Patient Information sheet

Title of research proposal: **Effect of Plasma rich in growth factor with bridge flap in management of Miller's class I and II gingival recession defects**

Study Sponsor: Self

Investigator's Name: Dr. Mohit Das

Institution Address:

Institute of Dental Sciences,

Siksha 'O' Anusandhan University,

Bhubaneswar

TelephoneNumber: 7008093223

AfterOfficehours: _____

_____

Patients' Screening Number: /_/_/-/_/_/

Patient's study ID number: _____

Patient's Individual Identification Code (initials):_____

Dear Patient,

Please read this document carefully. You may ask your study doctor any questions about the clinical study. Please keep this document till completion of the study.

We appreciate your interest in participation in this clinical study. This document contains information about the study you are going to take part in if you give your consent, and we decide that you may be included in the study. Please contact your study doctor or employees of the study center n case of any questions that you may have after reading this document, or if you do not understand any part of the provided information. Do not sign the Informed Consent Form until you receive satisfying answers to the asked questions and decide that you want to participate in this study.

INTRODUCTION:

You have been invited to participate in the present research study.

Before you decide, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully and discuss it explained to you and you will be given the chance to ask questions. Do not sign the Informed Consent Form until you receive satisfying answers to the asked questions and decided that you want to participate in this study.

If you agree to take part, you will be asked to fill out, sign and date.This information and consent form in 2 copies. A copy will be given to you as a useful reference on study details and personal contacts.

By signing the consent form, you will be agreeing to participate and adhere to the requirements of this study.

You are asked to make a voluntary decision to participate in this study.

1) **What is the purpose of the study?**

   The purpose of the present clinical study was to compare the clinical efficacy of DLSBF with and without PRGF for the management of gingival recession in the mandibular anterior teeth..

2) **What is the active substance, if any?**

   PRGF

3) **What are the study objectives and goals?**

   To compare the clinical efficacy of DLSBF with and without PRGF for the management of gingival recession in the mandibular anterior teeth..

4) **Who is the study sponsor? Who are the participating institutions?**
   Self

5) **What are the eligibility criteria to participate in the study and is my participation voluntary?**
   Subjects reporting to the OPD with a chief complaint of gingival recess=ion in lower anteriors

6) **Describe about exclusion criteria**
    - Previous periodontal surgery at the study site.
    - * Antibiotics taken within the last 3 months.
    - * Patients having cervical restorations or root caries.
    - * Tobacco smoking or smokeless tobacco use.
    - * Systemic diseases such as diabetes mellitus or hypertension.
    - * Medications associated with gingival enlargement.
    - * Presence of trauma from occlusion.

7) **Are there any special instructions for me (patient)?**
    Take medications on time as prescribed

8) **What are my responsibilities?**
    Do regular follow-ups.

9) **What is the information about study drug safety?**
    It is safe

10) **What are the possible benefits of taking part in the study?**
    Gingival Recession Coverage

11) **Alternatives to being in the study:** The alternative is not to participate in the study.

12) **Am I insured and will I be compensated for research related injury during the study?**
    No

13) **Withdrawal from the study due to any reasons:**Your participation is voluntary.

14) **Follow-up procedures for discontinued patients:**If you withdraw or discontinue participation, the investigator may contact you to assess your clinical condition and provide appropriate advice or further dental care, where required.

15) **Additional information about this research study or the research results:** Nil

16) **Are my patients' rights protected?**

    Yes

17) **Questions and claims?**

If you have any questions, concerns, complaints or claims regarding the study, its procedures, your participation, or any problems experienced during the study, you may contact the Principal Investigator or the Department of Periodontics and Oral Implantology.

18) Will confidentiality be observed?

Yes

19) Who can I contact if I have further questions?

Principal investigator and the Department

INFORMED CONSENT FORM

Title of the proposal:Clinical and radiographic evaluation of Plasma Rich in Growth Factors (PRGF) for alveolar ridge preservation in the anterior maxilla

Study Number:

Patient's Initial: XYZ Patient's Name: ABC

Date of Birth: /X/Y/ZZ/ Age: XY (Completed years)

Address of the Patient: Qualification: _____

Bhubaneswar

Occupation: Student/Self-Employed/Service/Housewife/Others (Please tick as appropriate)

If 'Others', please specify: _____

Annual income of the Patient: _____ Name and address of the nominee (s) and his

Relation to the Patient *(for the purpose of compensation in case of trial related death)*:

_____

_____

	Patient's Declaration	Please initial box (Patient)
i.	I confirm that I have read and understood the information sheet dated for the above study and have had the opportunity to ask questions.	
ii.	I understand that my participation in the study is voluntary and that I am	

	free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	
iii.	My personal data is kept confidential. However, I understand that the Sponsor of the proposal, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that ma be conducted in relation to it, even if I withdraw from the proposal. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published	
iv.	I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s)	
v.	I will be debarred and will lose my claim to compensation in cases of Cross-participation, Incorrect medical history, alcohol consumption	
vi.	I agree to take part in the above study and I had been informed that I will receive a copy duly filled signed and dated/ thumb impression "Informed Consent Form".	
vii.	I have been informed that in case of study related injury or death, M/s sponsor will provide complete medical care along with compensation for the injury or death.	
viii.	I agree that I have informed my participation in the study to my family members and they have no objection to my participation in the study.	

Name of the Patient		Date:____/____/_____ day/month/year
Signature/Thumb Impression of the patient		Time:

Name of Legally Acceptable Representative (LAR)		Date:____/____/_____ day/month/year
Signature/Thumb Impression of the LAR		Time:

Relationship to Patient		Age of LAR:
Address of LAR		

Investigator's Declaration I declare that the information given in this informed consent document was verbally presented to this participant and that ample time and opportunity were given for this participant / witness to read and understand the contents of this document and enquire about details of the study and to decide whether or not to participate in the study. I further certify that I have discussed the research project with this participant and explained to him or her in non-technical terms any risks and adverse reactions that may be expected to occur. I encouraged this participant to ask questions and all question asked were answered to the satisfaction of the participant. Following this, the participant (and an impartial witness, in case of illiterate participant) signed/attested this informed consent form in my presence.		
Investigator Name: Dr. Tejas Rajkumar Pande		Date:____/____/_____ day/month/year
Signature of the Investigator:		Time:____/____ hh/mm
Witness Declaration		
I confirm that I have read and understood the information regarding the study and that it has been explained by the investigator to the participant has given his/her consent freely/voluntarily to participate in this study.		
Name of the Impartial Witness		Date:____/____/_____ day/month/year
Signature of the Impartial Witness		Time:____/____ hh/mm

(Copy of the Patient Information Sheet and duly filled Informed Consent Form shall be handed over to you or your attendant)