

**Human Research Protection Office**Barnes-Jewish Hospital  
St. Louis Children's Hospital  
Washington UniversityMark Watson, MD, PhD  
Immunology (General)  
Box 8118

July 6, 2009

HRPO Number: 08-0754  
Title: Human Microbiome Project - Core Microbiome Sampling  
Funding Source: National Institute of Health (NIH)

This project was reviewed and approved by the Washington University Human Research Protection Office (HRPO) according to the terms and conditions described below:

- IRB Approval Date: 7/6/2009
- Expiration Date: 7/5/2010
- Research Risk Level: Minimal
- Reviewing Committee: 08 MRCC
- Type of Review: Minimal Risk Cont. Review (Expedited 9)
- HIPAA Compliance: Compliant with Authorization

Released for accrual.

HRPO complies with Federal regulations 45 CFR 46, 45 CFR 164, 21 CFR 50, and 21 CFR 56, which allow the use of an expedited review procedure for research which presents no more than minimal risk to human participants and meets the criteria for one or more of the categories of research published in the Federal Register. All actions and recommendations approved under expedited review are reported to a Full Committee.

You are expected to comply with the requirements outlined in the WU HRPO Assurance of Commitment and Policies Procedures (<https://hrpo.wustl.edu>). This includes reporting any unanticipated problems involving risk to research participants or others.

Changes in the conduct of the study, including the consent process or materials, require submission of an amendment application which must be approved by HRPO prior to implementation of the changes.

According to Federal regulations, this project requires IRB continuing review. As such, prior to the project expiration date above, you must submit either a Renewal or the Final Report. If you have questions or require additional information, please contact HRPO at (314) 633-7400 or [eIRB@msnotes.wustl.edu](mailto:eIRB@msnotes.wustl.edu).

Sincerely,



Philip A. Ludbrook, M.D.  
Executive Chair and Associate Dean



**INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY**

Participant's Name \_\_\_\_\_ HRPO # **08-0754**

Principal Investigator **Watson, Mark A. MD, PhD** PI's Phone Number **(314) 454-7919**  
Last First Credentials

Title of Project: **Human Microbiome Project (HMP): CORE MICROBIOME SAMPLING**

You are invited to take part in a research study by Dr. Watson 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 physical 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 250 healthy adult participants at 2 medical centers in the U.S.- approximately 125 participants will be recruited at Washington University and 125 participants at Baylor College of Medicine in Houston, TX.

### **3. What are the costs?**

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 (swab) 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 becomes 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 you are injured because you took part in this study?** Washington University investigators and 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. Mark Watson at (314) 454-7919 and/or the Human Research Protection Office Executive Chairperson, Dr. Philip Ludbrook at (314) 633-7400 or 1-(800)-438-0445.

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.

A Certificate of Confidentiality has been obtained 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. 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 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 share your information with:**

- The Department of Health and Human Services (DHHS) (including the Office for Human Research Protection or the Food and Drug Administration) to complete federal responsibilities for audit or evaluation of this study.
- The National Institutes of Health (NIH).
- 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 or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

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 use the direct link: <http://hrpohome.wustl.edu/participants/WithdrawalTemplate.rtf>) 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 Privacy 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: Mark Watson, MD, PhD  
 Mailing Address: 660 S. Euclid Ave., Campus Box 8118  
 Telephone: (314) 454-7919

If you wish to talk to someone else, or have questions or concerns about your rights as a research participant, call Dr. Philip Ludbrook, Executive Chair of Washington University’s Human Research Protection Office (WU HRPO) at (314) 633-7400, or 1-(800)-438-0445.

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? If yes, we will need to look at your Protected Health Information (PHI) to check for study eligibility.	<input type="checkbox"/> Yes	<input type="checkbox"/> No
2. May other WU physicians conducting research on the human microbiome contact you? If yes, your PHI will be shared with other WU physicians.	<input type="checkbox"/> Yes	<input type="checkbox"/> No
3. May other physicians outside WU conducting research on the human microbiome contact you? If yes, your PHI will be shared with other outside physicians.	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Taking part in future studies is optional. You can ask us at 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. Watson at Washington University, (314) 454-7919 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.**

10. You will be given a signed copy of this consent form for your records. If your ability to consent for yourself changes, you or your legal representative may be asked to re-consent prior to your continued participation in this study.

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](http://grants.nih.gov/grants/funding/women_min/women_min.htm))

**Research Participant:**

I have read this consent form and the accompanying information sheet, "Human Microbiome Sample Collection", and 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: \_\_\_\_\_

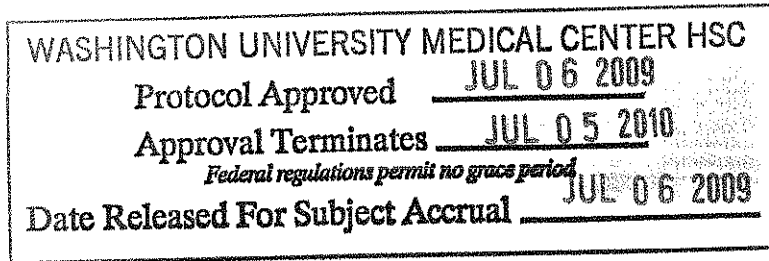
**Principal Investigator (or Designee):**

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: \_\_\_\_\_

**This form is valid only with the Human Research Protection Office's current stamp of approval.**



## Human Microbiome Project - Screening Script and Tool

### Script:

#### For volunteers located through a database search or through referral:

Hello, my name is \_\_ (insert your name) \_\_\_\_\_, and I am with Volunteer for Health at Washington University School of Medicine. I am calling to let you know about a clinical study for which you may qualify. The trial seeks to collect blood and specimens from multiple body sites in healthy volunteers. These specimens will be genetically analyzed to establish a baseline for discovery of the core bacteria typically found in various areas of the body. Would you like me to tell you more about this research?

If **"NO"**: Thank you so much for your time. Goodbye.

If **"YES"**: Great. As I mentioned, the goal of the study is to determine whether healthy individuals have the same types of bacteria growing on various body sites, specifically the oral cavity, skin, nasal cavity, GI tract and vagina. The information from this study can hopefully be used to help assess the differences in bacteria types in individuals who are diseased.

In order to determine your eligibility for this study, I need to ask you some confidential questions about your health history. This information will be used only for the purposes of conducting this research study. If you do pre-qualify for the study, I will forward your name and information to a study coordinator who will call you to schedule an appointment for you to be pre-screened. Do I have your permission to conduct the phone screening?

#### For volunteers who call in response to an advertisement:

Hello, my name is \_\_ (insert your name) \_\_\_\_\_, and I am with Volunteer for Health at Washington University School of Medicine. Thank you for your interest in the Human Microbiome Project. The trial seeks to collect blood and specimens from multiple body sites in healthy volunteers. These specimens will be genetically analyzed to establish a baseline for discovery of the core bacteria typically found in various areas of the body. Would you like me to tell you more about this research?

If **"NO"**: Thank you so much for your time. Goodbye.

If **"YES"**: Great. As I mentioned, the goal of the study is to determine whether healthy individuals have the same types of bacteria growing on various body sites, specifically the oral cavity, skin, nasal cavity, GI tract and vagina. The information from this study can hopefully be used to help assess the differences in bacteria types in individuals who are diseased.

In order to determine your eligibility for this study, I need to ask you some confidential questions about your health history. This information will be used only for purposes of conducting this research study. If you do pre-qualify for the study, I will forward your name and information to a study coordinator who will call you to a schedule an appointment for you to be pre-screened. Do I have your permission to conduct the phone screening?

## HMP Phone Screening Tool

Potential Participant Name: \_\_\_\_\_ M / F

Date Screened: \_\_\_\_\_

Screeener: \_\_\_\_\_

---

Are you between the age of 18 and 40 (inclusive)?  
(Must be YES) Yes No

Are you willing and able to provide a blood sample,  
as well as oral cavity, skin, nasal cavity and stool specimens?  
(FOR WOMEN: and vaginal)  
(Must be YES) Yes No

What is your current height? \_\_\_\_\_

What is your current weight? \_\_\_\_\_

Apply height and weight to body calculator.  
Is it between 18 and 35, inclusive?  
(Must be YES) Yes No

Have you had major abdominal surgery (with the exception  
of gallbladder or appendectomy) within the past 5 years?  
(Must be NO) Yes No

Do you have regular urinary incontinence that requires  
use of incontinence protection garments?  
(Must be NO) Yes No

Have you ever been positively tested for HIV, Hepatitis B or Hepatitis C?  
(Must be NO) Yes No

Have you been diagnosed with HPV (human papillomavirus)  
or condyloma (genital warts) within the past 2 years?  
(Must be NO) Yes No

Have you used any of the following prescription drugs or  
products within the last 6 months:  
-systemic antibiotics  
-oral, injected or inhaled corticosteroids  
-cytokines  
-methotrexate or immunosuppressive cytotoxic agents  
-large doses of commercial probiotics  
-for women, a combination hormone vaginal ring for contraception  
(Must be NO) Yes No

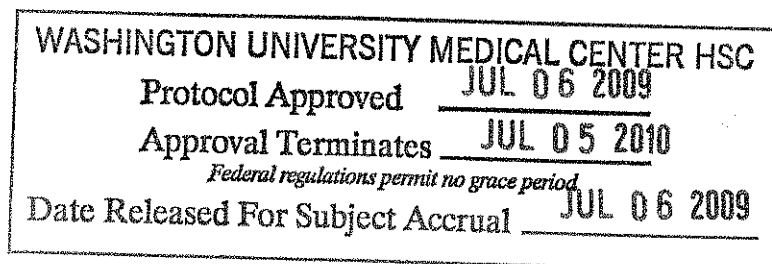
Do you have chronic dry mouth? (Must be NO)	Yes	No
Do you suffer from chronic, clinically significant pulmonary, cardiovascular, gastrointestinal, hepatic or renal function abnormality or disease (which has been diagnosed and requires ongoing medical management)? (Must be NO)	Yes	No
Are you currently suffering from any type of moderate or severe illness with or without fever? (Must be NO)	Yes	No
Have you had cancer (with the exception of squamous or basal cell carcinomas of the skin that have been removed)? (Must be NO)	Yes	No
Do you have any condition which causes your immune system to be compromised? (Must be NO)	Yes	No
Do you have a history of any of the following conditions? <ul style="list-style-type: none"> <li>-Inflammatory Bowel disease</li> <li>-Ulcerative colitis or indeterminate colitis</li> <li>-Crohn's disease</li> <li>-Irritable Bowel Syndrome (moderate-severe)</li> <li>-Persistent gastroenteritis, colitis or gastritis</li> <li>-Persistent diarrhea</li> <li>-Chronic constipation</li> <li>-Colorectal or gastric cancer</li> <li>-GI tract lymphoma</li> <li>-Any cancer of the GI tract</li> <li>-Unstable dietary history (major diet changes in last month)</li> <li>-Recurrent rashes in last 6 months</li> <li>-History of psoriasis or eczema</li> </ul> (Must be NO)	Yes	No
Do you have more than 8 missing teeth? (Must be NO)	Yes	No
Do you have any untreated cavities? (Must be NO)	Yes	No
Do you drink more than 5 drinks of alcohol per day? (Must be NO)	Yes	No

**For Women Only:**

Have you ever had toxic shock syndrome? (Must be NO)	Yes	No
Are you pregnant or lactating? (Must be NO)	Yes	No
Do you have a history of vulvar, vaginal or cervical dysplasia, in the past 5 years? (Must be NO)	Yes	No
Have you had an active STD (specifically chlamydia, gonorrhea, syphilis, genital herpes or trichomoniasis) within the past 2 months? (Must be NO)	Yes	No
Have you had a hysterectomy? (Must be NO)	Yes	No
Are you post-menopausal?	Yes	No
Do you have a regular menstrual cycle (21-35 days)? If NO, did you have regular menstrual cycles before beginning a contraceptive method that affected the cycle length?	Yes	No
	Yes	No

**If volunteer does not pass phone screening:** Based upon the information you have provided, it looks like you do not qualify for this study. The protected health information you have shared with me today will be destroyed in accordance with the guidelines set forth by the Human Research Protections Office at Washington University. That means Volunteer for Health will not keep your information or share it with anyone else. Thank you for your time.

**If volunteer passes phone screening:** Based upon the information you have provided, it looks like you may be a candidate for this study. In order to determine if you do qualify, I will need to schedule an appointment for you to come in and be pre-screened and examined by a study coordinator, by a dentist and (for women, by an ob/gyn). What times and days work best for you?




08-0154

# Human Microbiome Project – Core Microbiome Sampling Protocol A

**HMP Protocol Number:**  
HMP-07-001

**Sponsored by:**  
National Institutes of Health (NIH)

**NIH Funding Mechanism:**  
U54-HG003273 – Baylor College of Medicine  
U54-HG003079 – Washington University  
N01-HG-62088 - Coriell Institute of Medical Research

Approved <sup>PS</sup> JUL 06 2009  
  
Philip A. Ludbrook, M.D.  
Associate Dean and Chairman

**Draft or Version Number:**  
Version 5.0

**Date:**  
30 March 2009

**Principal Lead Sites:**

<b>Baylor College of Medicine</b>	
<p>James Versalovic, MD, PhD Baylor College of Medicine Texas Children's Hospital 6621 Fannin Street, MC 1-2261 Houston, TX 77030 (832) 824-2213 jamesv@bcm.edu</p>	<p>Wendy Keitel, MD Department of Molecular Virology and Microbiology Baylor College of Medicine 280 One Baylor Plaza Houston, TX 77030 (713) 798-5250 wkeitel@bcm.edu</p>
<b>Washington University</b>	
<p>Mark Watson, MD, PhD Washington University School of Medicine Campus Box 8118 660 S. Euclid Avenue St. Louis, MO 63110 (314) 454-7919 watsonm@wustl.edu</p>	<p>Michael Dunne, PhD Washington University School of Medicine 258A Barnes-Jewish Hospital Service Building St. Louis, MO 63110 (314) 362-1547 dunne@wustl.edu</p>