Free and Informed Consent Form

(Document prepared on November 28, 2025)

Title: **"RESEARCH PROTOCOL FOR CLINICAL AND FUNCTIONAL EVALUATION OF ORTHOBIOLOGICAL THERAPIES IN MUSCULOSKELETAL DISORDERS"**

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Ethics and Research Committee of UNIVATES - Sector A - Building 1 - Room 309. Email: coep@univates.br or phone (51) 3714 7000 / Extension 5339.

Dear participant,

You are invited to participate in the research project "Research Protocol for Clinical and Functional Evaluation of Orthobiological Therapies in Musculoskeletal Disorders", developed by student Andre Kruel, a graduate student in the Biotechnology Graduate Program at the University of Vale do Taquari - Univates, under the guidance of Professor Dr. Guilherme Liberato da Silva, a researcher at the same institution.

The central objective of the study is to evaluate the clinical and functional effects of the use of orthobiological therapies (hyaluronic acid, platelet-rich plasma, bone marrow aspirate, nanofat, and others) in the treatment of various musculoskeletal diseases in patients routinely treated at the Proregen Medical Clinic, located in the municipality of Bento Gonçalves/RS. The methodology used in this study is part of an umbrella project, which aims to prospectively record and analyze the clinical and functional outcomes associated with the use of these therapies in patients treated according to institutional medical indication. Patients with various osteoarticular pathologies who undergo routine orthobiological treatment at the Proregen Medical Clinic or one of its affiliates will be included.

<u>Why are you being invited?</u>

Your participation is due to our need to recruit participants, over 18 years of age, with a clinical and/or radiological diagnosis of an eligible musculoskeletal condition, and who have a formal clinical indication for treatment with orthobiological agents, according to routine care.

Researcher rubric Participant rubric

Your participation is voluntary, that is, it is not mandatory, and you have full autonomy to decide whether or not you want to participate, as well as to withdraw your participation at any time. You will not be penalized in any way if you decide not to consent to your participation, or to withdraw from it. However, it is very important for the execution of the research. The confidentiality and privacy of the information you provide will be guaranteed. Participants will not receive any type of reward or payment for participating in the research.

Mechanisms to guarantee confidentiality and privacy Any data that could identify you will be omitted in the dissemination of the research results, and the material will be stored in a secure location. At any time during or after the research, you may request information from the researcher about your participation and/or about the research, which can be done through the contact methods specified in this Agreement.

Detailed procedures that will be used in the research

Your participation will consist of:

• Answering the necessary research questions, such as: name, phone number, gender, age, clinical data such as: type of surgery, operated side, current and previous illnesses, medications used continuously, reports of laboratory and imaging exams, weight, height, date of surgery, length of hospital stay, any complications that may have occurred as a result of the procedure, evaluation of pain and function scales according to the disease and affected joint.

• Giving permission to the responsible physician to choose the type of orthobiological (hyaluronic acid, PRP, BMAC, nanofat, etc.) to be used, based on the clinical characteristics of the case.

• Receiving the orthobiological intervention designated by the responsible physician and following the post-procedure instructions provided.

• Returning for previously scheduled appointments to monitor the progress of the procedure.

Research Duration

Data collection from participants will occur at defined times: Pre-treatment, short-term (4–6 weeks), medium-term (3–6 months), and long-term (>6 months). During each consultation, the physician will allocate the necessary time to collect data and clarify any doubts, always respecting the conditions of each participant.

Data and material collected in the research will be stored

The data obtained will be transcribed and stored in digital files, but only the student and their supervising professor will have access to them. At the end of the research, all material will be kept on file for at least 5 years, according to CNS Resolution No. 466/12. After 5 years, this material will be destroyed.

Benefits to Research Participants

Participants will not receive any direct benefit. This research is justified by the lack of unanimity in the literature on the subject and the impossibility of providing definitive data on which orthobiological device to use and at what time it is most efficient, safe, and entails the lowest financial and personal cost to the patient undergoing the procedure. This discussion is fueled by the divergent ways of performing the procedures and the variety of products available on the market, considering that no procedure will be performed without proper indication according to current medical literature. The techniques used are based on the extensive experience of the physicians. Therefore, indirectly, the research will provide the benefit of a better understanding of the techniques, their complications, and results, contributing to assisting in future decision-making.

Risks or discomforts

The risks are minimal, but patients, potential participants in the study, upon being invited to participate in this research, may experience some discomfort or embarrassment, feel coerced, or disrespected regarding their human dignity, cultural, social, psychological, moral, ethical, intellectual, religious values, habits, beliefs, and customs. Should any adverse reaction occur that could cause harm to the study participant, they will be immediately referred to a specialized team and it will be explained that the invitee does not need to participate in the research, that they have the right to refuse the invitation, and that this will not in any way harm their current or future treatment, if any. Furthermore, the confidentiality and privacy of the information obtained will be guaranteed. The information will be recorded and subsequently destroyed. Data related to the identification of each participant will not be disclosed. The researchers will be the only ones to have access to the data and the Informed Consent Form and will take all necessary measures to maintain confidentiality. However, there is always the remote possibility of a breach of confidentiality, even if involuntary and unintentional, the consequences of which will be dealt with in accordance with the law. Obviously, the researchers guarantee confidentiality and will do everything in their power to maintain it. The patients' names will be replaced by numerical codes in the database; no personal information that could identify them will be collected, only

postoperative results. We will strive not to violate the integrity of documents, medical records, and imaging exams. Upon perceiving any risk or breach of confidentiality, the researchers will notify the ethics committee and the institutions involved, exclude the patient from the study, and immediately suspend the study until the necessary adjustments are made. There is no conflict of interest between the researchers and the research subjects. There is no sponsor for the project. The researchers are readily available in case of any eventuality, and if you have any questions during the research, the participant may contact them by phone and email at the end of this document.

Regarding the dissemination of research results

The results will be disseminated in individual reports for participants, scientific articles, seminars, and in the researcher's doctoral thesis.

If you have any doubts regarding the ethical conduct of the study, please contact the Research Ethics Committee of Univates (Coep/Univates). The Ethics Committee is the body that aims to defend the interests of research participants in their integrity and dignity and to contribute to the development of research within ethical standards. Thus, the committee has the role of evaluating and monitoring the progress of the project so that the research respects the ethical principles of protection of human rights, dignity, autonomy, non-maleficence, confidentiality and privacy. Contacts: (51) 3714.7000, extension 5339 and coep@univates.br.
Contact with student and researcher: (54) 99689-1295

I declare that I understand the objectives and conditions of my participation in the research and agree to participate.
Signature of the research participant:_____
Location and Date:_____

Name and signature of the researcher:_____