INFORMED CONSENT FORM

Protocol Title:	Impact of treatment with plasma rich in growth factors (PRGF) in patients with severe dry eye. (version 1. 31/01/26)
Study Sponsor:	Laboratorios Lansier
Study Promoter	Clínica Visualiza
Physician in charge of the study:	Mario Renato Papa Vettorazzi 4th Avenue A 11-54, Zone 9
Visualiza telephone number:	2414-0800
Mobile phone:	3574-5899

1. **Why did I receive this document to read?**

You are invited to participate in a research project evaluating treatment with plasma rich in growth factors eye drops (drops produced from your own blood) for severe dry eye disease, which may cause symptoms such as itching, burning, tearing, or a sensation of sand or debris in the eye. This project is being conducted by Dr. Renato Papa (Research, Cornea and Anterior Segment Department, Clínica Visualiza).

The purpose of this consent form is to provide you with the information you need to help you decide whether or not you wish to participate. Before deciding to participate and signing this consent form, please read it carefully. You may ask questions about what you will be required to do, the risks, benefits, your rights as a volunteer, or any other aspect of the research or this form that is unclear to you. Once all your questions have been answered to your complete satisfaction, you may decide whether or not you wish to participate in this study. If you decide to participate and sign the form, you will receive a copy of this form for your records. Your decision to participate in this study is voluntary.

2. **Purpose of the Study:**

The purpose of this study is to evaluate the outcomes of plasma rich in growth factors for the treatment of severe dry eye compared with the usual postoperative eye-drop treatment for 1 month.

As part of the research, we must make sure that you meet the requirements to participate in the study. If you do, you will be randomly assigned (like tossing a coin) to one of 2 treatment groups: either the conventional treatment group for severe dry eye or the conventional treatment plus PRGF group. Each treatment group will include 50 patients.

3. **What should I know if I join this study?**

If you agree to join this study, the following section explains what will happen during the study.

Procedures:

Number of subjects: 100 patients will be evaluated in Guatemala (50 patients in each treatment group).

Study duration and number of visits: your participation in the study will last 4 weeks.

Your participation will include a visit to the clinic and a complete ophthalmologic examination, in addition to the tests used to diagnose dry eye.

All patients will have 20 milliliters of blood drawn by puncturing a vein (usually in the arm) using sterile technique and materials. This blood will be used to prepare your plasma rich in growth factors eye drops (if you are assigned to this treatment group). If you are assigned to the conventional treatment group, your sample will be discarded. Blood collection is generally safe, but some discomfort may occur, such as mild pain at the puncture site, a small bruise, slight bleeding, or local swelling.

There will be telephone contacts between you and the study staff, during which the study staff will ask about your current health status (whether you have experienced any adverse event, medical procedure, change in medication, etc.).

After signing the Informed Consent Form (Screening): once you have been informed about the study and the procedures to be performed, if you decide to participate, you must sign this consent document.

Treatment Period: if you meet the requirements to participate in the study, you will undergo "randomization." Randomization means that you will be assigned by chance to one of the two groups listed below. You will have an "equal" chance, or a 50% probability (like tossing a coin), of receiving conventional dry eye treatment or conventional treatment plus plasma rich in growth factors (PRGF) eye drops. The group in which you participate will be assigned using a list previously generated by a computer.

If you are assigned to the conventional treatment group, you must follow the following treatment for 1 month: eyelid hygiene once daily with a preservative-free foaming solution; preservative-free sodium hyaluronate 3% drops as needed; preservative-free cyclosporine 0.05% twice daily; loteprednol 0.2% twice daily for 15 days and then once daily for 7 days; polyacrylic acid 0.2% as needed; and you will receive 1 dropper of balanced saline solution 0.9% (as placebo), which you must apply 4 times daily for 1 month.

If you are assigned to the conventional treatment plus plasma rich in growth factors (PRGF) group, you must use all treatment as described above and, in addition, use the plasma eye drops 4 times daily for 1 month (instead of the placebo).

As part of the research, the results obtained from the tests used to diagnose dry eye will be analyzed: tear meniscus height (measures tear quantity), TBUT (measures tear evaporation time), meibography (measures the function and quality of the glands along the eyelid margin), conjunctival hyperemia (measures the degree of eye redness), and corneal staining (to determine whether there are scratches on the cornea), as well as the OSDI-6 questionnaire result (a questionnaire that assesses the number of symptoms in patients with dry eye). These results will be compared with the results of the same tests and questionnaire after treatment. These tests are routinely performed for the diagnosis and follow-up of dry eye and will be provided at no cost to you.

Your visits: regardless of the group to which you are assigned, will take place one month after starting treatment. At this visit, you will be asked to repeat all dry eye diagnostic tests as well as the OSDI-6 questionnaire. A complete ophthalmologic examination will also be performed.

Collection of Adverse Events/Serious Adverse Events: your doctor will ask whether you have experienced any change in your health, whether any medication has recently been added, whether you have had any hospitalization or clinic visits, or any planned/unplanned surgical procedure, in order to assess your overall well-being and ensure your safety.

4. Rights and responsibilities

If you have read this document and decided to participate, please understand that your participation is voluntary and that you have the right to decline participation or withdraw from the study and revoke your consent at any time, without any penalty or loss of benefits to which you would otherwise be entitled. Withdrawal will not affect activities already performed or data obtained after the initial signature and before withdrawal of consent. You must notify the physician in writing at any time.

The principal investigator will continue to retain and use your information (including data arising from analyses performed up to the time of withdrawal), in accordance with local laws. This is done to ensure that the study results can be verified, to determine the effects of the study treatment, and to ensure complete study documentation.

If you agree to participate, your responsibilities include:

- Attend all required visits.
- Follow all instructions given by the physician.
- Report if you forget to follow the physician's instructions.
- Inform the study physicians of any change in your health and any medication you use during the study.

Dr. Mario Renato Papa Vettorazzi will inform you if any new information becomes available that could affect your decision to continue participating in the study.

5. What will happen if the physician cannot contact me?

If the physician cannot contact you, the person(s) you identified as contact(s), or your personal physician, the physician or study staff will search publicly available sources (for example, Internet searches) to find updated contact information, to contact you, and/or to obtain information about your health status.

If the physician or study staff still cannot contact you or cannot find information about your health status, they may provide your personal information (for example, your name, address, telephone number, and date of birth) to a patient-locating service. This service will attempt to obtain updated contact information and/or information about your health status using available public records and/or social media.

6. Are there reasons why the treatment or participation in the study may be stopped early?

The physician may withdraw you from this study for any justified reason and will discuss your options with you.

The following are some examples of why you may have to stop some or all study-related activities, including study treatment:

- You need a treatment that is not permitted in this study.
- You do not follow the instructions.
- The physician believes that keeping you in the study could be harmful and is not in your best interest.

7. Who owns the data and results created during the study?

The principal investigator will own all data and results generated during this study.

8. Risks and benefits:

Risks are possible effects other than the intended effects of the study treatment and the tests performed during the study.

In clinical studies, there is a possibility that you may experience these unintended effects. It is important for you to know that not all possible side effects of the study treatment are known at this time.

You must inform the physician if you have unusual symptoms, behaviors, or side effects, if you have visited other physicians, or if you have been hospitalized outside the context of the study.

Possible side effects of the study treatment include the following:

Related to conventional treatment for severe dry eye: local pain and inflammation (in the eye), eye redness, burning, sensitivity to light, infection, decreased vision, appearance of optical phenomena (such as flashes, shadows, reflections, etc.), and increased intraocular pressure (pressure inside the eye).

Related to the use of plasma rich in growth factors (PRGF): local pain and inflammation (in the eye), eye redness, burning, sensitivity to light, infection, decreased vision, and appearance of optical phenomena (such as flashes, shadows, reflections, etc.).

The expected benefits of this research are to provide valuable and useful information for the management and treatment of patients with severe dry eye, with the aim of improving their quality of life and ocular health. All medications, consultations, and diagnostic tests required during the research study will be provided at no cost to you.

9. What other options do I have if I choose not to join this study?

If you decide not to participate in the study, you may continue with the treatment recommended by your physician without any penalty or loss of benefits to which you would otherwise be entitled.

10. Payment/compensation

You will not receive any payment for participating in this clinical trial.

Compensation in case of injury: The principal investigator and the medical team will make every effort to prevent you from being injured as a result of your participation in this study. Immediate care, emergency treatment, and any necessary services will be available to you at Clínica Visualiza or Hospital Multimédica.

It is important that you inform Dr. Mario Renato Papa Vettorazzi if you believe you have suffered an injury due to your participation in this study, by calling 2414-0800 or 3574-5899, 24 hours a day, 7 days a week.

11. Costs

All medications required during follow-up and all consultations required until completion of the clinical trial will be provided at no cost to you.

12. Privacy and Confidentiality.

Your participation in this study will be treated with complete confidentiality in accordance with Article 35 of the Political Constitution of the Republic of Guatemala and Initiative 4090-2009, the Personal Data Protection Law and guarantee of digital rights regarding the processing of personal data and the free movement of such data.

The physician will collect your personal data, including your name, address, sex, age/date of birth, medical information, and study procedures.

If you have a primary care physician, the study physician may inform that physician that you are participating in this clinical trial.

When entering your data into the electronic data capture system, the physician will replace your name and other general identifying information, except your age/date of birth and sex, with a special code that identifies you. The physician will associate this code with the study information.

Your participation in this study will be treated with complete confidentiality. No subject will be identified by name in any publication of the study results. The principal investigator agrees to anonymize personal data, which means that your personal data cannot be used to identify you. The principal investigator may share these anonymized data with external third parties. Regulatory agencies and representatives of the Research Ethics Committee responsible for the trial are authorized to review your medical record to verify the study results without violating confidentiality.

You are asked to authorize the principal investigator and collaborators to access your personal data for educational and research purposes, while ensuring the privacy and confidentiality of these data. Your data will be stored for the period required by local regulations after the end of the study.

Your specific rights regarding your personal data:
You have the right to review your personal data. However, during the study, access to personal data may be limited to protect the integrity of the study. You may be able to access your personal data at the end of the study.

13. Contacts

For any questions or communications regarding the study, you may contact the following entities/persons:

For questions about your rights as a participant in the clinical study, contact:

Independent Ethics Committee: Latin Ethics, Dr. Mariano Guerrero
Telephone: 2234-6106
Address: 14 Calle 7-13, Zone 9, Torreblanca Building, Level 10, Guatemala, 01009

Principal Investigator: Mario Renato Papa Vettorazzi
Center telephone: 2414-0800
Mobile phone: 3574-5899, 24 hours a day, 7 days a week
Email: mario.papa@visualiza.org.gt

Sub-Investigator: Daniela Chavarria
Center telephone: 2414-0800
Mobile phone: 4941-9108, 24 hours a day, 7 days a week
Email: daniela.chavarria@visualiza.org.gtdaniela.chavarria@visualiza.org.gt

If you experience any injury attributable to the study or in case of an emergency during business hours (7:00 a.m. - 5:00 p.m.), go to Clínica Visualiza, 4th Avenue "A" 11-54, Zone 9, or call 2414-0800 or 4716-8107. In case of an emergency outside business hours, the referral hospital will be Hospital Multimédica, Blvd. Vista Hermosa 25-19, Zone 15, Guatemala. Tel: 2231-8100

12. Signature Page

By signing this consent form, I authorize the use, access, and exchange of my anonymized personal data as explained in this document.

By signing this consent form, I certify that:

ㄹ I freely and voluntarily consent to participate in the research study

ㄹ I have read the patient information sheet provided to me

ㄹ I have received sufficient information, my questions have been clarified, and all my questions about this study have been answered satisfactorily

ㄹ I understand that I may freely withdraw from the study without giving a reason and that my decision will not affect my future care.

ㄹ I understand that I will be informed of the results and conclusions obtained from this study once it has been completed, either in physical form or electronically.

ㄹ I will receive a signed and dated copy of this informed consent form

_____ _____

Patient name * DPI

_____ _____

Signature Date

_____ _____

Principal Investigator/ DPI

Sub-Investigator

_____ _____

Signature Date

_____ _____

Witness name (if applicable) * DPI

_____ _____

Signature Date