UNIVERSITY OF PENNSYLVANIA
RESEARCH SUBJECT
INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title: REcovery of the MicroBiome from ANtibiotics for Dental implanTs (REMBRANDT)

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Research Study Summary for Potential Subjects

You are being invited to participate in a research study. Your participation is voluntary, and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

The research study is being conducted to determine whether pet ownership impacts disruption of the gut microbiome following antibiotic therapy and the risk of C. difficile (C. diff) infection.

If you agree to join the study, you will be asked to complete the following research procedures:
1) Answer a series of questions about yourself
2) Send in stool samples on a total of five days (before you undergo the implant procedure, then 3, 10, 30 and 90 days thereafter).
3) If you have pets, we will ask you to send in a stool sample from one of your pets and answer some questions about them.

Your participation will end after you have completed these research procedures.
The information that we gather may help us to provide invaluable data on ways of preventing C. diff infection.
You will receive payments up to a total of $100 at different points of the study.

Please note that there are other factors to consider before agreeing to participate such as additional procedures, use of your personal information, costs, and other possible risks not discussed here. If you are interested in participating, a member of the study team will review the full information with you. You are free to decline or stop participation at any time during or after the initial consenting process.

Why am I being asked to volunteer?
You are being invited to participate in a research study because you will be taking a course of antibiotic therapy at the University of Pennsylvania School of Dental Medicine.

You do not have to participate in any research study. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. You may also decide to discuss the study with your family, friends, or family doctor. Being in a research study is different from being a patient. If you decide to participate, you will be asked to sign this form.

What is the purpose of this research study?
The purpose of this research study is to determine whether owning pets reduces the risk of gut microbiome disruption associated with antibiotic therapy.

How long will I be in the study?
Being in the study requires you to send in a total of five rectal swabs from yourself, with the last being sent 90 days after you begin your antibiotics. We are planning to enroll approximately 200 participants over the course of 4 years.

What am I being asked to do?
1) Answer a series of questions about yourself
2) Send in stool samples on a total of five days (before undergoing your implant procedure, then 3, 10, 30, and 90 thereafter).
3) If you have pets, we will ask you to send in a stool sample from one of your pets and answer some questions about them.

We will provide you with collection kits and detailed instructions on how to collect, store and ship the samples back to us. All costs associated with this process are covered by the study. You will not have to pay for anything.

What are the possible risks or discomforts?
The risks to the study include potential loss of confidentiality, though all measures will be taken to ensure that your information is kept confidential, and only the principal investigator, the study team and the IRB may use or share your information.

What if new information becomes available about the study?
During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?
You are not expected to get any benefit from being in this research study.

What other choices do I have if I do not participate?
You can choose not to participate in the study.

Will I be paid for being in this study?

You will receive $25 on a Clincard at enrollment, $25 upon receipt of your third sample, and $50 upon completion of the study.

Will I have to pay for anything?

No. All costs associated with shipping us a stool sample will be covered by the study.

Will I receive the results of research testing?

Most tests done in research studies are only for research and have no clear meaning for health care. Research results for this study will not be returned to you because they would not be relevant to your healthcare.

When is the Study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all research tasks, and all information has been collected. This study may also be stopped at any time by the investigator or the study Sponsor without your consent because:

- The Primary Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The Sponsor, the study Principal Investigatorhas decided to stop the study.

If you decide to participate, you are free to leave the study at anytime. Withdrawal will not interfere with your future care.

How will my personal information be protected during the study?

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. The Institutional Review Board (IRB) at the University of Pennsylvania will have access to your records. All data collected will be stored in password-protected, encrypted, University-controlled databases.

What may happen to my information and samples collected on this study?

Your samples may be used to create products, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

Whole genome sequencing will not be conducted on your samples. Whole genome sequencing involves analyzing your entire personal genetic code.

Future Use of Data and/or Specimens

Your information and samples will be stored for future research purposes.
Future researchers may receive information that could identify you. This can be done without again seeking your consent in the future, as permitted by law. The future use of your information and samples only applies to the information and samples collected on this study.

The following identifiers will be retained with your information and samples: Date of birth, phone number, email address.

Your information and samples may be stored and used for future research purposes for a period of three years. There are no plans to tell you about any of the specific research that will be done.
We may share your identifiable information and samples with other researchers within Penn, or other research institutions, as well as pharmaceutical, device, or biotechnology companies.

We will not follow up with you to tell you about the specific research that will be done. We will not give you any results from these studies. It is possible that you may have chosen not to participate in these future research studies, had you been approached for participation.

There is a risk of breach of confidentiality (unintentional release of your information). We will do our best to make sure that this doesn't happen. However, we cannot guarantee total privacy. We will protect your confidentiality during storage and sharing by maintain data in password-protected, encrypted databases and stool samples in locked storage units.

You will likely not directly benefit from future research with your information and samples. Research with your identifiable information and samples may help others by improving our understanding of health and disease, improving health care and making safer or more effective medical therapies, and developing new scientific knowledge.

If you have questions about the storage of your information and samples, or have changed your mind, you can contact Laurel Redding at 484-999-1545
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Why is my information being used?

Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- do the research
- oversee the research
- to see if the research was done right
- to evaluate and manage research functions.

Who may use and share information about me?

The following individuals may use or share your information for this research study:

- The investigator for the study and the study team
- Other authorized personnel at Penn, including offices that support research operations

- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB
- Your personal health information will **not** be disclosed to anyone not involved with the study or outside of the University of Pennsylvania

How long may the School of Medicine use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?

Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the investigator for the study. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study.

By signing this document, you are permitting the School of Veterinary Medicine to use and disclose personal health information collected about you for research purposes as described above.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the IRB at the number on page one of this form.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you.

Print Name of Subject_____

Signature of Subject _____

Date _____

Print Name of Person obtaining consent_____

Signature of Person obtaining consent_____

Date_____