PATIENT INFORMATION SHEET AND INFORMED CONSENT FORM

(for adult subjects and interventional studies)

1. **Title of study**: **Economic evaluation and clinical impact of home medication review (HMR) by community pharmacists among patients with type 2 diabetes mellitus (T2DM)**

2. **Name of investigator and institution:**
   a. Mohd Rozaini b Rosli (PhD Student, Faculty of Pharmacy, Universiti Teknologi MARA)
   b. Dr Neoh Chin Fen (Senior Lecturer, Faculty of Pharmacy, Universiti Teknologi MARA)
   c. Dr Mahmathi Karuppannam (Senior Lecturer, Faculty of Pharmacy, Universiti Teknologi MARA)
   d. Datin Dr Wan Nazariah binti Wan Hassan (Family Medicine Specialist, Bandar Pasir Mas Health Clinic)
   e. Dr Mahani binti Mahmud (Medical Officer, Bandar Pasir Mas Health Clinic)
   f. Nor Afifah binti Rahimi (Senior Pharmacist, Bandar Pasir Mas Health Clinic)
   g. Azlina binti Ahmad (PhD Student, Faculty of Pharmacy, Universiti Teknologi MARA)

3. **Name of sponsor**: Self-sponsored

4. Introduction:

You are invited to participate in a research study because you have uncontrolled Type 2 Diabetes Mellitus (T2DM) that requires home medication review. The details of the research trial are described in this document. It is important that you understand why the research is being done 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. Ask the study staff if anything is unclear or if you like 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; you may harm 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 want 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, Ministry of Health Malaysia.

5. What is the purpose of the study?

The purpose of this study is to develop and evaluate home medication review by community pharmacists (HMR-CP) programme in optimising diabetes care in Malaysia for the treatment of uncontrolled T2DM. This research is necessary to determine the economic and clinical impact of the HMR-CP.

A total of 166 subjects from Bandar Pasir Mas Health Clinic will be participating in this study. The whole study will last about 20 months and your participation will be about 10 months.

6. What kind of study procedures will I receive?

If you agree to participate in the study and you are deemed suitable, you will be randomly (by chance, like flipping a coin) assigned to one of the treatment groups below. You have equal chance of being assigned to each of the groups. Neither you nor the researchers will know which group you are assigned to but in case of emergencies, this information is available to your researchers.

Group 1: Intervention group which will have 3 times of HMR-CP; O-month, 3-moth, and 6-month.
Group 2: Controlled group will have no HMR-CP, will be received normal treatment by Bandar Pasir Mas Health Clinic.

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

a) If you are selected to be with intervention group, you will received 3 times of HMR-CP; O-month, 3-month, and 6-month. During the visits, a community pharmacist will give counseling on medication issues in terms of storage, adherence, and anything related to pharmaceutical care issues. There are no invasive procedure will be carried out during HMR-CP.
b) If you are in controlled group, you will received normal treatment procedure by Bandar Pasir Mas Health Clinic. Your clinical data will be recorded at O-month, 3-moth, and 6-month.

8. When will I receive the HMR by community pharmacists?

You will be visit by community pharmacists at your house for the three times at O-month, 3-month, and 6-month within one week after each appointment with FMS/MO, starting from today for intervention group and you will receive normal treatment by Bandar Pasir Mas Health Clinic if you are in controlled group.

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

It is important that you answer all of the questions asked by the community pharmacists who are doing HMR-CP 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 be informed very rapidly of any eventual 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?

The chance of an adverse event or unforeseen events occurring is minimal and can be negligible given the nature of this project. For the controlled group, researchers will only extract information that readily available in patients' medical records . For the intervention group, there are no any invasive procedure or additional research product that need to be taken. Thus, there is no adverse reaction or unforeseen events anticipated.

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 protocol 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.

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 offiecer. In the event of a bodily injury or illness directly resulting from the study product or a medical procedure required for this study, the sponsor will pay for reasonable and necessary treatment. The sponsor 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. You can continue your standard treatment provided by Bandar Pasir Mas Health Clinic. The study doctor will discuss in more details the benefits and risks of those treatments with you

15. Who is funding the research?

This is self-sponsored study. All the drugs and procedures in the health clinics are provided by Bandar Pasir Mas Health Clinic as the subjects is their patients. The home medication review service by community pharmacists are volunteered by community pharmacist who joint this program. There is no money reimbursement for this program.

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

The study doctor or the researchers 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 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.

With your permission your family doctor will be informed of your participation in the study.

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 researcher,

a. Mohd Rozaini b Rosli at 0122729345
b. 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 03-22874032.

INFORMED CONSENT FORM

Title of Study: **Economic evaluation and clinical impact of home medication review (HMR) by community pharmacists among patients with type 2 diabetes mellitus (T2DM**

By signing below I confirm the following:

- I have been given oral and written information for the above study and have read and understood the information given.
- I have had sufficient time to consider participation in the study and have had the opportunity to ask questions and all my questions have been answered satisfactorily.
- I understand that my participation is voluntary and I can at any time free withdraw from the study without giving a reason and this will in no way affect my future treatment. I am not taking part in any other research study at this time. I understand the risks and benefits, and I freely give my informed consent to participate under the conditions stated. I understand that I must follow the study doctor's (investigator's) instructions related to my participation in the study.
- I understand that study staff, qualified monitors and auditors, the sponsor or its affiliates, and governmental or regulatory authorities, have direct access to my medical record in order to make sure that the study is conducted correctly and the data are recorded correctly. All personal details will be treated as STRICTLY CONFIDENTIAL
- I will receive a copy of this subject information/informed consent form signed and dated to bring home.
- I agree/disagree* for my family doctor to be informed of my participation in this study. (*delete which is not applicable)

Subject:

Signature: I/C number:

Name: Date:

Investigator conducting informed consent:

Signature: I/C number:

Name: Date:

Impartial witness: (Required if subject is illiterate and contents of patient information sheet is orally communicated to subject)

Signature: I/C number:

Name: Date: