1. **Title of the study:** Effect of Photobiomodulation on Waist Circumference Reduction

2. **Objective:** This study aims to compare the effectiveness of different types of lights to reduce fat in the abdomen (fat accumulated in the belly)

3. **Purpose of the research:** The search for a perfect body drives men and women to perform aesthetic procedures. Taking into account the risks of the invasive procedures, the use of phototherapy (light treatment), as a non-invasive aesthetic procedure (procedures without surgical cuts), for the reduction of localized fat is an interesting alternative. However the effectiveness of this therapy needs to be proved.

4. **Type of Research Intervention:**

   **1st Part:** In the first part of your participation you will answer questions to a trained professional of this research group about your personal and family health history and your life habits. Then, you will fill two other questionnaires with questions about your quality of life and your self-image. This stage will be carried out in a private room and it is estimated a period of 20-30 minutes for the completion of the first part.

   **2nd Part:** Next, you will be subjected to the collection (taking a sample) of about 5 mL of blood (volume equivalent to a teaspoon of blood). This sample will be used to measure cholesterol and triglyceride levels (fat in the blood) and liver function. In a private room, trained researchers will measure your weight, height, the circumference of the abdomen using a tape. The skin folds will be measured by using a caliper in different regions of your body to assess the amount of fat. The bioimpedance (examination performed on equipment that analyzes body composition, indicating the approximate amount of muscles, bones and fat) is performed as a weighing on a scale. You will also be submitted to an ultrasound examination of the abdomen, which will be performed by a trained professional. It is estimated that this second part of the research, whose objective will be to evaluate body measurements and blood collection to assess blood fat levels and fat layer in the abdomen, will last approximately one hour.

   **3rd Part:** You will receive the treatment twice a week for four weeks (totaling one month of treatment) at times previously scheduled with the researchers. During the appointments, waist circumference measurements will be performed with a tape measure and then you will be positioned in the horizontal supine position (back region on the stretcher and “belly” upwards), and a light belt will be applied to your abdomen for 30 minutes, according to the treatment group selected by draw. You may be placed...
in the group of people who will receive light for therapeutic purposes (which has an action on the organism) or in the other group, which will receive the placebo treatment, that is, with a light belt without therapeutic purpose (without effect). After the end of this study, it will be guaranteed by the researchers to apply the best treatment obtained in this research to patients who received the treatment called placebo (without therapeutic purpose).

4th Part: after the treatment is finished, you will be submitted again to the evaluations of phase 1 (questionnaires) and phase 2 (measurements), after the last light application session. You will be summoned for reevaluation 15, 90 and 180 days after the end of treatment.

5. Discomfort or Risks and protective measures: Regarding the applied questionnaires, you may feel embarrassed when answering the instrument questions, however we make it clear that all information is completely confidential and you will answer the questionnaires in a private room, ensuring your privacy. During blood collection you may experience slight pain due to needle puncture. To minimize this discomfort this procedure will be performed by a properly trained professional. During the evaluation visits, it will be necessary to wear swimsuits or appropriate clothing for the gym, such as shorts, swimwear or swimsuits. This way, you may feel embarrassed due to the body. In order to reduce this effect, the professionals will make all the measurements and ultrasound examination in a private room. At the day of the evaluation visits, it will be necessary to fast at least 6 hours before the appointment. The researchers will make the agenda respecting your office hours, avoiding prolonged fasting. During the application of the light you can feel a small local heating and skin sensitization, the researchers properly trained to handle the light belt will be available to turn off the equipment in case of discomfort reported by the patient.

6. Research Benefits: The participant will have the opportunity to know the levels of body fat at the time of the research, as well as the update of exams regarding the lipid profile (Levels of circulating fats in the bloodstream) and liver function. In addition, the research aims to contribute to the scientific community, since the reduction of body fat directly affects the well-being, quality of life and health of the population.

7. Existing Alternative Methods: radiofrequency, intense pulsed light, high-powered laser and plastic surgery are alternative treatments. However, several are invasive treatments, leading to greater contraindications and risks.

8. Withdrawal of Consent: At any time during the survey, you may withdraw your consent, giving up participating in the survey, without any prejudice. You do not have to take part in this research if you do not wish to do so. It is your choice and all of your rights will still be respected.

9. Secrecy Guarantee: Researchers guarantee the confidentiality of all data and information provided by you for this research. At the end of the survey, you will be informed about the results obtained.

10. Forms of Reimbursement of Expenses arising from Participation in the Research: For this research there is no reimbursement of expenses of any kind.

11. Research Location: The research will be developed at Universidade Nove de Julho, located at
12. Research Ethics Committee (CEP): is an interdisciplinary and independent collegiate, which must exist in institutions that conduct research involving human beings in Brazil. It was created to defend the interests of research participants in their integrity, dignity and to contribute to the development of research within ethical standards (Norms and Regulatory Guidelines for Research involving Human Beings - Res. CNS nº 466/12 and Res. CNS 510/2016). The Ethics Committee is responsible for the evaluation and monitoring of research protocols in terms of ethical aspects. Uninove Ethics Committee address: Rua. Vergueiro nº 235/249 - 12th floor - Liberdade - São Paulo - SP Zip Code. 01504-001 Phone: 3385-9010, comiteeetica@uninove.br

Opening hours of the Ethics Committee: Monday to Friday - From 11:30 am to 1:00 pm and from 3:30 pm to 7:00 pm

13. Full name and telephone numbers of Researchers (Advisor and Students) to Contact:
Prof. Dr. Christiane Pavani - (011) 3385-9222, Marcelo Marreira - (011) 98160-0074.

14. Eventual complications that may arise in the course of the research may be discussed by the proper means.

15. Post-Information Consent:
I, after reading and understanding this term of information and consent, understand that my participation is voluntary, and that I can leave the study at any time, without prejudice. I confirm that I have received a copy of this consent form, and authorize the research work and the dissemination of data obtained only in this study in the scientific community.

São Paulo from 2020.

______________________________
Signature of Participant

16. I, __________________________________________ (Researcher responsible for this research), certify that:

a) Considering that research ethics implies respect for human dignity and the protection due to participants in scientific research involving human beings;

b) This study has scientific merit and the team of professionals duly mentioned in this term is trained, qualified and competent to perform the procedures described in this term;

____________________________________
(Marcelo Marreira)
Signature of the Researcher