IRB Review
IRB NUMBER: 21-072-2
IRB APPROVAL DATE: 07/21/2025

Microbiome Data Collection Form-Tonsils

Date:

Patient ID:

Diagnosis:

Duration of symptoms:

Obstructive symptoms? **Recurrent Infections?** **Both?**

Previous antibiotics in last year (list abx, route of administration, duration, frequency):

Previous antibiotics in last month (list abx, route of administration, duration, frequency):

Previous culture results:

History of Peri-tonsillar Abscess? **Required drainage?**

History of tonsil stones?

Previous surgeries:

Past medical history:

Smoking:

Other Relevant:

IRB Number: 21-0721J-2

INFORMED CONSENT FORM FOR RESEARCH STUDY

Title of Study: Comprehensive, Descriptive Study of the Ear, Nose, and Throat Mucosal Microbiome

Principal Investigator (PI): Daniel Roberts, M.D., PhD

PI Phone Number: 860-679-2804

Co-Investigator(s): Yanjiou Zhou, MD**;** Kourosh Parham, MD, PhD; Denis Lafreniere, MD; Jeffrey Spiro, MD; Hailun Wang, MD; Seth Brown, MD; Belachew Tessema, MD; Todd Falcone, MD , Nehal Navali, Grace Nichols, Khalil Rahman, MD, Davis Aasen, MD

Sponsor: None

Significant Financial Interest: Dr. Yanjiou Zhou has disclosed Significant Financial Interest in this study due to being a founder of General Biomics.

Name of Research Participant: _____

Overview of the Research

The microbiome includes bacteria, viruses, parasites, fungi, and all other organisms living on the surface of the human body. This has been studied in other fields, notably in the gut. We aim to study the microbiome of the human body in the surfaces of the ears, nose, and throat. Your participation in this study will help us to understand the basic microbiome in healthy patients in addition to understand possible differences of the microbiome in patients with certain chronic diseases. Understanding these differences may lead to improved identification of patients susceptible to these conditions as well as possible treatments. Your participation involves a single sample obtained during a medical procedure that has already been planned for your care. If you have taken antibiotics within the last 7 days, you will not be able to participate. Participation involves allowing researchers access to your medical record to gather information regarding medical conditions that may be related to the microbiome sample results. You are being invited to participate in this study to investigate the microbiome of the head and neck, including the ears, sinuses, tonsils, and larynx. Sample collections will be performed under the direction of Dr. Daniel Roberts, in the UConn Health Ear, Nose and Throat/Otolaryngology department. Sample processing will be conducted in UCHC Labs under the direction of Dr. Yanjiou Zhou.

Purpose of This Research

The study aims to explore the differences in the microbiome between patients with chronic infections/diseases compared to healthy counterparts, to see how these baseline differences can lead to differences in health. We will recruit 210 people to collect samples.

Confidentiality

If you agree to take part in the study, personal information about your health and your treatment will be collected and recorded by the study doctor. We will do our best to protect the confidentiality of the information we gather from you, but we cannot guarantee 100% confidentiality. Your research records, which contain information about your participation in this study and the results of procedures performed in this study, along with this consent form will not be part of your designated medical record. The study staff (principal investigator, research coordinator, coinvestigators etc.) will keep all physical research records locked in a secure location. These research records will not identify you by name; they will be labeled with a code. The code will be a 3 digit number that reflects how many people have enrolled in the study. Electronic research records will be stored encrypted. A master key, which links this code and your name, will be maintained in a separate and secure location. You should know that the Department of Health and Human Services (DHHS), the Food and Drug Administration (FDA), and the Health Center's Institutional Review Board and the Human Subjects Protection Office may inspect these records. They may inspect records to ensure that the study is being done correctly. In addition, your identity will not be revealed in any presentations or publication based on the results of the research study.

Study Procedures

Your participation in this study will involve sampling of one subsite from the four sites of interest in this study. The sites of interest include: outer and middle (past the eardrum) ears, sinuses, tonsils, and larynx (voice box). Outer ear samples will be taken in clinic. Middle ear samples will be taken under general anesthesia. Sinus swabs will be taken during anesthesia. Healthy tonsils will be swabbed in clinic. Chronic tonsillitis swabs will be taken after induction of general anesthesia, prior to tonsillectomy. Laryngeal samples will be taken after induction of general anesthesia. Patients will only have samples taken for one subsite. The subsite will be determined based upon your chief complaint and state of health. You may be asked to participate as a patient with frequent infections or disease of a certain subsite. You may be asked to participate as a healthy patient without any history of infections or abnormalities of the given subsite. If you agree to participate, a sample will be collected upon your scheduled appointment in the UConn Health Ear, Nose and Throat/Otolaryngology department. The visit will include sample collection during which time a swab stick will be used to obtain the sample from the site identified, if the site is the outer ear or a healthy tonsil. The swab stick will be rubbed on the area for approximately 5 seconds, but may be up to 30 seconds. For patients who are candidates for sample collection under anesthesia, such as those sampling from the middle ear, chronic tonsillitis patients, or those who will be providing larynx samples, we will conduct the sample collection at the time of the planned procedure. In these cases, surgery will be performed routinely as would otherwise be performed. The swab will be rubbed back and forth carefully on the surface for about 5 seconds. Additional time spent under anesthesia for the collection of sample will be about 5 seconds, but may be up to 30 seconds. Samples will be stored in a locked container within the UCHC Laboratory.

Microbiome study ICF 2

Risks Associated with the Study

The specimen collection process utilizes a swab stick and is safe with minimal risk. All samples will be obtained by a licensed physician. There is a small risk of bleeding from the site of sample collection. This will be prevented by taking samples gently and closely observing the site during sample collection. If bleeding does occur, pressure will be applied to the site until bleeding has stopped. There is a risk of an additional 5-30 seconds of anesthesia time if your sample is collected under anesthesia. Sample will be obtained as quickly as safely possible. For awake patients, there is a risk of discomfort. There is a small risk of confidentiality breach if the master key is breached. However, as mentioned above, these records will only be available to the coinvestigators and will otherwise be locked and encrypted. The procedure may involve risks that are currently unforeseeable. UConn Health does not provide insurance coverage to compensate subjects if injured during this research. However, compensation may still be available by filing a claim against the State of Connecticut. For a description of this process, contact a representative of UConn Health's Institutional Review Board (IRB) at 860-679-4849 or 860-679-8729. UConn Health does not offer free care. However, treatment for a research related injury may be obtained at UConn Health for the usual fee. Your patient care will not change as a result of enrolling or declining to enroll in this study. We may compare other information in your chart when analyzing data, such as other medical conditions, medications you are taking, previous surgeries, family history, prior culture results, and smoking status. Any information used will be in no way linked to your identity. Enrolling is entirely voluntary.

Benefits Associated with the Study

You will not personally benefit from this study. The goal is to be able to further characterize the microbiome of healthy versus chronically infected patients. This will help us develop a deeper understanding of the etiologies and characteristics of disease processes in the head and neck.

Compensation

No compensation will be offered to you for participating in this study

Cost

There are no charges to you for participation in this study, nor will there be any expenses or charges to your insurer for the testing. Your insurance will be billed for the standard of care procedures and service rendered at the time of your clinic or surgical visit outside of involvement in the study.

Study Participation, Length of Participation, and Termination

Your decision to take part in this study is entirely voluntary. You may not participate in this study if you have taken antibiotics within the past 7 days. If you decide not to participate your routine medical care at UConn Health/John Dempsey Hospital will not be affected in any way. There will be no penalty to you, and you will not lose any benefits that you are entitled to. You may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. Your participation will involve a short (few minute) swab and your active involvement will end after swabbing. Your participation may be terminated by the investigator without regard to consent if the sample obtained is contaminated or if an adverse event occurs that affects your health.

Specimens

The specimens you provide will be coded and remain confidential. Each specimen will be linked to a participant ID based on the order in which you enroll in the study. The masterkey linking the code will be separately located in an encrypted database. The specimens will be labeled with the participant ID and the subsite of collection when sent to Dr. Zhou's Laboratory. These specimens may contribute to subsequent research projects and/or may contribute to data collected and stored on online databases. If they are included for subsequent research projects, they will be de-identified, meaning all information that would identify you as an individual will not be included such that the samples cannot be traced back to you. Additionally, data collected from these specimens may result in generating revenue for the investigators or institution without any reimbursement to the participant. You may elect to have your specimens either discarded at the conclusion of this study or remain in use for future studies. If you elect to have your specimens remain in use, identifiers will be removed from the specimen. After such removal, the specimen can be used for further research studies or distributed to another investigator for future research studies without additional informed consent from the subject.

What if I have Questions?

The Principal Investigator is willing to answer any questions you have about the research. Dr. Roberts can be contacted at 860-679-2804. You are encouraged to ask questions before deciding whether to take part. You are also encouraged to ask questions during your study participation. If you have questions, complaints, or concerns about the research, you should call the Principal Investigator. You may also call a coordinator at the Institutional Review Board if you want to talk to someone who is not a member of the research team in order to pass along any suggestions, complaints, concerns or compliments about your involvement in the research, or to ask general questions or obtain information about participation in clinical research studies. The Institutional Review Board can be reached at 860-679-4849 or 860- 679-8729. Please do not call the Research Subject Advocate or IRB number for medical related issues or to schedule or cancel an appointment.

Consent to Participate

By signing this form, you acknowledge that you have read, or have had read to you, this informed consent document, have talked with research personnel about this study, have been given the opportunity to ask questions and have them satisfactorily answered, and voluntarily consent to participate in this project as described in this form. You have the opportunity to provide feedback if desired by contacting any of the numbers provided above.

Microbiome study ICF 4

Please indicate the site of collection:

o Ears (Middle and Outer) o Sinonasal o Tonsils o Larynx

If you choose option 2 below, your sample will still be de-identified. Following this study, the specimen may be used for further research studies or distributed to another investigator for future studies without additional informed consent.

Please initial your preference:

1. Discard sample at the conclusion of this study _____

2. Sample may be used for future studies _____

_____
(Participant) type or print name Date

_____
Signature

By signing this form you (the participant, legally authorized representative, parent(s) or guardian) acknowledge that you have read, or have had read to you, this informed consent document, have talked with research personnel about this study, have been given the opportunity to ask questions and have them satisfactorily answered, and voluntarily consent to participate in this project as described in this form. You acknowledge that you have the opportunity to voluntarily provide feedback about your experience as a research participant. You may ask for a copy of the Research Participant Feedback Form, you may obtain the form online at https://ovpr.uchc.edu/services/rics/hspp/volunteers/, or you may submit the form online at https://redcap.link/UConnHealth-Feedback-Research .

_____
(Consentor) type or print name Date

_____
Signature of Consentor

By signing this form the individual obtaining consent is confirming that the above information has been explained to the subject (and/or legally authorized representative, parents or legal guardians) and that a copy of this document, signed and dated by both the person giving consent and the person obtaining consent, along with a copy of the Research Feedback Form if requested, will be provided to the participant and/or representative.

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES

Information About the Research Study

Dr. Dan Roberts and his staff are conducting a research study called **Comprehensive, Descriptive Study of the Ear, Nose, and Throat Mucosal Microbiome**. The purpose of the study is to characterize the microbiome of the head and neck in healthy populations and compare to disease states.

Voluntary Status

Because of a federal law called the Health Insurance Portability & Accountability Act (HIPAA), we must get your permission to use and disclose your identifiable health information for this research study. This form is used to document that permission. Because of HIPAA you must also receive a copy of UConn Health's rules about privacy.

Your decision whether to give permission is voluntary. The only consequence of not granting permission is that you will not be allowed to participate in this research study. Your decision has no impact on your treatment, payment, or enrollment in any health plans, or effect on your eligibility for benefits

Information That Will be Used / Disclosed

The following information about you may be used and disclosed for the purpose of this research study:

- Data results from the swabs collected
- Name
- Medical Record Number
- Date of birth
- Diagnosis
- Past medical history
- Descriptors of disease process
- Procedures completed at time of sample collection

How the Information Will be Used / Disclosed

The information noted above will be used and disclosed for the following purpose(s):

- To characterize the microbiome of the head and neck in healthy and disease states

People/Offices That Will Have Access to Your Information
The following people/entities may use and disclose your protected health information.

- Dr. Dan Roberts and his staff
- UConn Health's Institutional Review Board and Human Subjects Protection Program
- UConn Health authorized representatives.
- Government representatives, such as the Food & Drug Administration or Office for Human Research Protections; when required by law.

The researchers and staff agree to protect your information by using and disclosing it only as stated in this document and as directed by state and federal law

Once your health information has been disclosed outside of this institution (for example to an external sponsor or collaborating institution) the information may no longer be protected under this authorization.

Reasons to share your information are to be able to conduct research, and to ensure that the research meets legal, institutional and/or accreditation requirements.

Right to Access Information
You may not be allowed to review the information collected for this research project. You do have the right to request that your medical record be released per your written direction.

Expiration of Permission
Your permission to use and disclose your protected health information expires upon completion of the research study.

How to Withdraw Permission
You can withdraw your permission at any time by sending a letter to Dr. Dan Roberts to inform him. If you withdraw your permission, you will no longer be allowed to participate in this study. If you withdraw your permission the PI and his staff will no longer be able to use and disclose your protected health information. There are exceptions to this. For example, the researchers may continue to use and disclose the protected health information that was collected for the research study prior to receiving the request to withdraw your permission.

Questions or Complaints
If you have any questions, concerns or complaints about your privacy rights, you may write to UConn Health's Privacy Office, 263 Farmington Avenue, Farmington, CT 06030-5329. If you have a complaint, you may also write to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, U.S. Dept. of Health and Human Services Government Center, J.F. Kennedy Federal Building, Room 1875, Boston MA 02203. Complaints should be sent within 180 days of when you knew, or should have known, of the problem.

State of Connecticut Requirement

In this study we are not asking for information about AIDS, HIV infection, behavioral health services, psychiatric care, or treatment for alcohol and/or drug abuse. If this information pertains to you, you should know there is a slight chance that it may be inadvertently disclosed during the course of the study. The State of Connecticut statutes require that any release of information pertaining to AIDS, HIV infection, behavioral health services, psychiatric care, or treatment for alcohol and/or drug abuse be specifically authorized. By signing this dual-purpose authorization you acknowledge that there is a chance that this information may be subject to use and/or disclosure as it relates to this project.

Permission for Use and Disclosure of Information

You are a voluntary participant in this research study. By signing you acknowledge that you have read this form, had the opportunity to ask questions, and obtain satisfactory explanations, and that you authorize the use and disclosure of protected health information as described in this form. You will receive a copy of this form after it is signed.

Commercial Value:

Medical research may result in new products, tests or discoveries. These may have commercial value and may be developed and owned by UConn Health, its faculty and/or others. Please initial to acknowledge that the intent that you will not share in the financial benefits, if any, from these products tests or discoveries has been explained to you.

_____You acknowledge that the provision that you will not share in the financial benefits, if any, from these products tests or discoveries has been explained.

_____

Signature of the research participant Date

_____

Printed name of the research participant

IRB Number: 21-0721J-2

INFORMED CONSENT FORM FOR RESEARCH STUDY

Title of Study: Comprehensive, Descriptive Study of the Ear, Nose, and Throat Mucosal Microbiome

Principal Investigator (PI): Daniel Roberts, M.D., PhD

PI Phone Number: 860-679-2804

Co-Investigator(s): Yanjiou Zhou, MD**;** Kourosh Parham, MD, PhD; Denis Lafreniere, MD; Jeffrey Spiro, MD; Hailun Wang, MD; Seth Brown, MD; Belachew Tessema, MD; Todd Falcone, MD , Nehal Navali, Grace Nichols, Khalil Rahman, MD, Davis Aasen, MD

Sponsor: None

Significant Financial Interest: Dr. Yanjiou Zhou has disclosed Significant Financial Interest in this study due to being a founder of General Biomics.

Name of Research Participant: _____

Overview of the Research

The microbiome includes bacteria, viruses, parasites, fungi, and all other organisms living on the surface of the human body. This has been studied in other fields, notably in the gut. We aim to study the microbiome of the human body in the surfaces of the ears, nose, and throat. Your participation in this study will help us to understand the basic microbiome in healthy patients in addition to understand possible differences of the microbiome in patients with certain chronic diseases. Understanding these differences may lead to improved identification of patients susceptible to these conditions as well as possible treatments. Your participation involves a single sample obtained during a medical procedure that has already been planned for your care. If you have taken antibiotics within the last 7 days, you will not be able to participate. Participation involves allowing researchers access to your medical record to gather information regarding medical conditions that may be related to the microbiome sample results. You are being invited to participate in this study to investigate the microbiome of the head and neck, including the ears, sinuses, tonsils, and larynx. Sample collections will be performed under the direction of Dr. Daniel Roberts, in the UConn Health Ear, Nose and Throat/Otolaryngology department. Sample processing will be conducted in UCHC Labs under the direction of Dr. Yanjiou Zhou.

Purpose of This Research

The study aims to explore the differences in the microbiome between patients with chronic infections/diseases compared to healthy counterparts, to see how these baseline differences can lead to differences in health. We will recruit 210 people to collect samples.

Confidentiality

If you agree to take part in the study, personal information about your health and your treatment will be collected and recorded by the study doctor. We will do our best to protect the confidentiality of the information we gather from you, but we cannot guarantee 100% confidentiality. Your research records, which contain information about your participation in this study and the results of procedures performed in this study, along with this consent form will not be part of your designated medical record. The study staff (principal investigator, research coordinator, coinvestigators etc.) will keep all physical research records locked in a secure location. These research records will not identify you by name; they will be labeled with a code. The code will be a 3 digit number that reflects how many people have enrolled in the study. Electronic research records will be stored encrypted. A master key, which links this code and your name, will be maintained in a separate and secure location. You should know that the Department of Health and Human Services (DHHS), the Food and Drug Administration (FDA), and the Health Center's Institutional Review Board and the Human Subjects Protection Office may inspect these records. They may inspect records to ensure that the study is being done correctly. In addition, your identity will not be revealed in any presentations or publication based on the results of the research study.

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Microbiome study ICF 2

Risks Associated with the Study

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Benefits Associated with the Study

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Compensation

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Cost

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The Principal Investigator is willing to answer any questions you have about the research. Dr. Roberts can be contacted at 860-679-2804. You are encouraged to ask questions before deciding whether to take part. You are also encouraged to ask questions during your study participation. If you have questions, complaints, or concerns about the research, you should call the Principal Investigator. You may also call a coordinator at the Institutional Review Board if you want to talk to someone who is not a member of the research team in order to pass along any suggestions, complaints, concerns or compliments about your involvement in the research, or to ask general questions or obtain information about participation in clinical research studies. The Institutional Review Board can be reached at 860-679-4849 or 860- 679-8729. Please do not call the Research Subject Advocate or IRB number for medical related issues or to schedule or cancel an appointment.

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Microbiome study ICF 4

Please indicate the site of collection:

o Ears (Middle and Outer) o Sinonasal o Tonsils o Larynx

If you choose option 2 below, your sample will still be de-identified. Following this study, the specimen may be used for further research studies or distributed to another investigator for future studies without additional informed consent.

Please initial your preference:

1. Discard sample at the conclusion of this study _____

2. Sample may be used for future studies _____

_____
(Participant) type or print name Date

_____
Signature

By signing this form you (the participant, legally authorized representative, parent(s) or guardian) acknowledge that you have read, or have had read to you, this informed consent document, have talked with research personnel about this study, have been given the opportunity to ask questions and have them satisfactorily answered, and voluntarily consent to participate in this project as described in this form. You acknowledge that you have the opportunity to voluntarily provide feedback about your experience as a research participant. You may ask for a copy of the Research Participant Feedback Form, you may obtain the form online at https://ovpr.uchc.edu/services/rics/hspp/volunteers/, or you may submit the form online at https://redcap.link/UConnHealth-Feedback-Research .

_____
(Consentor) type or print name Date

_____
Signature of Consentor

By signing this form the individual obtaining consent is confirming that the above information has been explained to the subject (and/or legally authorized representative, parents or legal guardians) and that a copy of this document, signed and dated by both the person giving consent and the person obtaining consent, along with a copy of the Research Feedback Form if requested, will be provided to the participant and/or representative.

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Information About the Research Study

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Voluntary Status

Because of a federal law called the Health Insurance Portability & Accountability Act (HIPAA), we must get your permission to use and disclose your identifiable health information for this research study. This form is used to document that permission. Because of HIPAA you must also receive a copy of UConn Health's rules about privacy.

Your decision whether to give permission is voluntary. The only consequence of not granting permission is that you will not be allowed to participate in this research study. Your decision has no impact on your treatment, payment, or enrollment in any health plans, or effect on your eligibility for benefits

Information That Will be Used / Disclosed

The following information about you may be used and disclosed for the purpose of this research study:

- Data results from the swabs collected
- Name
- Medical Record Number
- Date of birth
- Diagnosis
- Past medical history
- Descriptors of disease process
- Procedures completed at time of sample collection

How the Information Will be Used / Disclosed

The information noted above will be used and disclosed for the following purpose(s):

- To characterize the microbiome of the head and neck in healthy and disease states

People/Offices That Will Have Access to Your Information
The following people/entities may use and disclose your protected health information.

- Dr. Dan Roberts and his staff
- UConn Health's Institutional Review Board and Human Subjects Protection Program
- UConn Health authorized representatives.
- Government representatives, such as the Food & Drug Administration or Office for Human Research Protections; when required by law.

The researchers and staff agree to protect your information by using and disclosing it only as stated in this document and as directed by state and federal law

Once your health information has been disclosed outside of this institution (for example to an external sponsor or collaborating institution) the information may no longer be protected under this authorization.

Reasons to share your information are to be able to conduct research, and to ensure that the research meets legal, institutional and/or accreditation requirements.

Right to Access Information
You may not be allowed to review the information collected for this research project. You do have the right to request that your medical record be released per your written direction.

Expiration of Permission
Your permission to use and disclose your protected health information expires upon completion of the research study.

How to Withdraw Permission
You can withdraw your permission at any time by sending a letter to Dr. Dan Roberts to inform him. If you withdraw your permission, you will no longer be allowed to participate in this study. If you withdraw your permission the PI and his staff will no longer be able to use and disclose your protected health information. There are exceptions to this. For example, the researchers may continue to use and disclose the protected health information that was collected for the research study prior to receiving the request to withdraw your permission.

Questions or Complaints
If you have any questions, concerns or complaints about your privacy rights, you may write to UConn Health's Privacy Office, 263 Farmington Avenue, Farmington, CT 06030-5329. If you have a complaint, you may also write to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, U.S. Dept. of Health and Human Services Government Center, J.F. Kennedy Federal Building, Room 1875, Boston MA 02203. Complaints should be sent within 180 days of when you knew, or should have known, of the problem.

State of Connecticut Requirement

In this study we are not asking for information about AIDS, HIV infection, behavioral health services, psychiatric care, or treatment for alcohol and/or drug abuse. If this information pertains to you, you should know there is a slight chance that it may be inadvertently disclosed during the course of the study. The State of Connecticut statutes require that any release of information pertaining to AIDS, HIV infection, behavioral health services, psychiatric care, or treatment for alcohol and/or drug abuse be specifically authorized. By signing this dual-purpose authorization you acknowledge that there is a chance that this information may be subject to use and/or disclosure as it relates to this project.

Permission for Use and Disclosure of Information

You are a voluntary participant in this research study. By signing you acknowledge that you have read this form, had the opportunity to ask questions, and obtain satisfactory explanations, and that you authorize the use and disclosure of protected health information as described in this form. You will receive a copy of this form after it is signed.

Commercial Value:

Medical research may result in new products, tests or discoveries. These may have commercial value and may be developed and owned by UConn Health, its faculty and/or others. Please initial to acknowledge that the intent that you will not share in the financial benefits, if any, from these products tests or discoveries has been explained to you.

_____You acknowledge that the provision that you will not share in the financial benefits, if any, from these products tests or discoveries has been explained.

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Signature of the research participant Date

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Printed name of the research participant