[Informed Consent Form for Evaluating the Efficacy of Autogenous Tooth Graft (ATG) Material in Socket Preservation: A Clinical and Radiographic Study.]

You may provide the following information either as a running paragraph or under headings as shown below.

Name of Principle Investigator: LIM POH LING
Name of Organization: Faculty of Dentistry, MAHSA University
Name of Project: Evaluating the Efficacy of Autogenous Tooth Graft (ATG) Material in Socket Preservation: A Clinical and Radiographic Study.
Ethic Number: RMC/JANUARY/2025/EC07

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the study with you)**
- **Certificate of Consent (for signatures if you choose to participate)**

You will be given a copy of the full Informed Consent Form

Part I: Information Sheet

Study Title: Evaluating the Efficacy of Autogenous Tooth Graft (ATG) Material in Socket Preservation: A Clinical and Radiographic Study.

Introduction
We appreciate your participation in this study. Reduction of alveolar bone in the extraction socket following tooth extraction is common clinical issue . This will often complicate the subsequent procedure. A socket preservation is a technique to preserve the alveolar bone after extraction. While various graft material are available, this research aims to evaluate the efficacy of using tooth-derived graft material.

Purpose of the research
This study is to examine the dimensional changes following tooth extraction and to evaluate the efficacy of participant own tooth graft material and membrane which derived using participant wont blood in preserving the bone at the extraction site. For comparison, half of the participants will only received membrane which derived using participant own blood without any graft material

Procedure of the research
A clinical examination will be conducted on all the participants to screen and check for the suitability to be included as participant for the project. Cone Beam Tomography (CBCT- 3D xray) will be taken to assess the bone surrounding the tooth. Participant who meet the inclusion criteria will be enrolled into the study. Enrolled participants will receive full mouth scaling and oral care instructions, along with an oral care kit. An alginate mold will be taken for making a custom guide for clinical measurement.

On the extraction day, participant will be randomly assigned to either the test group or the control group.
At test group, after extraction the hopeless prognosis tooth, an autogenous tooth graft will be

prepared from your extracted tooth according to protocol following the guidelines. The graft will be placed at the extraction socket. The extraction site will be covered using Platelet Rich Fibrin (PRF) membrane which will be created by taking 20ml of blood from the participant. The flap will be approximated and secured with sutures.

For Control group, there will be no graft placed on the extraction socket however there is a PRF membrane placed which created using the patient's own blood and the flap will be approximated and secured with sutures.

Participants will have a follow-up appointment 2 weeks after surgery to review the surgical site and remove the suture. Participant will then be recalled 3 months and 6 months after the surgery. During these appointments, clinical measurement and Cone Beam Tomography (CBCT- 3D xray) will be taken for radiographic measurement.

For participants who eligible for implant placement during the research period, a bone sample will be obtained from the implant site to assess bone quality. The bone sample will be collected using a trephine bur before the initial drilling, preserved in a formalin container, and sent to the laboratory for histological examination.

Participant Selection

Participant that aged 18 years or older, who requires to extract lower and upper front teeth and lower premolar, and who desired replacement with dental implant. Participant should be healthy or have well-controlled systemic illness, nonsmoker and have adjacent tooth to the extracted site. Participants should maintain good oral hygiene with plaque score less than 25% and have adequate space to place for dental implant.

Voluntary Participation

Your participation in this research is entirely voluntary. If you choose not to participate, all the services you receive at this center will continue as usual, and nothing will change

Duration

The research study spans a period of 6 months. During this time, we will require you to attend at least 7 scheduled appointments. Each of this appointment will typically last around 1 hour except for the procedure day, which may take up to 2 hours to complete it.

Risks

Every procedure carries some level of risk. In this study, the risks will be

- During extraction, there is a risk of root fracture and uncontrolled bleeding. If root fracture, we will ensure it will be removed and the bleeding will be controlled
- When using local anaesthesia , the potential risks are not limited to bleeding, swelling, accidental choking, accidentally biting the lips, cheeks, tongue and difficulty swallowing or breathing.
- When withdrawing blood for the membrane, the potential risks include bruising, swelling
- When scaling, the potential risk are choking, accidental swallowing, bleeding, teeth sensitivity, tooth mobility, gum recession, flare up between appointments
- For graft material, although it is your own tooth, there remains a risk of infection and swelling

However, we will take all necessary precautions to minimize these risks. Trained professionals will perform blood draw using sterile technique, performing the procedure and monitor you closely throughout the process.

Benefits
There are potential long-term advantages. By using your own tooth as a graft material, the procedure may enhance the condition of your bone, making it more suitable for receiving a dental implant in the future. This could improve the outcomes of any subsequent dental restorative procedure you may undergo.

Reimbursements
You will not receive any financial incentives for taking part in this study. However, we will provide you with a basic oral hygiene kit as maintaining good oral hygiene is crucial throughout the study.

Confidentiality

The personal data of the patient either obtained/ used/ stored for the purpose of this study must be in compliance with the regulations in the Personal Data Protection Act 2010

Right to Refuse or Withdraw
You do not have to take part in this research if you do not wish to do so. You may stop the participating in the research before the procedure starts. Your participation in the research is entirely voluntary.

Who to Contact
If you have any question, you can ask now or later. If you wish to ask question later, you may contact any of the following:
Name: Lim Poh Ling
Number: +6011-20881658
Email: dperio24116034@mahsastudent.edu.my

Part II: Informed Consent Form

Title of study :
Evaluating the Efficacy of tooth Autogenous Tooth Graft (ATG) Material in Socket Preservation: A Clinical and Radiographic Study.

Patient Name: **Date:**
Gender **Age:**

PATIENT CONSENT FORM

I, _____,
Identity card no: _____ hereby agree to be participate in the research project, title " Evaluating the Efficacy of tooth Autogenous Tooth Graft (ATG) Material in Socket Preservation: A Clinical and Radiographic Study" to assess the efficacy of a biomaterial prepared from my own extracted tooth versus natural healing after extraction. Hereby, I also give consent for examination , clinical photography , and X-ray radiograph(s) necessary for my condition and the project.

The nature of the research has been explained to me by Dr._____ and interpreted by _____ to the best of his/her ability in English and/or _____ language/dialect.

I have been told about the nature of the research in terms of objectives, methodology and possible outcomes. After knowing and understanding all the possible advantages and disadvantages of this research. I voluntarily consent of my own free will to participate in the research specified above.

I understand that I can withdraw from this clinical research at anytime without assigning reason. Personal data obtained/used/stored for the purpose of this study will be comply with the regulations in the Personal Data Protection Act 2010

Date:_____ Signature:_____
( )

IN THE PRESENCE OF

Name: _____
Signature: _____
Date :_____
Day/month/year

I confirm that I have explained to the patient the nature of the above mentioned research

Date:_____ Signature :_____
( )