PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM

Title: Examination of changes to the microbiome and immune response of the nasal cavity and eye during inhalation of essential oils.

1. **What is the research study about?**

   You are invited to participate in this research study. This project aims to investigate whether the bacteria resident on the human nose and eye change after use of essential oils. The bacterial type and load will be determined by conventional culture and advanced genetic techniques (16s RNA sequencing) before and after inhalation of essential oils. This research is important because it will help us understand if essential oils impact the normal microorganisms in these areas and whether they can reduce harmful bacteria.

   Please read this consent form thoroughly, as it provides a description, and risks associated with participating in the study.

2. **Who is conducting this research?**

   The study is being carried out by the following researchers: Chief investigator (Professor Mark Willcox), Co-investigators (Dr Jerome Ozkan, and Dr Parthasarathi Kalaiselvan) and Student investigator (Biruk Bayleyegn Belete). All investigators are from School of Optometry and Vision Science.

   Research Funder: This research is being funded by UNSW.

3. **Inclusion/Exclusion Criteria**

   Before you decide to participate in this research study, we need to ensure that it is ok for you to take part. The research study is looking recruit people who meet the following criteria:

   - Individuals ≥ 18 years old
   - Able to read and comprehend English and give informed consent
   - Willing to follow the procedures informed by the investigators

   Participants who meet the following criteria will be excluded from the study:

   - Wear contact lenses during the day
   - Allergy or irritation to essential oils or fragrancies in general.
   - Have an eye or nasopharynx disease or allergy (such as hay fever), active infections, systemic disease.
   - Use of antibiotics, nasal spray or eye drops, anti-inflammatory, anti-allergy or immunosuppressive medication within 3 months prior to the study.
   - Individuals who are smoker/Vaper
   - Women who are pregnant, planning to become pregnant during the study period, or currently lactating.

4. Do I have to take part in this research study?

Participation in this research study is voluntary. If you do not want to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the study at any stage.

If you decide you want to take part in the research study, you will be asked to:

- Read the information carefully (ask questions if necessary).
- Sign and return the consent form if you decide to participate in the study.
- Take a copy of this form with you to keep.

5. What does participation in this research require, and are there any risks involved?

The research visit will be conducted at the School of Optometry and Vision Science. The initial visit will last approximately 30minutes (eligibility assessment using questioners, Swab sample collection, providing essential oil), while the following two visits will be around 15-20 minutes each (swab collection only). The costs for the swabs and any other necessary materials will be covered by the research team.

Screening: If you agree to participate, you will be asked to complete the screening questionnaires. Completing the screening measures will take approximately 15 minutes. You will then be advised on how and where to set-up the essential oil inhalation device at your workplace and home. If the screening questionnaire shows that you meet the criteria for inclusion, then you will be able to start the research project.

Randomisation: To ensure that each participant has an equal chance of being placed in any group to start with, a random allocation will be conducted using R software. Once randomised, participants will be allocated to one of the following groups.

Intervention	**Control**
Group1: Frankincense Essential oil	Group 4: Placebo control
Group2: Tea tree essential oil	
Group 3: Blended essential oil	

If you agree to participate you will be asked to complete the following research procedures.

A. Eye lid margin swab collection:

Description	Sterile swab will gently pass across your lower eyelid margin.

Risk	The risk of physical injury is low as the swab is gently swiped across eyelid margin. There may be some discomfort felt as the swab contacts your skin of eyelid margin, but it should subside quickly once the swab is completed.

B. Nasal swab collection:

Description	Sterile swab inserted into your anterior nares
Risk	Slight discomfort or itchiness may be experienced as the swab is gently inserted to your noses. The risk of physical injury is low due to the gentle pressure being applied. After the procedure, you may feel nothing at all, a slight, transient itchy sensation or desire to sneeze.

Any swab sample collected from eye and nose will be analysed for the purpose of this research and will be stored following testing, based on the guideline.

Intervention: Frankincense essential oil, tea tree essential oil and blended essential oil are used to inhibit pathogenic microbiomes without affecting normal commensal will be used in this research. Therefore, it is an experimental treatment for reducing ocular and nasal infection. This means that it must be tested to see if it is an effective treatment for inhibiting pathogenic microbes found in our eye and nose with simple rout of administration (Inhalation).

Frankincense essential oil, tea tree essential oil and blended essential oil are an experimental intervention. This means that it is not an approved treatment for external use to treat bacterial and fungal infections in Australia, and therefore, it must be tested to see if it is an effective treatment for disease causing microbiomes.

Experimental interventions likely to have minimal side effects as the rout of administration is through inhalation rather than ingestion. If at any time you experience changes to nasal symptoms, have more than usual nasal secretions, noticed changes such as redness around your eyes, experience unusual ocular symptoms such as itching, and to then immediately contact the study personnel. If you experience more severe reactions such as breathlessness or difficulty breathing, or severe ocular or nasal inflammation, you will stop use of essential oil and go to the nearest emergency unit for assessment and treatment.

Safety advice:

- ✓ Keep the product out of reach of children and pets.

- ✓ Always place it in a side, not towards on your face
- ✓ No direct inhalation, only use usual breathing
- ✓ Don't use in very small room like toilet.

6. **Additional Costs and Reimbursement:** There are no costs associated with participating in this research project, nor will you be paid. However, you will receive a $10 gift card for each attended visit as reimbursement for any reasonable travel, parking, meals and other expenses while participating in the study.
7. **What are the possible benefits of taking part?**
   We cannot guarantee or promise that you will receive any benefits from this research.
8. **What are the alternatives to taking part in the research?**
   This research is conduct on healthy volunteers and hence there are no alternative treatments to taking part in the research.
9. **What will happen to information about me?**
   By signing the consent form, you consent to the research team collecting and using information about you for the research study.
   The research team will store the data collected from you for this research project for a minimum of 5 years after the publication of the research results. The information about you will be stored in a non-identifiable format where your identity will be unknown.
   Information collected from you will be in an electronic format stored on a UNSW password protected OneDrive only accessible to the approved research investigators. This data may be used for secondary research purposes with your consent.
   Information collected from the questionnaire will be stored at the University of New South Wales School of Optometry and Vision Science. Only the approved research investigators will have access to this information.
   The information you provide is personal information for the purposes of the Privacy and Personal Information Protection Act 1998 (NSW). You have the right of access to personal information held about you by the University, the right to request correction and amendment of it, and the right to make a complaint about a breach of the Information Protection Principles as contained in the PPIP Act. Further information on how the University protects personal information is available in the: UNSW Privacy Management Plan.
10. **How and when will I find out what the results of the research study are?**

The research team intend to publish and/ report the findings in per-reviewed academic journal and will be also presented at scientific conferences. All Information will be published in a way that will not identify you. If you would like to receive a copy of the results you can let the research team know by inserting your email or mailing address in the consent form. We will only use these details to send you the results of the research.

11. **What if I want to withdraw from the research study?**

    If you do consent to participate, you may withdraw at any time. You can do so by completing the 'Withdrawal of Consent Form' which is provided at the end of this document, or you can contact the research team and inform them you no longer want to participate. Your decision not to participate or to withdraw from the study will not affect your relationship with UNSW Sydney or other working organizations. If you decide to leave the research study, the researchers will not collect additional information from you. You can request that any identifiable information about you be withdrawn from the research project.

12. **What if I have a complaint or any concerns about the research study and will I receive compensation if suffer any injuries or have complications?**

    If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

    Complaints Contact

    If you have a complaint regarding any aspect of the study or the way it is being conducted, please contact the UNSW Human Ethics Coordinator:

Position	UNSW Human Research Ethics Coordinator
Telephone	+ 61 2 9385 6222
Email	humanethics@unsw.edu.au
HC Reference Number	iRECS6996

13. **What should I do if I have further questions about my involvement in the research study?**

    The person you may need to contact will depend on the nature of your query. If you require further information regarding this study or if you have any problems which may be related to your involvement in the study, you can contact the following member/s of the research team:

    Research Team Contact Details

PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM

Title: Examination of changes to the microbiome and immune response of the nasal cavity and eye during inhalation of essential oils.

Position	**Chief Investigator**	**Student investigator**
Name	Professor Mark Willcox	Biruk Bayleyegn Belete
Telephone	+61409658313	+61430363982
Email	Email: m.willcox@unsw.edu.au	b.belete@unsw.edu.au

Consent Form – Participant providing own consent

Declaration by the participant

- ☐ I understand I am being asked to provide consent to participate in this research study.
- ☐ I have read the Participant Information Sheet, and I understand.
- ☐ I understand the purposes, study tasks and risks of the research described in the study.
- ☐ I understand that the research team will collect swabs from both eyelid margins and both nostrils. I provide my consent for this to happen
- ☐ I provide my consent for the information collected about me to be used for the purpose of this research study.
- ☐ I have had an opportunity to ask questions, and I am satisfied with the answers I have received.
- ☐ I freely agree to participate in this research study as described and understand that I am free to withdraw at any time during the study and withdrawal will not affect my relationship with any of the named organisations and/or research team members.
- ☐ I understand that I will be given a signed copy of this document to keep.
- ☐ I understand that aggregated data that doesn't identify me, will be made available on the website.

Optional Consent for reuse of data and future research:

- ☐ I provide my consent for the information collected about me to be used for future secondary research purposes, if necessary.

Participant Signature

Name of Participant_____

Signature: _____ Date: dd_____/mm_____yy_____

I would like to receive a copy of the study results via email or post, I have provided my details below and ask that they be used for this purpose only.

Name:_____

Address: _____

Email Address: _____

PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM

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Declaration by Researcher*

☐ I have given a verbal explanation of the research study, its study activities and risks and I believe that the participant has understood that explanation.

Researcher Signature*

Name of Researcher: _____

Signature_____ Date: dd_____mm_____yy_____

[+]An appropriately qualified member of the research team must provide the explanation of, and information concerning the research study. All parties signing the consent section must date their own signature.

Form for Withdrawal of Participation

I wish to **WITHDRAW** my consent to participate in this research study described above and understand that such withdrawal **WILL NOT** affect my relationship with The University of New South Wales, and other organizations.

☐ I am withdrawing my consent to participate in further components of this research and provide my permission for the research team to retain and/or use information collected about me which I have provided for the purpose of this research.

☐ I am withdrawing my consent, and I request that any information I have previously provided for this research be destroyed by the investigator.

Participant Signature

Name of Participant	
Signature of Research Participant	
Date	

The section for Withdrawal of Participation should be forwarded to:

CI Name:	Mark Willcox	Biruk Bayleyegn Belete (SI)
Email:	m.willcox@unsw.edu.au	b.belete@unsw.edu.au
Phone:	+61409658313	+61430363982
Postal Address:	Level 3, Rupert Myers Building, UNSW, Kensington, 2052	Level 3, Rupert Myers Building, UNSW, Kensington, 2052