Participant Information Sheet/Consent Form

Non-Interventional Study - *Adult providing own consent*

Royal Brisbane & Women's Hospital

Title	*A feasibility study to investigate taste changes and their association with genes and dietary behaviour in patients with head and neck cancer*
Short Title	*Taste, genes and dietary behaviour in head and neck cancer*
Protocol Number	*[Protocol Number]*
Project Sponsor	*RBWH Foundation Postdoctoral Research Fellowship - The Robert & Janelle Bird Fellowships*
Principal Investigator	*Dr Teresa Brown*
Associate Investigator(s)	*Dr Hwang (UQ), Ms Treleaven (RBWH), A/Prof Hughes (RBWH), Prof Kenny (RBWH), Dr Lin (RBWH), Prof Webb (QIMR), Dr Pelecanos (QIMR), A/Prof Bauer (UQ)*
Location	*Royal Brisbane & Women's Hospital*

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project, "A feasibility study to investigate taste changes and their associations with genes and dietary behaviour in patients with head and neck cancer". This is because you have a cancer in the mouth or throat and are planned to undergo chemoradiotherapy treatment.

The research project is aiming to understand how a person's taste changes and recovers following cancer treatment, and how it affects your eating. The research project is also aiming to see if some people are more susceptible to this side effect from treatment due to a genetic link.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the assessments and research involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

• Understand what you have read
• Consent to take part in the research project
• Consent to the tests and research that are described
• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

The aim of this study is to better understand how a person's taste changes and recovers following cancer treatment, and how these taste change affects your eating. From experience in working with patients with head and neck cancer, taste changes can occur due to the side effects from chemotherapy and/or radiotherapy. However, all patients seem to have their taste affected in different ways and recover at different rates.

It is thought there may be a genetic link to taste which would explain why this is different in different people. A person's ability to taste bitter substances is known to be affected by gene variations. It is estimated that 70% of the population are highly sensitive to bitter tastes and are described as being "super-tasters". The remaining 30% of the population are unable to detect the bitterness taste and are described as "non-tasters". This "taster status" has been shown to affect food choice and dietary habits in the healthy population, but it is unknown if it may influence taste changes that occur following cancer treatment.

Understanding the link between genes, taste and diet will hopefully help healthcare professionals identify who is most at risk of this side effect to provide more individualised patient care. Providing more targeted education will help to assist patients to better prepare for these treatment side effects, inform future management interventions and thus improve quality of life in survivorship.

This research has been initiated by the study lead, Dr Teresa Brown and has been funded by the RBWH Foundation Postdoctoral Research Fellowships – The Robert & Janelle Bird Fellowships.

3 What does participation in this research involve?

You have been provided with this form as your Oncologist has identified you as being eligible for this study. The Principal Investigator will contact you in the next day or so via the telephone to discuss if you would like to participate. A written consent form will be signed prior to any study assessments being performed.

If you agree to participate the following will be required:

1. Attendance at appointments (in person and/or via virtual telehealth clinics as described below) to complete assessments at the following times - Prior to radiotherapy starting, and repeated at 1 month, 3 months and 6 months post radiotherapy treatment.

2. For the 1st assessment the Research Assistant will measure your weight/height and complete a Nutrition Assessment. Attendance at the hospital is preferred. The first part can be completed by yourself - answering questions about your weight history, diet intake, symptoms affecting eating and your physical activity in the participant booklet provided. The Research Assistant completes the second part with a visual assessment/examination of your muscle stores in areas of the body that are easily accessible (e.g. arms, legs, neck, shoulders, face). Overall this assessment is expected to take approximately 15 minutes.

3. The 2nd assessment is completed at home through an online survey to recall your food intake for the previous 24 hours. This assessment is expected to take approximately 30 minutes.

4. The 3rd assessment will be undertaken via a telehealth virtual clinic with the Research Assistant. You will need to have access to the internet to complete the Taste Test procedures online. The Research Assistant will guide you through the testing procedures via the telehealth appointment. You will have been provided with Taste Kits at the hospital for you to take home. You will need to supply a cup and a bottle/glass of water. You will be asked to taste the different solutions provided. There are 6 solutions to taste and smell. You are required to place the liquid solution in your mouth and hold it there for 5 seconds to experience the taste and then spit out. You rinse your mouth with water between each test. This assessment is expected to take approximately 20-30 minutes.

5. The 4th assessment is to complete a brief survey on how you found completing all the other assessments in the participant booklet provided.

6. Your medical record will be accessed to confirm your personal details (age, sex), medical details of your diagnosis and medical history and treatment details.

The Research Assistant will follow you up for the duration of the study and advise when your assessments are due. Where possible, any appointments required at the hospital for this research project will be scheduled to align with any other hospital appointments you already have booked to save on extra travel.

There are no costs associated with participating in this research project, nor will you be paid. You will be reimbursed for the following costs that you incur as a result of participating in this research project. The cost of car parking if you are visiting the hospital solely for an appointment for this research study (at a rate of $18 per 1.5hr visit). This is anticipated to occur at the most on two occasions during the study period – and thus the maximum reimbursement will be $36.

You will be involved in the study from the commencement of your radiotherapy treatment until 6 months post treatment, with four assessments required at four timepoints during this time. The research study itself is anticipated to run for approximately 12-14 months, to allow for recruitment of patients and all of their follow up assessments to be completed.

The research has been approved by the Hospital Ethics Committee and will be monitored by the Ethics Committee and the Funding body with annual progress reports required to be submitted by the Principal Investigator.

4 What do I have to do?

As this is an observational study of how your taste and diet intake is affected following radiotherapy – there are no restrictions on what you can and can't do – the researchers are simply observing what happens to you over time.

To fully participate in the study the research team are seeking your commitment to participate in the assessments at each timepoint as described above.

To enable participation in the study you will need access to appropriate technology (e.g. computer/tablet/smart phone with internet connection) to support the telehealth/virtual clinic sessions and completion of the online dietary and taste assessments.

You will need to consent to your personal information (your email address) being provided to a third party so that the website links to access the online assessment tools can be sent to you.

5 Other relevant information about the research project

It is expected there will be 50 patients participating in this study, recruited over a period of 6 months. All participants follow the same procedures.

This study is a feasibility study to determine whether a larger research trial is needed, and so currently is only occurring at the Royal Brisbane & Women's Hospital.

The research team consists of a collaboration of researchers and clinicians from Royal Brisbane & Women's Hospital, The University of Queensland and QIMR, who all have relevant experience and expertise for this research project.

6 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish 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 project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with the Royal Brisbane & Women's Hospital.

8 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research, however possible benefits to you may include receiving more detailed information on your dietary intake and more detailed assessment of your taste function and recovery compared to what patients typically receive.

It is hoped this research will benefit future patients receiving the same treatment as you, as the findings from this study will help clinicians have a better understanding of how taste may be affected, and therefore improved education can be given to patients on what to expect during and post treatment.

9 What are the possible risks and disadvantages of taking part?

There are no anticipated risks of harm from the participation in this research study.

There is a risk that you may experience discomfort when completing the taste test assessments, if any side effects from your treatment have not yet improved (e.g. mouth ulcers). If you feel uncomfortable proceeding with the taste test, you can request that the testing is ceased.

There is also the burden of the additional time required for you to participate in the extra appointments and assessments. However, there will be some flexibility in how and when these assessments can be completed with the use of virtual clinics/telehealth and online assessment tools that can be completed from home.

13 What if I withdraw from this research project?

If you decide to withdraw from this research project, please notify a member of the research team before you withdraw. A member of the research team will inform you if there are any special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the research team will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

14 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include withdrawal of funding, no access to the online assessment tools or Taste Kits which are provided by external companies or due to research staff deployment for an emergency response for COVID-19 pandemic escalation.

15 What happens when the research project ends?

The research project is expected to be completed by June 2021. A summary of results can be provided to participants after study completion. If you are interested in receiving a copy, please ask a member of the research team.

Part 2 How is the research project being conducted?

16 What will happen to information about me?

By signing the consent form, you consent to the research team collecting and using personal information about you and from your health record for the research project as described. Any information obtained in connection with this research project that can identify you will remain confidential. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. All data collected will be managed according to the Information Privacy Act 2009 (Qld).

The online diet survey assessment is conducted using the ASA24 tool which is supplied by the National Cancer Institute in the United States of America. Information you provide on this survey will be transferred to ASA24's server in the United States of America. By completing this survey, you agree to this transfer.

The taste test is being conducted using the Monell Flavor Quiz which is based in the United States of America. Information you provide on this survey will be transferred to Monell's server in the United States of America. By completing this test, you agree to this transfer.

The data collected from you will be re-identifiable (coded) for the duration of the study until your last follow up assessment has been completed. After this time, it will be de-identified for analysis. The data will be kept on password protected databases on a secure server on a Queensland Health computer. Only members of the research team will have access to your records. Records will be destroyed/deleted after 15 years. Information about your participation in this research project may be recorded in your health records.

Your health records and any information obtained during the research project are subject to inspection for the purpose of verifying the procedures and the data. This review may be done by the relevant authorities and authorised representatives of the institution relevant to this Participant Information Sheet, RBWH Human Research Ethics Committee, or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant research personnel and regulatory authorities as noted above.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. Confidentiality is maintained by ensuring all data is de-identified before analysis and dissemination of results.

In accordance with relevant Australian and/or Queensland privacy and other relevant laws, you have the right to request access to the information collected and stored by the research team about you. You also have the right to request that any information with which you disagree be corrected. Please contact the research team member named at the end of this document if you would like to access your information.

17 Complaints and compensation

If you suffer any injuries or complications as a direct 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. If you have any complaints regarding your treatment or experience that is not specific to this research study, please contact the RBWH Patient Liaison Service – by phone (07) 3646 8216 or by email rbwh-patient-liaison-service@health.qld.gov.au

18 Who is organising and funding the research?

This research project is being conducted by Dr Teresa Brown and funded by the RWBH Foundation. There are no declarations of interest by any member of the research team. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

19 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Royal Brisbane & Women's Hospital.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

20 Further information and who to contact

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project you can contact the principal investigator.

Clinical contact person

Name	Dr Teresa Brown
Position	Principal Investigator / Assistant Director Nutrition & Dietetics
Telephone	(07) 3646 0543
Email	Teresa.Brown@health.qld.gov.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	Royal Brisbane & Women's Hospital HREC
HREC Executive Officer	Dr Gordon McGurk
Telephone	(07) 3646 0331
Email	Gordon.McGurk@health.qld.gov.au

Local HREC Office contact (Single Site - Research Governance Officer)

Name	Rebekah Steele
Position	RBWH Research Governance
Telephone	Ph: (07) 3646 8579
Email	RBWH-RGO@health.qld.gov.au

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Location	*Royal Brisbane & Women's Hospital*

Declaration by Participant

- I have read the Participant Information Sheet or someone has read it to me in a language that I understand.
- I understand the purposes, procedures and risks of the research described in the project.
- 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 project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.
- I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _____

Name of Witness* to Participant's Signature (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the research project; its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/ Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

Form for Withdrawal of Participation - *Adult providing own consent*

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Location	*Royal Brisbane & Women's Hospital*

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Royal Brisbane & Women's Hospital.

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.