MANIPAL COLLEGE OF DENTAL SCIENCES
MANGALORE
(A constituent unit of MAHE, Manipal)

AISHWARYA SUKUMARAN NAIR
[Name of Principle Investigator]

[Informed Consent Form for Oral Cancer Patients and Healthy Controls]

This Informed Consent Form is for men and women who attend Kasturba Medical College (KMC), Attavar and Manipal College of Dental Sciences (MCODS), LHH Road in Mangalore who we are inviting to participate in research on oral cancer. The title of our research project is **"COMPARISON OF SALIVARY MICRORNA LEVELS IN PATIENTS DIAGNOSED WITH ORAL SQUAMOUS CELL CARCINOMA WITH CONTROLS WITHOUT OSCC FOR IDENTIFYING A PANEL OF DYSREGULATED MICRO-RNA: A CASE-CONTROL STUDY"**

[Name of Principal Investigator]:	**Aishwarya Sukumaran Nair**
[Name of Organization]:	**Manipal College of Dental Sciences, Mangalore**
[Name of Sponsor]:	**None**
[Name of Proposal and Version]:	**Comparison of Salivary Micro-RNA Levels in Patients Diagnosed with Oral Squamous Cell Carcinoma with Controls Without OSCC for Identifying a Panel of Dysregulated Micro-RNA: A Case-Control Study (Version 1)**

This Informed Consent Form has two parts:

- **Information Sheet** (to share information about the research with you)
- **Certificate of Consent** (for signatures if you agree to take part)

YOU WILL BE GIVEN A COPY OF THE FULL INFORMED CONSENT FORM

PART I: Information Sheet

i.) BASIC INFORMATION

Introduction

I am Dr. Aishwarya Sukumaran Nair, a student working for MCODS, Mangalore. We are researching oral cancer, which is very common in this country. I will give you information and invite you to be part of this research. You do not have to decide today whether you will participate in this research. Before you decide, you can talk to anyone you feel comfortable with about the research. That can include but is not limited to your family and friends.

There may be some words that you do not understand. YOU CAN STOP ME IF YOU DO NOT UNDERSTAND the information, and I will take time to explain. If you have questions later, you can ask me or the staff

Purpose of the Research

Oral Cancer is one of the most common and dangerous diseases in our country. The tests conducted currently to identify oral cancer may not confirm the severity of the outcome of cancer. Also, oral cancer may be identified in the late stages. In fact, if diagnosed early on the outcome of cancer is good. There is a new way to identify oral cancer in an early stage. The reason we are doing this research is to find out if the new method will help us find markers that tell us if something has become a cancer or not with the help of only your saliva

Type of Research Intervention

This study will involve collecting your saliva sample and searching saliva for substances/molecules that mark onset of cancer. (minimally invasive)

Participant Selection: (Why are you being asked?)

1. We are inviting adults diagnosed with oral cancer to participate in our research to find substances in their saliva
2. We are also inviting adults who have no history of cancer for the research
3. This will help us identify cancer onset early on and help us understand how good or poor the outcome of the cancer could be.

(For the Researcher) ***Ask the participant the following question:***

1. *Do you know why we are asking you to take part in this study?*

2. *Do you know what the research is about?*

	Yes	No
Q 1.		
Q 2.		

Voluntary Participation

1. Your participation in this research is entirely voluntary. It is your choice whether to participate or not.
2. Whether you choose to participate or not, all the services you receive at this clinic will continue, and nothing will change.
3. If you choose not to participate in this research project, you will be offered the routine treatment for your Oral Cancer in this clinic/hospital, and we will tell you more about it later.
4. You may change your mind later and stop participating even if you agreed earlier.

	Confirmatory Questions	Yes, I know	No, I don't know
1.	*Do you know that you do no need to participate in this study?*		
2.	*Do you know that you will have no difference in treatment or procedures if you do not wish to participate?*		

PART I: Information Sheet

ii.) PROCEDURES

A. Unfamiliar Procedures

We will take saliva from your mouth using a saliva collection tube. You are required to drool into the tube. No invasive method will be used in the collection. Each time, we will take about a tablespoon of saliva. We will take about 10 ml of saliva only once. At the end of the research, in 3 years, ANY LEFTOVER SALIVA SAMPLE WILL BE DESTROYED.

B. Description of the Process

During the research, you are expected to provide samples **ONLY DURING THE FIRST VISIT**.

- In the first visit, ***around 1.5 tablespoon of saliva*** will be taken from your mouth.
- ***DO NOT eat or drink for a period of one hour before*** the sample collection. This will be done only during morning hours from **9 am to 11 am.**
- ***Take a deep breath and relax***, then ***drool into the collection tube for less than or equal to*** **15 minutes**.
- This saliva will be tested for the presence of substances that help identify cancer.
- We will also ask you a few questions about your ***general health*** and measure how tall you are and how much you weigh.
- We will also ask you questions regarding your habits, such as ***tobacco and alcohol use***.
- We will note your ***contact information*** and interact with you only to reconfirm the history based on the test findings and ONLY IF NEEDED. **YOU NEED NOT COME FOR THE SECOND TIME**.

iii.) PROTOCOL

Duration

1. **The research requires you to be available to us ONLY ONCE**.
2. During that time, it will be necessary for you to come to the clinic/hospital/health facility
3. You will have to refrain from eating and drinking for a period of 1 hour before the collection time.
4. At the end of three years, the research will be finished.

	Confirmatory Questions	Yes, I know	No, I don't know
1.	*Can you tell me if you remember how many times, we asked you to come to the hospital to complete the research project?*		
2.	*Do you know how much saliva will be taken from your mouth using a collection tube and for how long?*		
3.	*Do you know the procedure with which we will be taking saliva?*		

Side Effects

As mentioned, this intervention of collecting saliva samples has **NO KNOWN UNWANTED EFFECTS**. However, we will follow you closely and keep track of any unwanted effects or problems.

Risks

By participating in this research, there is no risk that you will be exposed to, as saliva samples will be collected non-invasively. As there is no clinical intervention or change in your treatment plan, the risk to you is the same as the risk without this intervention.

Benefits

There may not be any benefit for you, but your participation will likely help us find the answer to the research question. There may not be any benefit to society at this stage, but future generations will likely benefit.

PART I: Information Sheet

Confidentiality

With this research, something out of the ordinary is being done in your community. It is possible that if others in the community are aware that you are participating, they may ask you questions. We will not be sharing the identity of those participating in the research.

The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away, and only the researchers will be able to see it. **Any information about you will have a number on it instead of your name**. Only the principal investigator and guide of the principal investigator will know what your number is, and we will lock that information up with a lock and key or password-protected document. **It will not be shared with or given to anyone except Dr. Aishwarya S. Nair and Dr. Junaid Ahmed**

Sharing the Results

The knowledge we get from this research will be shared with you through community meetings before making it widely available to the public. CONFIDENTIAL INFORMATION WILL NOT BE SHARED. There will be small meetings in the community, and these will be announced. After these meetings, we will publish the results so that other interested people may learn from our research.

Right to Refuse or Withdraw

1. You do not have to participate in this research if you do not wish to do so.
2. You may also stop participating in the research at any time you choose.
3. It is your choice, and all your rights will still be respected.

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iv.) WHOM TO CONTACT

If you have any questions, you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following:

NAME**:** **DR. AISHWARYA SUKUMARAN NAIR**
PHONE: **9611712410/9347331601**
EMAIL ID**:** **aishwaryas.nair0@gmail.com**
ADDRESS: Manipal College of Dental Sciences (MCODS), LHH Road, Hampankatta, Mangalore - 575001, Karnataka, India

This proposal has been reviewed and approved by the Institutional Ethics Committee (IEC), MCODS, Mangalore whose task is to ensure that research participants are protected from harm. If you wish to learn more about the IEC, please contact

EC/NEW/INST /2022/2573	INSTITUTIONAL ETHICS COMMITTEE, MCODS, MANGALORE	Manipal College of Dental Sciences, Mangalore, Light House Hill Road, Hampankatta, Mangalore, Dakshina Kannada, Karnataka 575001 **Email**: **iec.mcodsmlr@manipal.edu**

It has also been reviewed by the Institutional Protocol Approval Committee (IPAC), that supports it.

Confirmatory Questions	**Yes, I know**	**No, I don't know**
1. *Do you know that you DO NOT have to participate in this study if you do not wish to? You can say No if you wish to.*		
2. *Do you know that YOU CAN ASK me questions later if you wish to?*		
3. *Do you know that I have given the contact details of the person who can give you more information about the study?*		

You can ask me more questions about any part of the research study if you wish. Do you have any questions?

PART II: Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it, and any questions I have asked, have been answered satisfactorily. I consent voluntarily to participate in this research.

Print Name of Participant_____ **Signature of Participant** _____

Date _____
(DD/MM/YYYY**)**

If illiterate

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ **AND** **Thumb print of participant**

Signature of witness _____

Date _____
(DD/MM/YYYY**)**

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant and to the best of my ability, made sure that the participant understands that the following will be done:

1. Saliva sample will be collected for a period of 15 minutes
2. Detailed case history will be taken
3. Details about tobacco and alcohol use and other personal habits will also be taken

I confirm that the participant was allowed to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily. A copy of this ICF has been provided to the participant.

Name of Researcher taking Consent _____

Signature of Researcher taking Consent _____

Date (DD/MM/YYYY) _____