Participant Information Sheet

1. **Protocol title:**
   Comparing Anti-Inflammatory Effect between Ibuprofen and Water Extract of Curly Kale Leaves in Patients Following Wisdom Tooth Extraction: A Randomized Controlled Study

2. **Investigators:**
   a. Vuttinun Chatupos, D.D.S.
   b. Sansanee Neelawatanasook, D.D.S.
   c. Tidanut Sangutai, D.D.S.
   d. Atit Khanutwong, D.D.S.
   e. Piyanart Chatiketu, D.D.S.
   f. Somdet Srichairatanakool, Ph.D.

3. **Objectives:**

   To compare the effectiveness between the kale extract capsule product and ibuprofen in reducing pain and inflammation in patients after lower third molar extraction

4. **You have been invited/selected to participate in the research study because:**
   a. You are between the ages of 18 and 25 years old.
   b. You are in good physical health, including not being pregnant or breastfeeding.
   c. You have lower third molars on both the left and right sides that are similarly positioned close to the center and without any pathological conditions, inflammation, or pain.
   d. Your impacted molars do not exhibit any pathological conditions, inflammation, or pain.
   e. You are able to receive treatment and follow-up as scheduled.
   f. You have no history of taking pain-relief or anti-inflammatory medication, whether orally or by injection, within one week prior to the surgery.
5. **Participants:** A total of 20 individuals participated in the research project. Data collection took place from November 2565 to May 2566.
6. **Tasks for the participants:**
   a. Participants will undergo wisdom tooth extraction surgery twice by a dentist, with each surgery approximately one month apart.
   b. Participants will self-assess pain symptoms from days 1-7 post-surgery, noting the time of the first painkiller intake and the total number of painkillers taken (researchers will provide a form for recording).
   c. Participants will return to meet the researchers on days 1, 4, and 7 post-surgery at the Oral Surgery Clinic (Room No. 3), Faculty of Dentistry, Chiang Mai University, to provide saliva samples.
   d. Participants will not be allowed to take any medication other than what is provided by the researchers during the first week post-surgery.
   e. Participants may take additional painkillers but must inform the researchers.
7. **Benefits for participants and the overall study:**
   a. Participants will receive lower wisdom tooth extraction surgery performed by specialized dentists.
   b. Participants will receive compensation in the form of oral hygiene equipment upon completion of the study.
   c. Participants will receive oral cavity examinations and guidance on oral health care.
   d. The study results will be used to reduce pain symptoms from lower third molar extraction surgeries in future patients.
8. **Risks associated with participating in the research project:**
   a. There are risks associated with wisdom tooth extraction surgery, including:

i. Bleeding from the surgical wound within the first 24-48 hours, which can be initially managed by applying pressure with gauze on the wound.
ii. Possibility of infection or inflammation of the jawbone or formation of pus at the surgical site.
iii. Numbness or tingling sensation around the lips or tongue due to the proximity of nerves to the wisdom tooth or adjacent surgical area where anesthesia is administered.
iv. Necessity to leave the tooth root within the surgical wound if the root is curved or close to a nerve, provided it is less than 2 millimeters in size.
v. Adjacent teeth may become loose or sensitive upon contact.
vi. Fracture of the jawbone, especially if adjacent bone needs to be removed extensively to extract the wisdom tooth.

9. In case participants experience severe pain that is intolerable, researchers will provide emergency pain relief medication, and participants can contact Dr. Sansanee Neelawatanasook at 085-000-9468 for additional assistance.
10. Participants will receive assistance and care for any side effects resulting from the research according to medical standards by contacting Dr. Sansanee Neelawatanasook at 085-000-9468, Oral Surgery and Maxillofacial Clinic, Faculty of Dentistry, Chiang Mai University at 053-944455.
11. Participants will return the questionnaires directly to the researchers at the Oral Surgery and Maxillofacial Clinic, Faculty of Dentistry, Chiang Mai University, on the 7th day after each surgery.
12. Participants' personal information will be kept confidential in a secure document cabinet, and only researchers can access it. Researchers will disclose information for academic purposes without identifying individuals. Personal data of research participants will be kept confidential and not disclosed to the public individually but will be reported collectively.
13. Participants have the right to withdraw from the research project at any time. Their decision will not affect future treatment, care, or any loss of benefits. If participants decide not to continue or withdraw from the study at any time, the information they have disclosed will remain confidential.

If there are any parts of this document that you do not understand, please ask the project leader or representative for clarification until you fully understand. You can take this document home to read and understand or discuss it with your family, friends, or dentist to help make a decision about participating in this research project.