PARTICIPANT INFORMATION SHEET

1. **Title of study**: Post Laparoscopy Pain Reduction Project (POLYPREP III): Intraperitoneal Normal Saline (INSI) Infusion Versus Intraperitoneal Ringer Lactate (INRL) Infusion: A Randomised Control Trial

2. **Name of investigator and institution:**

   Professor Dr. Aizura Syafinaz bt Ahmad Adlan, Dr Teing Shu Jun of Department of Obstetrics & Gynaecology, UMMC.

3. **Introduction:**

   You are invited to participate in a research study because you have been planned for laparoscopic surgery. The details of the research trial are described in this document. It is important that you understand why the research is being carried out and what it will involve. Please take your time to read through and consider this information carefully before you decide if you are willing to participate. Kindly ask the study staff if anything is unclear or if you would like to know more information. After you are properly satisfied that you understand this study, and that you wish to participate, you must sign this informed consent form. To participate in this study, you may be required to provide your doctor with information on your health history (which is also important, with or without participation in this study); without which it may be harmful to yourself if you are not truthful with the information provided.

   Your participation in this study is **voluntary**. You do not have to be in this study if you do not wish to. You may also refuse to answer any questions you do not want to answer. If you volunteer to be in this study, you may withdraw from it at any time. If you withdraw, any data collected from you up to your withdrawal will still be used for the study. Your refusal to participate or withdrawal will not affect any medical or health benefits to which you are otherwise entitled.

   This study has been approved by the Medical Research and Ethics Committee, University Malaya Medical Centre.

5. **What is the purpose of the study?**

   The purpose of this study is to evaluate the effectiveness of the proposed treatment (intraperitoneal normal saline infusion versus intraperitoneal Ringer Lactate infusion) in reducing pain after the operation.

   Pain after laparoscopic surgery or 'key-hole' surgery is common. Although it is less severe than conventional 'open' surgery, patients experience pain over the shoulder and upper abdominal region (which is not related to the skin incision site) particularly after 24 hours of surgery. Painkillers do not seem to be effective in eliminating this pain.

   Intraperitoneal normal saline infusion (infusing salt water in your abdomen) has been shown to be effective in reducing pain after laparoscopic surgery; however there is only one study done previously that really look into this and we feel

that our population would benefit from a local research and data on this intervention. On the other hand, intraperitoneal Ringer Lactate (RL) solution (another types of salt water) has been used intraperitoneal safely as intraperitoneal wash during surgery and effective in preventing intraperitoneal adhesion. For both crystalloid solution, NS has only been studied and beneficial in removing post laparoscopic CO2 retention. However, to date, there is no study to answer whether RL solution is another choice of solution to use for eliminate the post laparoscopic CO2 retention. Thus, it is necessary and clinically relevant to examine the post-laparoscopic pain relieve effects by comparing using intraperitoneal infusion laparoscopically of these two crystalloids .

A total of 80 people like you will be participating in this study. The whole study will last about 1 year and your participation will be 3 days after the surgery.

6. What kind of study products/ procedure will I receive?

If you agree to participate in the study, the doctor may need to perform some tests and examinations to determine if you are suitable for the study. If you are deemed suitable, you will be randomly assigned to one of the treatment groups below. You have equal chance of being assigned to each of the groups.

The study products do not contain porcine, bovine or animal components

Group 1: Intraperitoneal normal saline infusion – salt water will be left inside your abdomen before removing the camera.

Group 2: : Intraperitoneal Ringer Lactate infusion – salt water will be left inside your abdomen before removing the camera.

7. What will happen if I decide to take part?

a) A questionnaires will be given to you and you will be explained on how to fill up the questionnaires.

b) Surgery will be done and additional treatment will depends on which group you are allocated to.

c) Routine cares before and after surgery will be the same as others who did not participate in the study.

c) After the operation you are required to fill up the questionnaires. A study staff will approach you and assist you in filling up the questionnaires. If you are discharged earlier (before 72 hours post surgery), you will be provided a copy of pain scale with number 0 to 10. The research assistant will contact you via telephone to complete the questionnaires.

8. When will I receive the trial product and how should it be kept?

No trial product will be provided.

9. What are my responsibilities when taking part in this study?

It is important that you answer all of the questions asked by the study staff honestly and completely. If your condition or circumstances change during the study, you must tell the study doctor. There may be certain medications that you cannot take while participating in this study. The doctor will discuss those medications with you. You must not take any other medications without consulting your study doctor. You must inform your study doctor immediately if you make any changes to any of your current treatments, even those which you have been taking for a long time.

It is very important that your study doctor is informed quickly of any changes to your health during your participation in the study. For your own security, it is important that you follow your study doctor's instructions throughout the entire duration of the study.

10. What kind of treatment will I receive after my participation in the trial?

No study product will be given to you at the end of your participation in the study. Whether you complete the study or withdraw early, your doctor will discuss the best alternatives for your future treatment with you.

11. What are the potential risks and side effects of being in this study?

You may experience nausea, vomiting, bloatedness, abdominal discomfort and shortness of breath.

Please ask your study doctor if you need more information on risks and side effects. The trial staff will inform you in a timely manner about any new findings or changes about the study procedure, which may affect your health or willingness to continue in this study. Where necessary, you may be asked to re-consent to participate.

12. What are the benefits of being in this study?

There may or may not be any benefits to you. Information obtained from this study will help improve the treatment or management of other patients with the same disease or condition in the future.

13. What if I am injured during this study?

If you are injured as a result of being in this study, you should contact your study doctor. Care and management of a bodily injury or illness will be as per standard management protocol. UMMC is not responsible for medical expenses due to pre-existing medical conditions, any underlying diseases, any ongoing treatment process, your negligence or willful misconduct, the negligence or willful misconduct of your study doctor or the study site or any third parties. You do not lose any of your legal rights to seek compensation by signing this form.

14. What are my alternatives if I do not participate in this study?

You do not have to participate in this study to get treatment for your disease or condition. There are still alternative

treatments, which are available. The study doctor will discuss in more details the benefits and risks of those treatments with you.

15. Who is funding the research?

The research is self-funded by the researcher.

16. Can the research or my participation be terminated early?

The study doctor or UMMC may due to concerns for your safety, stop the study or your participation at any time. If the study is stopped early for any reason you will be informed and arrangements will be made for your future care. You may be asked to attend a final follow-up visit.

17. Will my medical information be kept private?

All your information obtained in this study will be kept and handled in a confidential manner, in accordance with applicable laws and/or regulations. When publishing or presenting the study results, your identity will not be revealed without your expressed consent. Individuals involved in this study and in your medical care, qualified monitors and auditors, the sponsor or its affiliates and governmental or regulatory authorities may inspect and copy your medical records, where appropriate and necessary.

Data from the study will be archived and may be transmitted outside the country for the purpose of analysis, but your identity will not be revealed at any time.

18. Who should I call if I have questions?

If you have any questions about the study or if you think you have a study related injury and you want information about treatment, please contact the study doctor, Dr Teing Shu Jun (012 5297948).

If you have any questions about your rights as a participant in this study, please contact: The Secretary, Medical Research & Ethics Committee, Ministry of Health Malaysia, at telephone number 03-2287 4032.