

Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Consent to participate in the Human Microbiome Project

H-22895- THE HUMAN MICROBIOME PROJECT (HMP): CORE MICROBIOME SAMPLING
PROTOCOL A

Background

You are invited to take part in a research study. Please read this information and feel free to ask any questions before you agree to take part.

Our bodies carry around trillions of microbes—bacteria, viruses, and other tiny living things. These microbes live in many places on and inside our bodies, such as the skin, mouth, nose, gut, and (in women) vagina. While we still don't know how they do it, many of these microbes help 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 we don't know about yet.

People and microbes both have nucleic acids (DNA and RNA), the material that contains genetic instructions. The microbes' genetic material affects how they live with each other and how they act in our bodies. Our own genetic material 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."

We invite you to participate in the Human Microbiome Project (HMP): a project to learn about the human microbiome and to put all the information that we learn in scientific databases available over the Internet, so that researchers around the world can use it in future studies related to health and disease. Many different researchers around the country are participating 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>.

This research study is sponsored by National Institutes of Health. This research study is funded by National Institutes of Health.

Purpose

In the first part of the HMP (the part we are inviting you to participate in), we will collect blood, oral, nasal, skin, stool, and (in women) vaginal samples from about 250 generally healthy 18-40 year old adults and study the genetic material (the DNA and possibly the RNA) in their microbes and the human DNA to develop a core resource. This core resource will form the foundation for the second part of the HMP, in which new samples from different people—some who are healthy and some who have certain diseases--will be collected and studied. By comparing the microbes in these two sets of samples with the microbes in the core resource, and by doing experiments to see how the microbes interact with each and with their human hosts, researchers will begin to understand more about the complicated relationships between microbes and many diseases. Many researchers in universities, hospitals, non-profit groups, companies, and government laboratories around the world will use the resource we develop.

Procedures

The research will be conducted at the following location(s): Baylor College of Medicine.

After you have had an opportunity to have your questions answered and have documented your interest

Protocol Version 7.0; 21SEP2009

CONSENT FORM

HIPAA Compliant

Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Consent to participate in the Human Microbiome Project

H-22895- THE HUMAN MICROBIOME PROJECT (HMP): CORE MICROBIOME SAMPLING PROTOCOL A

in and agreement to participate by signing this consent form, we will interview you about your background and general health history, and health care professionals will give you a physical examination, including a thorough dental examination, a detailed skin examination, and for women, an examination of the vagina. We will collect a blood sample (approximately 2 teaspoons, or 10mL) to test for the presence of active hepatitis B, hepatitis C and HIV infection. Women who are capable of bearing children will have a urine pregnancy test. The screening interview and examinations will help us determine whether or not you are eligible to give samples for the project. The screening visit and examinations will take about 1-2 hours.

We will contact you by electronic mail or telephone 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, then we will schedule a time for you to return after a minimum period of 48 hours following the screening visit. We will ask you to avoid certain activities or using certain products that could alter the microbes on and in your body for a certain period of time just before your next scheduled visit. The activities and products you must avoid, and how long you must avoid them, are explained on the accompanying Information Sheet.

We will send you a kit with instructions for self-collecting a stool sample, which you will bring in with you when you return. When you return, we will ask you some follow-up questions and perform some additional clinical evaluations in order to make sure you are still eligible to participate. If we find that you are still eligible, we will draw about two tablespoons of your blood (30mL). Trained medical professionals will then use simple swabs and/or scrapes to take samples of the microbes from your skin, mouth, nose, and (in women) vagina. This first sampling visit will take about 3-4 hours.

We will call you back within one year after your first sampling visit to reconfirm your willingness to participate in the project. If you are still willing to participate, we will ask you to give us a second set of samples from the same parts of your body and another stool sample (but not another blood sample). This second sampling visit will take about 3-4 hours.

We may invite some people back later to participate in separate studies related to the Human Microbiome Project. Some of these will take more extensive samples from the gut. However, if we invite you to join any one of these new studies, we will first ask you to sign a separate consent form.

What will happen to the information and samples you give us:

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

- 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 only to qualified researchers so that it can be used in many future studies.

Protocol Version 7.0; 21SEP2009

CONSENT FORM

HIPAA Compliant

Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Consent to participate in the Human Microbiome Project

H-22895- THE HUMAN MICROBIOME PROJECT (HMP): CORE MICROBIOME SAMPLING PROTOCOL A

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 genetic material by "sequencing" it (reading out the complete genetic code in each sample);
 - project researchers will make every effort to remove any human DNA data from the microbe genetic data to make it very hard for anyone who looks at the data about your microbe genetic material to tell anything about your human DNA);
 - project researchers will compare the genetic material they find in the samples with the genetic material 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 BCM 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 BCM 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).

This is what will happen to the first blood sample you give us (the sample you give 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; and
- * we will report the results of these tests to the health department, as required by law.

This is what will happen to the second blood sample you give us (the sample you give 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;

Protocol Version 7.0; 21SEP2009

CONSENT FORM

HIPAA Compliant

Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Consent to participate in the Human Microbiome Project

**H-22895- THE HUMAN MICROBIOME PROJECT (HMP): CORE MICROBIOME SAMPLING
PROTOCOL A**

- 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 only to qualified researchers so that it can 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 (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).

The BCM laboratory will process a portion of the blood to separate the serum from the blood cells. This serum will be stored for use in future research studies related to the human microbiome

BCM would like your permission to allow the serum sample to also be used in research unrelated to the human microbiome--such as in research that involves testing for antibodies against other viruses, bacteria or other microbes. This serum sample would be coded and stored at BCM. 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 your serum sample to be available for future research that is not necessarily related to the human microbiome. Your decision can be changed at any time by notifying the study doctors or nurses in writing. Your decision will not affect your participation in this project or in other studies.

Please initial below to indicate your decision about possible future use of your serum sample in research that is not related to the human microbiome (indicate only ONE option):

_____ YES, you may store my coded serum sample for an indefinite period of time for future research unrelated to the human microbiome.

_____ NO, you may not use my serum sample for future research unrelated to the human microbiome.

Your research doctor may never be able to provide you with your research related health information.

Potential Risks and Discomforts

You may be exposed to some physical discomforts or risks when we collect the samples, as follows:

Skin samples: Your skin may feel slightly irritated, or may turn temporarily red, near the place where we take the samples.

Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Consent to participate in the Human Microbiome Project

**H-22895- THE HUMAN MICROBIOME PROJECT (HMP): CORE MICROBIOME SAMPLING
PROTOCOL A**

Mouth samples: Your mouth may feel slightly dry for a short time (less than 5 minutes), and your gums may feel slightly tender.

Nose samples: Your nose may feel slightly irritated.

Stool sample: Your skin could get temporarily contaminated with some of the stool from the collection container.

Vaginal samples (women only): You may feel some embarrassment when we take the samples. You may have some discomfort during the sample collection, and your vagina may feel slightly irritated.

Blood sample: You may have some brief pain and bruising. There is also a small chance that you may get an infection, have excess bleeding, become dizzy, or faint.

The physical examinations we give you as part of your screening visit may make you feel embarrassed. Some questions that we ask may make you feel uncomfortable (especially, for women, questions about your sexual history). 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 samples from you.

There is a small risk that someone outside the project could learn some information about you. For example, this could happen if any of the following were to occur:

- a hacker violated the security of the computer that will store the codes that link your information to your name, or if a researcher accidentally disclosed the codes;
- we were required by law to disclose your information to someone outside the project; or
- somebody figured out how to link some of the information in the databases back to you.

When we study the DNA from your blood samples, we will generate data about your entire genetic code. Despite the measures we take to protect this data, and although there is now a federal law that prohibits genetic discrimination in health insurance and employment, there is a risk that somebody could learn some information about you and then try to use it to discriminate in some way against you or your family members. For example, genetic data from this study could possibly be used by a disability, life, or long term insurance company to deny you coverage, or by law enforcement officials to try 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.

A Certificate of Confidentiality has been obtained that will prevent BCM from being forced to disclose identifying information about you 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

Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Consent to participate in the Human Microbiome Project

**H-22895- THE HUMAN MICROBIOME PROJECT (HMP): CORE MICROBIOME SAMPLING
PROTOCOL A**

actively protect your own privacy. The Certificate also does not prevent us from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

We 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.

We cannot always foresee the results of research, so new risks may come up in the future that we cannot predict now.

If you decide to withdraw your permission before the samples are studied, the samples will be destroyed. If the samples have already been shared with other researchers, then we will try to get them back and destroy them, but this may not be possible if the samples have already been distributed widely. Once the samples have been studied and information has been placed in the database, the information from the study of the samples cannot be withdrawn; however, if you withdraw your permission, we will not put any NEW information into the database.

Study staff will update you in a timely way on any new information that may affect your decision to stay in the study.

Potential Benefits

You will receive no direct benefit from your participation in this study. However, your participation may help the investigators better understand more about the human microbiome and how it relates to health and disease. Many people get great satisfaction from making such a contribution to research.

As part of your screening visit, you will receive a physical examination by health care professionals. This examination will give you a free evaluation of your overall health status, and we will encourage you to consult with your usual health care provider, where appropriate

Alternatives

You may choose to not participate in this study.

Investigator Withdrawal of Subject from a Study

CONSENT FORM

HIPAA Compliant

Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Consent to participate in the Human Microbiome Project

H-22895- THE HUMAN MICROBIOME PROJECT (HMP): CORE MICROBIOME SAMPLING PROTOCOL A

The investigator or sponsor may decide to stop you from taking part in this study at any time. You could be removed from the study for reasons related only to you (for example, if you move to another city), or because the entire study is stopped. The sponsor, investigator, or Institutional Review Board may stop the study at any time.

Subject Costs and Payments

You will not be asked to pay any costs related to this research.

You will receive \$35 for the screening visit if all procedures are completed and a blood sample is collected for hepatitis B, hepatitis C, and HIV testing.

You will receive \$40 for each sample collected at the first sampling visit (blood, skin, nose, mouth, stool and vagina for women; \$240 for women and \$200 for men).

You will receive \$40 for each sample collected at the second sampling visit within approximately one year (skin, nose, mouth, stool and vagina for women; \$200 for women and \$160 for men)

Therefore, you will receive \$475 total (for women) or \$395 (for men) if all samples at all visits are collected.

This institution does not plan to pay royalties to you if a commercial product is developed from blood or tissue obtained from you during this study.

Subject's Rights

Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

Your Health Information

We may be collecting health information that could be linked to you (protected health information). This protected health information might have your name, address, social security number or something else that identifies you attached to it. Federal law wants us to get your permission to use your protected health information for this study. Your signature on this form means that you give us permission to use

Protocol Version 7.0; 21SEP2009

CONSENT FORM

HIPAA Compliant

Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Consent to participate in the Human Microbiome Project

H-22895- THE HUMAN MICROBIOME PROJECT (HMP): CORE MICROBIOME SAMPLING PROTOCOL A

your protected health information for this research study.

If you decide to take part in the study, your protected health information will not be given out except as allowed by law or as described in this form. Everyone working with your protected health information will work to keep this information private. The results of the data from the study may be published. However, you will not be identified by name.

People who give medical care and ensure quality from the institutions where the research is being done, the sponsor(s) listed in the sections above, representatives of the sponsor, and regulatory agencies such as the U.S. Department of Health and Human Services will be allowed to look at sections of your medical and research records related to this study. Because of the need for the investigator and study staff to release information to these parties, complete privacy cannot be guaranteed.

The people listed above will be able to access your information for as long as they need to, even after the study is completed.

If you decide to stop taking part in the study or if you are removed from the study, you may decide that you no longer allow protected health information that identifies you to be used in this research study. Contact the study staff to tell them of this decision, and they will give you an address so that you can inform the investigator in writing. The investigator will honor your decision unless not being able to use your identifiable health information would affect the safety or quality of the research study.

The investigator, WENDY A. KEITEL, and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: WENDY A. KEITEL or her staff at 713-798-4912 during the day or after hours.

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The IRB office number is (713) 798-6970. Call the IRB office if you would like to speak to a person independent of the investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

CONSENT FORM

HIPAA Compliant

Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Consent to participate in the Human Microbiome Project

H-22895- THE HUMAN MICROBIOME PROJECT (HMP): CORE MICROBIOME SAMPLING
PROTOCOL A

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

Subject

Date

Investigator or Designee Obtaining Consent

Date

Witness (if applicable)

Date

Translator (if applicable)

Date

Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals**AMENDMENT**

Protocol Number: H-22895
Principal Investigator: WENDY A. KEITEL
Initial Submit Date: 06/03/2008
Amendment Submit Date: 09/23/2009
Protocol Title: THE HUMAN MICROBIOME PROJECT (HMP): CORE MICROBIOME SAMPLING PROTOCOL A

Reason: Other Amendment

Description: The purpose of this amendment is to revise slightly the exclusion criteria to include receipt of live attenuated flu vaccine within the previous 28 days, as this may influence the nasal flora. This minor revision does not affect the consent form, as these issues are addressed in the screening script, screening visit, and subject information sheet.

This change has been incorporated into the protocol (now version 7.0), Subject Information Sheet (now v. 6.0), Manual of Procedures (now V. 9.0), and screening script (now v.4.0). In addition to these documents, the summary of protocol changes (v. 7.0), study document changes, and summary of MOP changes (v.9.0) are also attached for your review and approval.


There are no substantial changes to the consent form. I have added the eligible age range of subjects which inadvertently was omitted (18-40 years), and updated the footer to reflect the protocol version.



Baylor College of Medicine
Office of Research
One Baylor Plaza, 600D
Houston, Texas 77030
Phone : (713) 798-6970
Fax: (713) 798-6990
Email: irb@bcm.tmc.edu

MEMORANDUM

TO: WENDY A. KEITEL
MOLECULAR VIROLOGY & MICROBIOLOGY

FROM: JULIE PAMELA KATKIN, M.D. 
Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

DATE: October 07, 2009

RE: **H-22895 - THE HUMAN MICROBIOME PROJECT (HMP): CORE MICROBIOME SAMPLING
PROTOCOL A**

Your amendment, detailed below, has been reviewed and approved. NOTE: Approved advertisement(s) should only be posted at the institution(s) where the research is being performed including approved recruitment site(s). This is not applicable to the following advertisement modes: billboards, radio, television, internet, or website.

Description:

The purpose of this amendment is to revise slightly the exclusion criteria to include receipt of live attenuated flu vaccine within the previous 28 days, as this may influence the nasal flora. This minor revision does not affect the consent form, as these issues are addressed in the screening script, screening visit, and subject information sheet.

This change has been incorporated into the protocol (now version 7.0), Subject Information Sheet (now v. 6.0), Manual of Procedures (now V. 9.0), and screening script (now v.4.0). In addition to these documents, the summary of protocol changes (v. 7.0), study document changes, and summary of MOP changes (v.9.0) are also attached for your review and approval.

There are no substantial changes to the consent form. I have added the eligible age range of subjects which inadvertently was omitted (18-40 years), and updated the footer to reflect the protocol version.

October 07, 2009



WENDY A. KEITEL
BAYLOR COLLEGE OF MEDICINE
MOLECULAR VIROLOGY & MICROBIOLOGY

Baylor College of Medicine
Office of Research
One Baylor Plaza, 600D
Houston, Texas 77030
Phone: (713) 798-6970
Fax: (713) 798-6990
Email: irb@bcm.tmc.edu

**H-22895 - THE HUMAN MICROBIOME PROJECT (HMP): CORE MICROBIOME SAMPLING PROTOCOL A
APPROVAL VALID FROM 4/22/2009 TO 4/21/2010**

Dear Dr. KEITEL

The Institutional Review Board for Human Subject Research for Baylor College of Medicine and Affiliated Hospitals (BCM IRB) is pleased to inform you that the research protocol and consent form(s) named above were approved.

The study may not continue after the approval period without additional IRB review and approval for continuation. You will receive an email renewal reminder notice prior to study expiration; however, it is your responsibility to assure that this study is not conducted beyond the expiration date.

Please be aware that only IRB-approved informed consent forms may be used when written informed consent is required.

Any changes in study or informed consent procedure must receive review and approval prior to implementation unless the change is necessary for the safety of subjects. In addition, you must inform the IRB of adverse events encountered during the study or of any new and significant information that may impact a research participants' safety or willingness to continue in your study.

The BCM IRB is organized, operates, and is registered with the United States Office for Human Research Protections according to the regulations codified in the United States Code of Federal Regulations at 45 CFR 46 and 21 CFR 56. The BCM IRB operates under the BCM Federal Wide Assurance No. 00000286, as well as those of hospitals and institutions affiliated with the College.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Julie P. Katkin, M.D.", written in a cursive style.

JULIE PAMELA KATKIN, M.D.

Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals



View Attachments

Attachment	File Name	File Size	Uplo:
Section F2: Procedure	090923152203IRB attachment describing sample dispositon.doc	60928	9/23/2
Section J1a: Questionnaire Cover Sheet	090923152203HMP Products List.xls	67584	9/23/2
Z_attachment name no longer in use	090923152204HMP_Protocol_Version_2_0_052208.doc	428032	9/23/2
Z_attachment name no longer in use	090923152205Subject_Info_Sheet_v1.0_062608.doc	81920	9/23/2
Section K: Certificate of Confidentiality 2	090923152205CoC.pdf	1218017	9/23/2
Z_attachment name no longer in use	090923152206Human Microbiome Project script wak edit.doc	43520	9/23/2
Z_attachment name no longer in use	090923152206Human Microbiome Project script v.2.0.doc	46592	9/23/2
Z_attachment name no longer in use	090923152206HMP_Subject_Information_Sheet_v2_0_101708(2).doc	246784	9/23/2
Z_attachment name no longer in use	090923152206HMP_Subject_Information_Sheet_v3.0_111008.doc	247296	9/23/2
Z_attachment name no longer in use	090923152207HMP_Protocol_Version_3_0_111008.doc	445952	9/23/2
Z_attachment name no longer in use	090923152207HMP_Protocol_changes_v3.0_111008.doc	51200	9/23/2
Z_attachment name no longer in use	090923152207Permission to Contact(1).doc	25600	9/23/2
Z_attachment name no longer in use	090923152207Personal Care Products Information_111208.doc	258560	9/23/2
Z_attachment name no longer in use	090923152207HMP_Subject_Information_Sheet_v4.0_111708.doc	247808	9/23/2
Z_attachment name no longer in use	090923152207HMP_Protocol_Version_4_0_111708.doc	448512	9/23/2
Z_attachment name no longer in use	090923152207HMP_Screening_Script_V2.0_111708.doc	44544	9/23/2
Z_attachment name no longer in use	090923152207HMP_Protocol_changes_v4.0_final_111708.doc	59904	9/23/2
Z_attachment name no longer in use	090923152208BCM Human Microbiome Project telephone screening script v.3.0.doc	48640	9/23/2
Z_attachment name no longer in use	090923152208HMP_Protocol_Version_5_0_033009.doc	431104	9/23/2
Z_attachment name no longer in use	090923152208HMP_Protocol_changes_V5.0_033009.doc	32768	9/23/2
Z_attachment name no longer in use	090923152208HMPMOPchangesVersion6percent.pdf	626010	9/23/2
Z_attachment name no longer in use	090923152208HMP_Screening_Script_V3.0_072809.doc	45568	9/23/2
Z_attachment name no longer in use	090923152208Third_Sampling_Subject_Info_V1_0_072809.doc	248320	9/23/2
Z_attachment name no longer in use	090923152208HMP_Subject_Information_Sheet_v5.0_072809.doc	247808	9/23/2
Z_attachment name no longer in use	090923152209HMP_Study_Document_Changes_072809.doc	33792	9/23/2
Z_attachment name no longer in use	090923152209HMP_Protocol_Version_6_0_072809.doc	455168	9/23/2
Z_attachment name no longer in use			

use	090923152209HMP_Protocol_changes_V6.0_072809.doc	51200	9/23/20
Z_attachment name no longer in use	090923152209HMP_MOP_Version8_0_072809.doc	2054656	9/23/20
Z_attachment name no longer in use	090923152211HMP_MOP_changes_V8.0_072809.doc	47104	9/23/20
Z_Additional Attachments	HMP_Subject_Information_Sheet_v6.0_092109.doc	252928	9/23/20
Z_additional attachments	HMP_Study_Document_Changes_092109.doc	33280	9/23/20
Z_additional attachments	HMP_Protocol_changes_V7.0_092109.doc	41472	9/23/20
Z_additional attachments	HMP_Screening_Script_V4.0_092109.doc	46080	9/23/20
Z_additional attachments	HMP_MOP_Version9_0_092109.doc	2141184	9/23/20
Z_attachment name no longer in use	HMP_Protocol_Version_7_0_092109.doc	444928	9/23/20
Z_attachment name no longer in use	HMP_MOP_changes_V9.0_092109.doc	40960	9/23/20



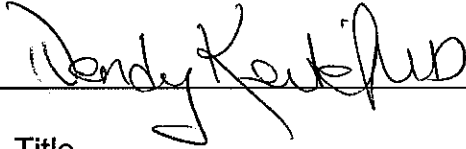
Signature Page

I have read the protocol, including all of the appendices and the Manual of Procedures. I agree that these documents contain all of the necessary information to conduct this study as described. I will conduct this study as outlined herein, in accordance with the regulations stated in the Federal Code of Regulations for Protection of Human Subjects Title 45 and the International Conference on Harmonisation Good Clinical Practices Guidelines (E6), and will make a reasonable effort to complete the study within the time designated.

Clinical Site Principal Investigator:

Signed:

Date:



Title

