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PATIENT INFORMATION SHEET

Study Title: (Study title here, must be the same as stated in the study protocol)

**MREC ID No.:**

Version No: Version 1 (Version number and date to be updated every time there is a revision/amendment made)

Version Date: 3 March 2021

We would like to invite you to take part in a research study. Before you decide whether to participate, you need to understand why the research is being done and what it would involve. Please take time to read the following information carefully; talk to others about the study if you wish.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

***Attention to the investigator: Please fill in simple layman language as you would speak to research subjects.  Do not delete any of the questions. If it does not apply to your study, please state “Not applicable”.* Please ensure the PIS is thoroughly checked for correct grammar and spelling. Delete these red notes when submitting for application. Please write the PIS according to the target group of the study (eg. If the target is children, the PIS should be written for the parents, and it should address the participation of the child ie. Your child is invited..)**

1. What is the purpose of this study?

(Note: State the purpose/objective of this study in layman language)

2. Why is this study important?

(Note: State the reasons for conducting this study and how it will help fill in the knowledge gap or improve services/care for patients)

3. What type of study is this?

(Note: If this is a randomised control trial, case control study, prospective cohort study etc., please explain in layman language eg. Comparison between group 1 and 2, randomised means that there is an equal chance of getting arm A or B, like a flip of a coin, will follow up/observe your health status, blinding procedures, etc. Please also state the target number of recruitment in this study)

4. What is the procedure that is being tested? (If applicable)

(Note: Explain the new procedure/intervention/programme that is being tested or compared to here)

5. Does the investigatory product contain cultural sensitive ingredients eg: bovine orporcine? (if applicable)

(Note: State whether this is applicable or not in your study)

6. Why have I been invited to participate in this study?

(Note: The inclusion criteria should be stated here)

7. Who should not participate in the study?

(Note: The exclusion criteria should be stated here)

8. Can I refuse to take part in the study?Yes. Your participation in this study is voluntary. You do not have to be in this study if you do not want to. 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.

(Note: For patients, they must be assured that standard of care/standard therapy will not be compromised, that they will still receive it if they choose not to participate in the study. For students, their study progress, evaluation will not be compromised if they choose not to participate. For healthcare workers/professionals, it will not affect their work/service.)

9. What will happen to me if I take part?

(Note: Explain what happens to patients from the moment their consent is sought, the procedures, and what is expected of the patients ie. Follow up visits. If the follow up visits/calls is complex, to provide a table or timeline for them. Please state if there are any anticipated expenses to the patient/participants for participating in the study or state which expenses will be covered by the researcher)

10. How long will I be involved in this study?

(Note: How many weeks/months/years including follow up. If one-off interview/questionnaire, please state what is the estimated time to complete the questionnaire)

11. What are the possible disadvantages and risks?

(Note: Please state all possible risks of procedure ie. Allergic reaction, pain at injection, etc. and any possible risks from other factors such as breach of confidentiality, COVID-19 infection, stress from sensitive questions, fatigue from long questionnaires etc. Please include the ways researcher would minimise the risks. Please also explain the possible circumstances or reasons for terminating a subject participation ie. Patients developing serious adverse events)

12. What are the possible benefits to me?

(Note: To state the benefits to patients/participants. If there are no direct benefits, please state so and state the benefit of the outcome of the study to improve the care of other/future patients or if it will help health providers or the current department improve its services.)

13. Who will have access to my medical records and research data?

(Note: Investigators and sub/co-investigators, statistician. Please disclose if there is a third party who has access to the research data and how the data is being protected. State how the research data is being kept securely eg. Password protected that only the PI/co-I has access to or co-I would need permission from PI to access etc. State how hardcopy research data is managed ie. Locked in a designated cabinet in which Department that only the PI or HOD has access to, etc.)

14. Will my records/data be kept confidential?All your information obtained in this study will be kept and handled in a confidential manner, in accordance with applicable laws and/or regulations. The data collection sheets and informed consents will be placed in a locked folder and stored at the office of the researchers. Only non-identifiable data with your respective identifying numbers will be transferred and analyzed on a personal computer and they will be subsequently stored on an encrypted external hard disk drive. Study data will be destroyed after a period of 7 years following the completion of the study.

(Note: Explain how research data is kept confidential. State how patient/participants identifiable information will be kept anonymous. Will patient’s identity be able to be retraced/retrieved? Only PI or co-I will be able to deidentify the patient/participants. Please store research data for at least 7 years before data is destroyed)

15. What will happen to any samples I give? (If applicable)

(Note: Please explain how samples are handled/stored and where will the laboratory testing be conducted, and how samples will be disposed of)

16. What will happen if I don’t want to carry on with the study?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.

(Note: Please explain that the participants can withdraw at any time/point of the study. The participants can withdraw without any reasons, just let the investigators know. Please state whether the data collected will still be used for the study or not. Please assure participants that withdrawal from the study will not affect any medical or health care they are entitled to)

17. What if relevant new information about the procedure/ drug/ intervention becomesavailable? (If applicable)

(Note: Please explain to participants if there are any new information that is available, participants will be made aware of and if reconsenting would be necessary in future if any new information is made available)

18. What happens when the research study stops? (If applicable)

(Note: Please explain what happens if the study is stopped prematurely and what happens to research data. Please explain how patients/participants will be informed and what happens to their follow up)

19. What will happen to the results of the research study?Results from this study will be kept and analysed in a confidential manner. The results of the study will be analysed and reported in a thesis report. The results may also be presented or published in a scientific journal.

(Note: Explain what researchers plan to do with the results of the study ie. Presentation for a degree/Master requirement, Publication in a scientific journal or presentation in international/local scientific conference, used for improvement of health service, results to be used to conduct further research, results would be shared in a dialogue/forum/webinar etc.)

20. Will I receive compensation for participating in this study?

(Note: State the amount of compensation/reimbursement for travel and inconvenience whether it will be given per visit or one-off. State if there is any compensation and treatment for study-related injuries)

21. Who funds this study?

(Note: State whether your study is funded, and who the funder is ie. Research Grant, Pharmaceutical company.)

22. Who should I contact if I have additional questions/problems during the course of the study?

● Name of investigator 1:   
Affiliation: Medical Officer, Department of   
Telephone number:

● Name of investigator 2: Dr   
Affiliation: Medical Officer, Department of

Telephone number:

(Note: Contact number of at least one investigator must be provided. It could be a designated phone number for research and must be contactable)

23. Who should I contact if I am unhappy with how the study is being conducted?

Medical Research Ethics Committee  
University of Malaya Medical Centre  
Telephone number: 03-7949 3209/2251

BK-MIS-1116-E03

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LEMBARAN MAKLUMAT PESERTA

**Tajuk Kajian:**

**MREC ID No.:**

**No. Versi:**

**Tarikh Versi:**

Kami ingin menjemput anda untuk mengambil bahagian dalam penyelidikan ini. Sebelum anda memutuskan untuk mengambil bahagian, anda perlu memahami mengapa penyelidikan itu dilakukan dan apa yang akan dilakukan. Luangkan masa untuk membaca maklumat berikut dengan teliti; berbincang dengan orang lain mengenai kajian jika anda berminat.

Tanyakan kepada kami jika ada perkara yang tidak jelas atau jika anda mahukan lebih banyak maklumat. Luangkan masa untuk memutuskan sama ada anda mahu menyertai atau tidak.

***Perhatian kepada penyelidik: Sila isi/menjawab menggunakan bahasa awam seperti mana anda akan bercakap dengan peserta kajian.***

1. **Apakah tujuan kajian ini?**
2. **Mengapakah kajian ini penting?**
3. **Apakah jenis kajian ini?**
4. **Apakah prosedur yang akan diuji? (jika berkenaan)**
5. **Adakah produk penyiasatan mengandungi bahan sensitif seperti sapi atau khinzir? (jika berkenaan)**
6. **Mengapakah saya dijemput untuk mengambil bahagian dalam kajian ini?**
7. **Siapa yang tidak boleh mengambil bahagian dalam kajian ini?**
8. **Bolehkah saya enggan mengambil bahagian dalam kajian ini?**
9. **Apa yang akan berlaku kepada saya sekiranya saya mengambil bahagian?**
10. **Berapa lama saya akan terlibat dalam kajian ini?**
11. **Apakah kemungkinan kesan sampingan dan risiko mengikuti kajian ini?**
12. **Apakah kemungkinan faedah bagi saya?**
13. **Siapa yang akan mempunyai akses ke rekod perubatan dan data penyelidikan saya?**
14. **Adakah rekod/data saya akan dirahsiakan?**
15. **Apa yang akan berlaku pada sampel yang saya berikan?**
16. **Apa yang akan berlaku sekiranya saya tidak mahu meneruskan kajian ini?**
17. **Bagaimana jika maklumat baru yang relevan mengenai prosedur/ubat/campur tangan tersedia?**
18. **Apa yang akan berlaku apabila kajian penyelidikan selesai?**
19. **Apa yang akan berlaku dengan hasil kajian penyelidikan?**
20. **Adakah saya akan mendapat pampasan untuk menyertai kajian ini?**
21. **Siapa yang membiayai kajian ini?**
22. **Siapa yang harus saya hubungi sekiranya saya mempunyai soalan/masalah tambahan semasa pengajian?**

Nama penyelidik 1:

Affiliasi:

Nombor telefon (Mobile number):

Nama penyelidik 2:

Affiliasi:

Nombor telefon (Mobile number):

1. **Siapa yang harus saya hubungi sekiranya saya tidak berpuas hati dengan bagaimana kajian ini dijalankan?**

Jawatankuasa Etika Penyelidikan Perubatan

Pusat Perubatan Universiti Malaya

Nombor telefon: 03-7949 3209/2251