**Informed Consent**

# Title: Microbial Basis of Systemic Malodor and "People Allergic To Me" Condition (PATM)

ClinicalTrials.gov Identifier: NCT03582826

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Information provided by (Responsible Party): Irene Gabashvili, PhD, Principal Investigator

**Research study:** Dynamics of the Gut Microbiota in Idiopathic Malodor Production

NCT03582826 English Life Quality Test Espa ol Prueba de calidad de vida Blog

- **Being in a study is voluntary – your choice.**
- **If you join this study, you can still stop at any time.**
- **No one can promise that a study will help you.**
- **Do not join this study unless all of your questions are answered.**

Before you decide whether to participate in this research study, you should review:

1. The purpose of the research study
2. The study procedures
3. How long your involvement in the research will last
4. Any procedures that are experimental
5. Any reasonably foreseeable risks, discomforts, and benefits of the research
6. Any potentially beneficial alternative procedures or treatments
7. How the confidentiality of your data will be maintained
8. The possibility of unforeseeable risks
9. Any added costs to you
10. What happens if you decide to stop participating
11. New findings that may affect your willingness to participate
12. How many people will be in the study

## Introduction

**MEBO Research, Inc.**, (“MEBO”) is a sufferer-founded patient advocacy international campaign registered in the State of Florida, U.S., since April 21, 2010, under section 501(c)(3) of the Internal Revenue Code, classification of Public Charity. MEBO Research is also registered in England and Wales as a Not For Profit, Limited by Guarantee Company (2009). MEBO is a NORD and EURORDIS Organization Member and its directors are moderators of the Trimethylaminuria Community at RareConnect.org. MEBO is referenced as an Advocacy and Support Organization in websites like the Genetic Alliance and Orphanet.

MEBO means metabolic body odor and it includes systemic body odor, bad breath and continuing episodes of malodor NOT related to hygiene or exces

sive gas. PATM denotes "People Allergic To Me" condition.

## PURPOSE OF RESEARCH

You are invited to participate in a research study of microbial dynamics in MEBO and PATM conditions. We hope to learn what micro bial communities are associated with flare ups and remissions of these conditions and best ways to reduce the symptoms.

You were selected as a possible participant in this study because you demonstrated good communication skills and willingness to foll ow nutritionally balanced dietary regimes and contribute follow-up outcome data.

If you decide to terminate your participation in this study, you should notify Maria de la Torre at maria.delatorre@meboresearch.org

This research study is looking for up to 100 people with all manifestations of body malodor, halitosis and/or PATM. We expect to enr oll research study participants, throughout the United States and internationally.

## VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care. You can decide to participate now or withdraw your consent at any time throughout the study process without any loss of benefits or medical care to which you m ay be entitled, if any.

## DURATI ON OF STUDY I NVOLVEMENT

This research study is expected to take approximately one year.

## PROCEDURES

If you choose to participate, the Protocol Director, Irene Gabashvili, PhD, and her research study staff, Maria de la Torre will address all matters regardin g this research process with you in writing via email to the email address you provide. Your formal reply to said communications will also need to be in wr iting via email. In this manner, clear instructions, charts, graphs, results, calendar, and your feedback will be presented in an orderly manner.

None of the surveys or other procedures used by the investigators in this Research study are invasive or experimental. The procedures involved do not i nvolve significant risks, and no compensation or treatment is available if injury occurs as a result of participation. Swabs and other materials used for sa mple collection are sterilized prior to shipment and must be handled with proper care and hygiene. Should you be uncomfortable handling the collection kit and accepting responsibility for its use, please reconsider your participation in this study.

We are asking you to self-sample with three uBiome gut microbiome kits and fill in this questionnaire:

# MEBO/PATM Life Quality Test

MEBO means metabolic body odor and it includes systemic body odor, bad breath and any episodes of malodor NOT related to hygiene or flatulence. PATM denotes "People Allergic To Me" condition. The survey asks about symptoms In the past 24 hours or past few days, up to a week before taking this test. Our estimated time for completion is 3-5 minutes. We'll appreciate if you spend a few more minutes for the last free-text question.

* Required

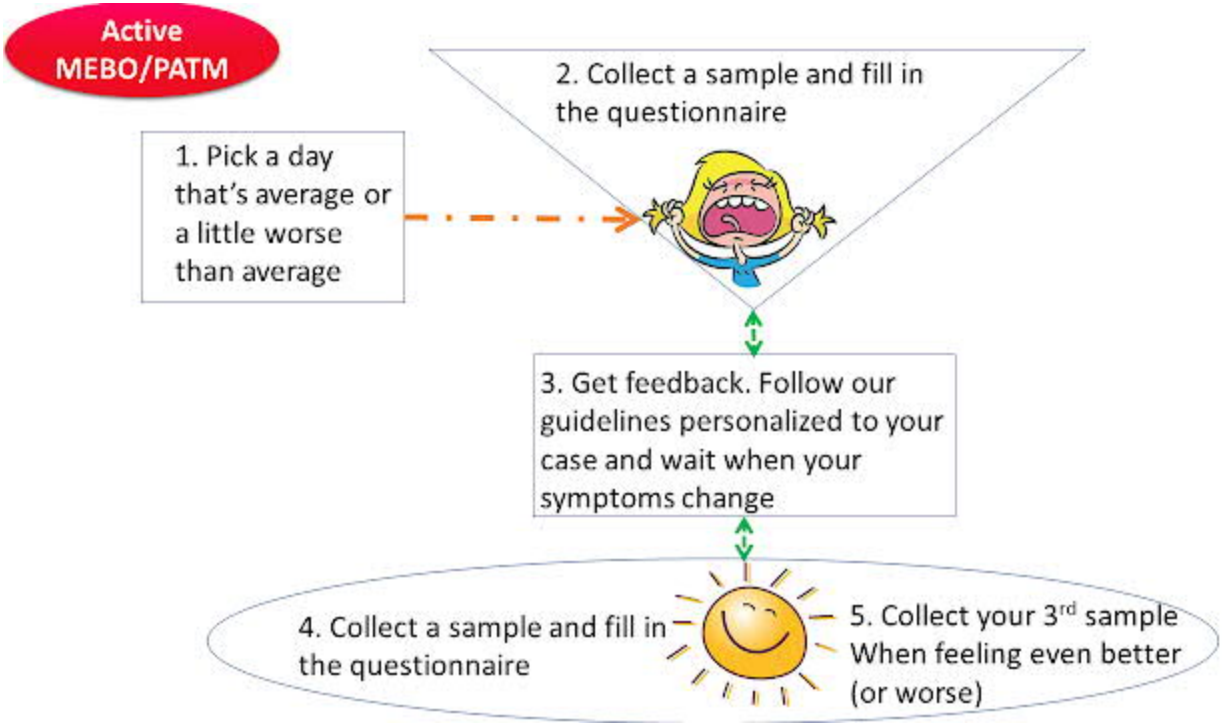
MEBO ID or contact information if you don't have an ID but would like to be invited to participate in the study. *

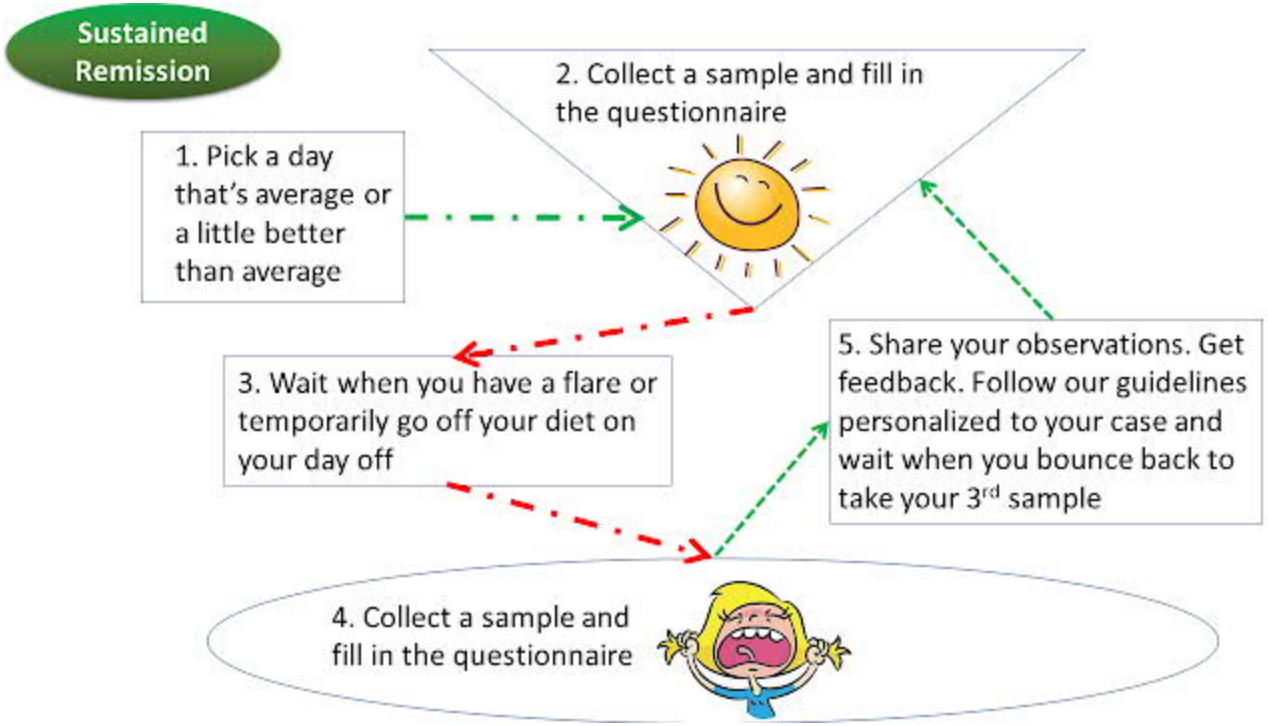
Your answer

Your uBiome kit # (N/A if you are not sending your sample this time) *

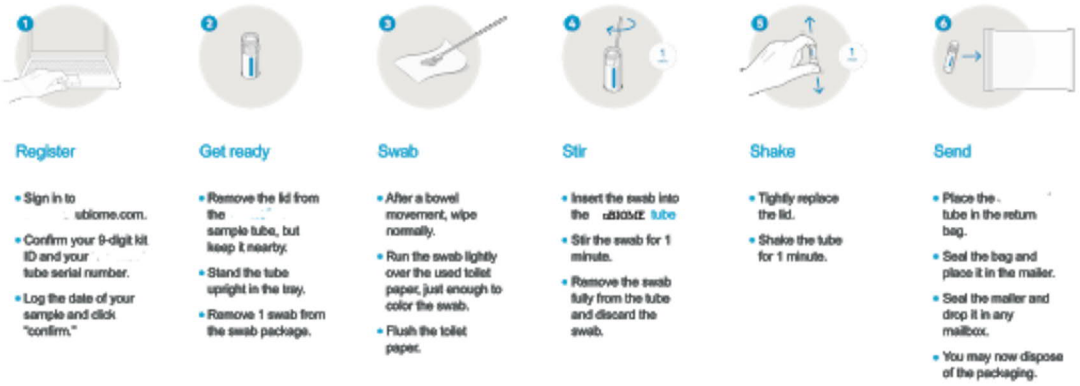
Your answer

These charts describe when you could collect the three samples depending if your condition is in active state or in remission:


Active
MEBO/PATM
1. Pick a day that's average or a little worse than average
2. Collect a sample and fill in the questionnaire
3. Get feedback. Follow our guidelines personalized to your case and wait when your symptoms change
4. Collect a sample and fill in the questionnaire
5. Collect your 3rd sample When feeling even better (or worse)

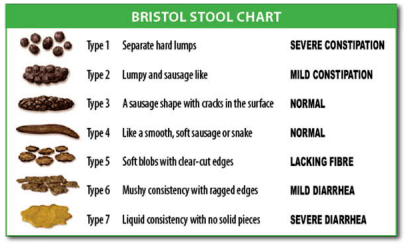



When you are ready to begin sampling, follow the instructions below to collect your sample:




You may also want to answer uBiome questions about your stool type, symptoms and wellbeing.

After you return your sample via the prepaid mailer, your uBiome Explorer test report will be available via your patient portal approximately 6 weeks later. You will also receive an email notifying you that your results are ready.




Any of your samples which are used in research may result in new products, tests or discoveries. In some instances, these may have potential commercial value and may be developed and owned by uBiome or others. Our agreement with Ubiome allows them to file any patents relating to test results. However, donors of samples do not retain any property rights to the materials. Therefore, you would not share in any financial benefits from these products, tests or discoveries.

The results of the study of your samples from this project will be used for research purposes only. Regarding informing you of the test results, you should understand the following:

- The information may be too limited to give you particular details or consequences;

Information from analyses of your coded samples and your coded medical information will be put into one of the National Institutes of Health (NIH) databases along with information from the other research participants and will be used for future research. These databases will be accessible by the Internet. Only anonymous information from the analyses will be put in a completely public database, available to anyone on the Internet.

No traditionally-used identifying information about you, such as your name, address, telephone number, or social security number, will be put into the public database. While the public database will not contain information that is traditionally used to identify you, people may develop ways in the future that would allow someone to link your medical information in our databases back to you. For example, someone could compare information in our databases with information from you (or a blood relative) in another database and be able to identify you (or your blood relative). It also is possible that there could be violations to the security of the computer systems used to store the codes linking your genetic and medical information to you.

However, your privacy is very important to us and we will use safety measures to protect it. Despite all of the safety measures that we will use, we cannot guarantee that your identity will never become known.

## PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Tell the Protocol Director or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Keep your diaries as instructed.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.
- Destroy or return any unused tests kits to uBiome.

## WITHDRAWAL FROM STUDY

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you would otherwise be entitled.

If you decide to withdraw your consent to participate in this study, you should notify Maria de la Torre at maria.delatorre@meboresearch.org.
You should destroy or return any unused test kits or other materials to uBiome at the completion or earlier termination of this study.

## POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Protocol Director if you have any questions.

• Some survey questions may make you or your family members uncomfortable.

• Your data, survey responses, and/or personally identifying information may be compromised in the event of a security breach or failure to follow protocol. In the event of such a breach, if your data are associated with your identity, they may be made public and it may have social and psychological consequences for you or your loved ones.

• When investigators publish results from this study, your information may be included within pooled summaries that are made public. Identification of your individual-level data from those summaries would be extremely difficult, but it is possible that a third party that has obtained partial data from you could compare their partial data to the published results and indirectly determine some of your

survey responses.

• While the information we keep will not include names, and the microbiome is not uniquely identifiable, human genetic information i s unique and can be used to identify people by linking or tracing DNA in public databases.

• As with any online service, if you disclose your account password to others, they may be able to access your account and your infor mation. There may be additional risks to participation that are currently unforeseeable.

## POTENTI AL BENEFI TS

We cannot and do not guarantee or promise that you will receive any benefits from this study.

## ALTERNATI VES

The alternative is not to participate in this study.

## PARTI CI PANT'S RI GHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If y ou decide not to participate, tell the Protocol Director.

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

**ClinicalTrials.gov: NCT03582826**

A description of this clinical trial will be available on *https://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

**CONFIDENTIALITY**

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed except as authorized by you or as required by law. However, there is always some risk that even de-identified information might be re-identified.

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

# Authorization To Use Your Health Information For Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

## What is the purpose of this research study and how will my health information be utilized in the study?

The purpose of this study is to learn what microbial communities are associated with flare ups and remissions of malodor and PATM conditions. The information in some form will be submitted to the sponsor, uBiome. Your de-identified information may be included within pooled summaries when investigators publish results from this study.

## Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study. Signing the form is not a condition for receiving any medical care outside the study.

## If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revo

cation, your health information will no longer be used or disclosed in the study, except to the extent that th e law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to Irene Gabashvili at irene.gabashvili@meboresearch.org

**What Personal Information Will Be Obtained, Used or Disclosed?**
Your health information related to this study, may be used or disclosed in connection with this research stud y, including, but not limited to severity of your symptoms and laboratory test results.

**Who May Use or Disclose the Information?**
The following parties are authorized to use and/or disclose your health information in connection with this r esearch study:

- The Protocol Director (Irene Gabashvili)
- Research Staff (Maria de la Torre)

**Who May Receive or Use the Information?**
The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services

**When will my authorization expire?**
Your authorization for the use and/or disclosure of your health information will end on December 31, 2019 o r when the research project ends, whichever is earlier.

**Will access to my medical record be limited during the study?**
To maintain the integrity of this research study, you may not have access to any health information develop ed as part of this study until it is completed. At that point, you would have access to such health informatio n if it was used to make a medical or billing decision about you (e.g., if included in your official medical reco rd).

## FINANCIAL CONSIDERATIONS

Payment/Reimbursement

You will not be paid to participate in this research study.

Costs
There is no cost to you for participating in this study, other than basic expenses like Internet usage and the personal time it will take to fill in the questionnaires.

International participants may be asked to donate to MEBO Research to partially compensate for shipping costs.

Sponsor

uBiome and MEBO Research are providing financial support and/or material for this study. uBiome is supporting microbiome testing and partial analysis of the results, and domestic shipping costs. MEBO Research will be covering International shipping costs.

## COMPENSATION for Research-Related Injury

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. **You will be responsible for any associated co-payments or deductibles as required by your insurance.**

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

You do not waive any liability rights for personal injury by signing this form.

## CONTACT INFORMATION

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director.

Injury Notification: If you feel you have been hurt by being a part of this study, please contact the Protocol Director or Research Staff.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the MEBO Institutional Review Board (IRB) to speak to someone independent of the research team at mike@meboresearch.org

Alternate Contact: If you cannot reach the Protocol Director, please contact Maria de la Torre at maria.delatorre@meboresearch.org

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Irene Gabashvili at irene.gabashvili@meboresearch.org. You should also contact her at any time if you feel you have been hurt by being a part of this study.

## EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;

- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any e lement of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

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