Participant Information Sheet/Consent Form – Patient.

**[Interventional Study – Patient consenting to participation.]**

Title Medical treatment of osteoradionecrosis of the mandible: A treatment paradigm shift in an Australian population group.

Co-ordinating principal investigator: Dr Vishal Bulsara

Associate investigators: Dr Emma Lewis, Professor Max K Bulsara

Location: Fiona Stanley Hospital

**What does your participation involve?**

1. Introduction

You are invited to participate in the study described below, because you have been diagnosed with a condition called OsteoRadioNecrosis (ORN) of your lower jaw or mandible. This means that some of the bone in your jaw has died and requires treatment. You have developed ORN as a side effect of the radiotherapy that you received as part of your cancer treatment and some other type of trauma such as a dental extraction or a cut on your gum. The aim of this study is to describe the outcomes of two therapies for the treatment of osteoradionecrosis (ORN) of the mandible. The first is a high-pressure oxygen therapy (Hyperbaric oxygen therapy) and the second is a new therapy that involves taking tablet medications for a period of up to 18 months. Both of these therapies are designed to be undertaken prior to needing any type of surgical treatment that may have been discussed with your surgeon previously.

This information sheet will attempt to explain the study to you and what will be involved if you choose to participate. Participation in this study is completely voluntary and you can withdraw from the study at any time.

Please read the information on this sheet carefully and if there is anything that you don’t fully understand or that you have concerns about then please discuss these with your family doctor, a family member or the doctor who has asked you to be a part of the study. It is important that you ask any questions you may have and that these have all been answered to your satisfaction before you agree to participate.

If you would like to participate then we ask that you sign the consent form attached to this information sheet, by signing this form you are telling us (the research team) that you:

* Understand what you have read and have asked any questions that you may initially have had.
* Consent to taking part in the research
* Consent to having the testing and treatment described to you.
* Consent to the use of the information that we gather from you in the ways that we have described to you.

You will be given a copy of this form and the consent form to keep for your own records.

**What is the purpose of this research?**

The aim of this research is to describe the effect of two treatments for osteoradionecrosis (ORN) of the lower jaw. The first treatment, which has been used for decades, involves sitting in a sealed chamber in a high-pressure oxygen environment to help the bone to heal. The second treatment is quite new and has been trialled in both France and the United Kingdom; it involves taking a combination of tablets to treat the condition. Both of these therapies are designed to be trialled prior to any type of surgical procedure to correct the ORN and help the bone to heal, this is so that we can assess whether one treatment is superior to, the same or worse than the other without any bias that having surgical treatment may introduce.

We would like to assess if the new treatment is as good, better or worse than the existing high pressure oxygen treatment in healing, either partially or completely, the jaw bone and how long it takes to have an effect. This will help us to decide if we should offer the medication treatment here in Australia or if we should keep offering the oxygen treatment as well or instead.

This is a pilot study and should you agree to participate you will be randomly allocated to one of the two groups.

**What does participation involve?**

Firstly you will be asked to present for an appointment with the surgeon to decide how much of your jaw is involved and what treatment might be suitable for you as well as having some initial x-rays of your jaw. You will then be given a short course of medication for four weeks to help kill off any bacteria or fungus that may have infected the area and also a steroid medication to reduce inflammation and pain. Depending on which group you have been assigned to, you will then receive the treatment for that group and be asked to return to the same surgeon for regular appointments over the course of your treatment. They will take regular measurements and x-rays or CT scans as well as photographs, which would form part of your normal treatment anyway. An independent group of senior surgeons will then assess your de-identified photographs, measurements and xrays/CT scans without any information to identify you or which treatment group you are in to help us to determine how treatment is progressing. If the treatment that you have been assigned to isn’t working then we will offer you the alternative treatment or surgery. We will attempt to provide you with the best standard of care regardless of which group you have been assigned to.

Once we have gathered information about how you are progressing on your treatment or if you have completely healed, we will analyse the data and publish our results in a medical journal. All information collected will be anonymous in the publication and if one treatment is unsuccessful or one treatment is clearly better than the other then all participants will receive the preferred treatment.

**Do you have to take part in this project?**

If you do not wish to take part in this project then you do not have to. Your participation is entirely voluntary and you can withdraw your consent at any time. You will still receive the same standard of care regardless of whether you choose to take part or not.

If you withdraw your consent prior to the end of the trial then your data will be analysed up to the point at which you withdrew your consent but if the trial has ended and you then withdraw your consent after the data has been analysed and made anonymous it will not be possible for us to identify your data and remove it from the study.

**What are the possible benefits to taking part?**

You will be making a difference to the treatment of your condition going forward and still be receiving the best care possible. You will also be assisting the doctors and surgeons responsible for your care to try and discover new treatments as well as making sure that the treatments that we do offer are the best available.

**What are the possible risks to taking part?**

Because we are using a medication to treat your condition you could suffer an allergic reaction. This is a very rare possibility and should it occur we will attempt to change your medication to another medication of the same type. Other adverse effects of the treatment that you receive cannot be ruled out but these will be explained to you in detail prior to commencing any treatment.

**Consent**

If you have read and understood the information above and you are happy to be participate in this trial then please sign the consent form below. If you have nay other questions then please contact the doctor that you initially spoke with prior to signing this form.

I hereby consent to participating in the trial described above, I understand the implications, risks and benefits of my participation and I willingly accept these. being of sound mind to make such a decision.

Name:

Date of birth:

Address:

Signature: