Participant Information Sheet

1. **Protocol title:**
   Evaluation for effectiveness of lidocaine with epinephrine irrigation in reducing acute pain from surgical removal of mesioangular-impacted third molars

2. **Investigators:**

Investigator	Responsibility
1. Vuttinun Chatupos, D.D.S. Assistant Professor	Supervisor, Surgeon, Conceptualization, Ethics, Consent information, Project administration, Discussion
2. Sumatee Yuthavong, D.D.S.	Clinical investigator, Dentist, Data collector
3. Yanisa Naruenartwongsakul, D.D.S.	Clinical investigator, Dentist, VAS measurement, Data collector
4. Pratchanun Sanjitt, D.D.S.	Clinical investigator, Dentist, VAS measurement, Data collector
5. Mayuree Kuraoka, D.D.S.	Clinical investigator, Dentist, VAS measurement, Data collector
6. Ittiwat Pooripoosit , D.D.S.	Clinical investigator, Dentist, VAS measurement, Data collector
7. Pakamon Chutchawalkijkul, D.D.S.	Clinical investigator, Dentist, VAS measurement, Data collector
8. Pattaranee Srichairatanakool, MD., Lecturer	Conceptualization, Anesthesiologist, Clinical investigator
9. Wachiraporn Tipsuwan, PhD., Assistant Professor	Researcher, Data analysis, Report writing, Discussion
10. Somdet Srichairatanakool, Ph.D. Professor	Conceptualization, Researcher, Data analysis, Report writing, Discussion

3. **Ethics**

   This study received approval from the Human Experimentation Committee Research Institute for Health Sciences and signed by Professor Dr. Anak Iamaroon, D.D.S., M.S., Ph.D., a Chairman of the Committee, Faculty of Dentistry, Chiang Mai University, Chiang Mai 50200, Thailand (Certificate Number: 52/2014, Date: 3rd December 2014 and Certificate Number: 42/2016, Date: 24th August 2016). Adherence to ethical guidelines was a prime importance throughout the study process. All patients were fully informed about the particulars of the study and willingly provided their signatures on the consent forms before any study procedures were performed. This study followed the guidelines of the Helsinki Declaration 2008, revised in 2013: Ethical Principles for Medical Research Involving Human Subjects. Subjects' rights have been protected by an appropriate Institutional Review Board and written informed consent was granted from all subjects.

4. **Objectives:**

1. To select the appropriate local anesthetic for mandibular third molar surgery

2. To evaluate and compare the analgesic effects of lidocaine and bupivacaine after mandibular third molar surgery

3. To compare anti-pain and would healing effects between lidocaine plus epinephrine irrigation with normal saline solution irrigation in patients after surgical removal of mandibular third molars

5. 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.

6. **Participants:** In the research project, a total of 34 patients enrolled the studies, of which the patients were assigned for lidocaine (n = 17) and bupivacaine (n = 17) treatment. Data collection took place from 1st October 2015 (01/10/2015) to 30th September 2016 (30/09/2016).
7. **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 (OPD 3), Faculty of Dentistry, Chiang Mai University, for measurement of VAS values.
   d. Participants can take additional painkillers but must inform the researchers.
8. **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 indicate that irrigation of lidocaine plus epinephrine can relieve pain symptoms after surgical removal of lower third molars.
9. **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.

10. In case participants experience severe pain that is intolerable, researchers will provide emergency pain relief medication, and participants can contact Dr. Yanisa Naruenartwongsakul, D.D.S. or Assistant Professor Vuttinun Chatupos, D.D.S. at Oral Surgery and Maxillofacial Clinic (OPD 3) or Department of Oral Surgery and Maxillofacial, Faculty of Dentistry, Chiang Mai University at 053-944455or additional assistance.

11. Participants will receive assistance and care for any side effects resulting from the research according to medical standards by contacting Dr. Yanisa Naruenartwongsakul, D.D.S. or Assistant Professor Vuttinun Chatupos, D.D.S. at Oral Surgery and Maxillofacial Clinic (OPD 3) or Department of Oral Surgery and Maxillofacial, Faculty of Dentistry, Chiang Mai University at 053-944455.

12. 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.

13. 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.

14. 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 decision about participating in this research project.