabs – material used to collect specimens

NIH Human Microbiome Project Subject Information Sheet

Date of scheduled Baseline Sampling Visit: _____

During the indicated time periods before sample collection, you must NOT use the listed medications and cleansing products and you must AVOID the listed activities.

Six months before sample collection visit:

- Any antibiotic, antifungal, antiviral or antiparasitic drugs; by mouth, by injection or intravenous
- Any steroids; oral, intravenous, intramuscular, nasal or inhaled (such as prednisone, Flonase, dexamethasone, Flovent)
- Cytokines or drugs that can stimulate your immune system (such as Interleukin)
- Methotrexate or other agents that suppress your immune system (such as chemotherapy)
- Commercial probiotics in doses greater than or equal to 10^8 colony-forming units (cfu) or organisms per day, including tablets, capsules, lozenges, chewing gum or powders in which probiotic is a primary component. Note that it is acceptable to consume foods such as yogurt and fermented beverages/milks.
- for female subjects, combination hormone vaginal ring for contraception

Four weeks (28 days) before sample collection visit:

- Intranasal influenza vaccine (Note that flu shots are not included in this time restriction.)

Seven (7) days before sample collection visit:

Date to stop using products: _____

- Antibiotics or steroids applied as creams or ointments on the skin of the face, scalp, neck, arms, forearms or hands
- Vaginal or vulvar medications, including antifungals. Permitted vaginal contraceptives may be used until 48 hours before sample collection visit.

48 hours before sample collection visit:

Date and time to stop activities and use of products: _____

- Antimicrobial products including liquid hand soap, bar soap, face washes, hand or mouth washes, toothpaste (such as Softsoap, Dial, Zest, and Clearasil)
- Antiseptic products such as hand or mouth washes, toothpaste, perfumes and sanitizers (such as Listerine mouth wash and Purell hand wash)
- Hair dyes of any kind
- Use of a chlorinated pool or hot tub
- Vaginal, oral or anal sexual activity – This activity could introduce microorganisms to the mouth, the vagina or the lower gastrointestinal tract and could adversely affect the sampling from these sites.
- For women, douching, and use of contraceptive spermicides, diaphragms, cervical caps, contraceptive sponges, suppositories, feminine sprays, and genital wipes
- For women, menstrual blood flow should have stopped at least 48 hours before sampling.

12 hours before scheduled sample collection visit:

Date and time to stop activity:_____

- Showering, bathing, tooth brushing and flossing. Note that hand washing with soap provided in the personal care kit is allowable.

Acceptable Personal Care Products for the 48 Hours Prior to Sampling

Subjects enrolled in the Human Microbiome Project Protocol will be provided with a kit containing personal care products that are acceptable for use during the 48 hours prior to sampling. If you wish to use alternative products, please consult the following list of basic personal care products that do not contain antibacterial agents.

Soap	Camay Bar Soap (Procter & Gamble [P&G]) 100% Castile Soap (various specialty soap manufacturers) Ivory Classic Bar Soap (P&G) Olay Bar Soap (P&G) Tom's of Maine Natural Clear Body Bar Tone Bar Soap with Cocoa Butter (Henkel Corp)
Skin moisturizer	Aquaphor Healing Ointment (Eucerin) Johnson's Baby Oil (Johnson & Johnson [J&J]) Tone Hand and Body Lotion with Cocoa Butter (Henkel Corp) White Petrolatum (Vaseline)
Facial Cleanser	Aveeno Moisturizing Bar for Dry Skin (J&J) Neutrogena Original Formula Facial Cleansing Bar (J&J subsidiary) Oil of Olay Age Defying Series Daily Renewal Cleanser with Gentle Microbeads (P&G)
Shaving Cream	Old Spice Shave Cream (P&G) Gillette Series Gel – Ultra Comfort (P&G) Tom's of Maine Natural Conditioning Shave Cream
After-shave	Nivea for Men After Shave Extra Soothing Balm, Sensitive Skin (Nivea USA) Skintimate Moisturizing After Shave Gel (SCJohnson)
Shampoo	Pantene Pro-V Purity Clarifying Shampoo or Pantene Basic Care Classically Clean Shampoo (P&G) Pert Plus Deep Moisturizing Shampoo Plus Conditioner for Normal Hair (P&G) Walgreen's Pro-Vitamin Shampoo or Walgreen's Shampoo plus Conditioner for All Hair Types
Conditioner	Pantene Pro-V Sheer Volume Conditioner or Pantene Pro-V Daily Moisture Renewal Conditioner (P&G)
Toothpaste	Aquafresh Cavity Protection Toothpaste or Extra Fresh Toothpaste (GlaxoSmithKline) Crest Toothpaste varieties that do not contain Scope (P&G) Tom's of Maine Natural Anticavity Fluoride or Whole Care Toothpaste
Mouthwash	Homemade rinse of ½ tsp salt or ½ tsp baking soda in 8 ounces of water