INFORMED CONSENT FOR PARTICIPANTS

The purpose of this document is to invite you to participate in the study **"Bone Microarchitecture and Stabilization of Implants in Atrophic Upper Maxillae Reconstructed with Grafts Treated with Teriparatide¨.** whose principal investigator is Dr. Jessika Dethlefs Canto, Dental Surgeon, Specialist in Oral and Maxillofacial Surgery and Traumatology. So that you can make an informed decision, we will explain below what procedures will be involved in the execution of the investigation, as well as what your collaboration would consist of:

1. **Where and when the research will be carried out: The aforementioned research will be carried out in the Dental Clinic of the School of Dentistry of the University of Valparaíso between the years 2023 and 2025.**
2. **Relevance of the study and benefits:** Several scientific studies have proven that dental implants installed in conjunction with bone grafts have better results. Currently, other materials can also be used in conjunction with these grafts to improve the quality of the bone and consequently the final result of this treatment. One of these materials is teriparatide (Forteo®), a drug that has been extensively studied in bone repair and bone graft integrity. Therefore, we see that the association of this drug in conjunction with the grafts used in jaws with little bone quantity and quality would improve this condition and facilitate the earlier installation of dental implants.
3. **Objectives:** The objective of this project is to evaluate the effect, on bone quality and characteristics, of the mixture of a local dose, of a drug (Forteo®) with a bone graft in the elevation of the maxillary sinus of patients candidates for rehabilitation with dental implants in the upper jaw.
4. **What your participation consists of:** Your participation in this research is completely voluntary. As it is a clinical study, all candidates must undergo clinical and radiographic examinations to evaluate compliance with the requirement of the need to install dental implants in the posterior area of the upper jaw, and due to the decrease in the amount of bone in that sector, present the need for maxillary sinus augmentation. Once selected and agree to participate in this study you will be subjected to a selection process to be operated through the traditional sinus augmentation surgical procedure with the use of graft mixed with saline or through the traditional surgical procedure, but this graft will be mixed with a medication that has the purpose of improving bone quality and reducing bone healing time. The medication to be used is teriparatide, whose trade name is Forteo® (Lilly France, Technofarma Chile). It is authorized for use in Chile by the Institute of Public Health (ISPCH, Ref.MT610509/14, Reg. ISP N° B-1773/14). It is a drug used in medicine mainly in the treatment of osteoporosis and in the treatment of bone fractures. In dentistry is used in the treatment of various bone pathologies. According to the publications studied, this medicine has no adverse effect when used locally. Three months after graft placement, and being monitored clinically and radiographically, we will proceed with the placement of the dental implant. In that same procedure, a bone sample will be taken in the area where the implant will be installed.

This will then be analyzed under a microscope in order to evaluate its characteristics and quality. Finally, the time of osseointegration of the implant will be waited for the beginning of the preparation of the dental prosthesis. The time between graft surgery, implant placement and the beginning of the dental prosthesis manufacturing stage should be approximately 6 months. The control of all surgical stages will be carried out through clinical and imaging controls. It is very important that you attend these controls on the dates that will be informed. During this study you will be assisted both by the person in charge of this, Dr. Jessika Dethlefs Canto, and by specialist professionals who will be in your care. It should be noted that all surgical and rehabilitation treatment will be performed at the Dental Clinic of the School of Dentistry of the University of Valparaíso, located at Altamirano Subida Carvallo 211, Valparaíso

5. **Risks:** Despite the high predictability of this treatment, the risks are associated with the surgical technique itself and not with the drug under study. The complications described are: perforation of the sinus membrane, sinusitis, increased intrasinus and intranasal pressure, hemorrhage, pain, inflammation, hematoma, edema (swelling), infection, impossibility of placement of dental implants, autoimmune reaction of implants (rejection). All complications associated with the surgical stages of this study (grafting and installation of dental implants) will be treated in the Oral and Maxillofacial Surgery and Traumatology Service of the School of Dentistry of the University of Valparaíso by the principal investigator or, failing that, by a specialist in Oral and Maxillofacial Surgery and Traumatology belonging to that service. In case of rejection of the implants by autoimmune reaction, there will be the possibility of a new implant installation procedure.
6. **Use of Samples:** The samples donated by you, as well as the information related to them, will be used by researchers to analyze, and describe the bone quality that was achieved in the bone healing process.
7. **Costs and Payments:** You will not receive any compensation for participating in this study. The costs associated with planning (x-rays and images), surgical treatment (right to operation room, bone graft, collagen membrane, implants) and rehabilitation treatment are part of the normal budget for conventional treatment and is the one that must be paid both to the School of Dentistry, as well as to the suppliers of grafts, implants, prosthetic supplies and laboratories. However, by participating in this study you will have a 60% discount on the surgical benefits fee, in addition to a 15% discount for the purchase of bone graft and collagen membrane respectively, 22% on the purchase of implants and 30% on the radiographic images requested in the planned instances and that are required. The medications indicated for the surgical stages (decongestant, analgesics, anti-inflammatories, antibiotics) are part of the traditional treatment and are at the expense of the participants. However, the cost of the study drug (Forteo®), extraction, storage and analysis of the samples in addition to the pre and post-surgical clinical controls will not be included within that budget and should not be paid by the participant as part of the treatment.
8. **Rights of the participant:** If any doubt arises, you can consult it, the principal investigator Dr. Jessika Dethlefs Canto and / or her collaborators, at any time during the research, whom you can consult at the Dental Clinic of the University of Valparaíso, through your cell phone +56993231103 or your jessika.dethlefs@uv.cl email.

Your participation is completely voluntary, if you decide not to participate in this study anymore, you can do so at any time. Your decision must be communicated to the principal investigator through a letter addressed to the Service of Oral and Maxillofacial Surgery and Traumatology, School of Dentistry, University of Valparaíso, Subida Carvallo 211, Playa Ancha, Valparaíso. Your withdrawal from the study does not harm you in any case, that is, it will not affect any treatment that is being provided, nor will your care at the Dental Clinic of the Faculty of Dentistry of the University of Valparaíso be interrupted.

9. **Reservation of the identity of the participant:** The data obtained will be confidential, that is, their name and RUT will not be disclosed. Instead, a code (participant n° X) will be used. The sample donated for this research will have a registration number that will replace your identity (patient n° X, sample n° X), however, this background will be recorded in the database of the principal investigator, so only she will know that the sample whose sample it is. If you authorize the use of your samples for this and future research whose objective does not deviate from the purpose of this, the storage time is 5 years. After that period, these will be eliminated in a supervised manner.
10. **Confidentiality of the data:** All the information obtained by the research team is confidential, only the professionals who will attend it will have access and will be protected by the principal investigator in a digital file kept in the office of the Chair of Surgery of the School of Dentistry of the University of Valparaíso, located in Altamirano Subida Carvallo 211, Valparaíso
11. **Use and publication of findings:** The findings of this study will be known through scientific publications and could be used in other studies that do not stray from the objectives of this research, always preserving the identity of the participant.
12. **Bioethics Committee Evaluation and Contact:** This research has been evaluated and accepted by the Institutional Committee of Bioethics of Research in Human Beings of the University of Valparaíso. If you require it, you can contact any of its members through the institutional mail cec.uv@uv.

Contact details:

If you require more information or contact us for any reason related to this research, you can contact the researcher responsible for this study:

Teach. Dr. Jessika Dethlefs Canto

Mobile: +56993231103

Address: Subida Carvallo 211, Playa Ancha, Valparaíso

Email: jessika.dethlefs@uv.cl

Participant Name:

Participant's signature:

City in which it is signed:

Date of signature:

This document has 4 (three) pages, and is signed in two copies, leaving one for you.

INFORMED CONSENT DECLARATION

By agreeing to participate you declare that you do so in an informed manner, that is, that you have read and understood the conditions of your participation in this study in the terms indicated above and have had the opportunity to ask questions and that these have been answered adequately, without any doubt about it.

If you agree to participate in this study, please check the cell and sign below indicating that you agree to participate voluntarily.

Yes, I voluntarily agree to participate in this study ☐

Mandatory Signatures:

- Participant:
  Name:.....

  Signature:..... Date:.....

  Email of the participant for return of information:

- Responsible Researcher or Delegate:
  Name:.....

  Signature:..... Date:.....

City in which it is signed:

Email of the participant for return of information: