PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT FORM
(for adult subjects and interventional studies)

1. **Title of study**: Effect of pharmacist involvement in Diabetes medication therapy adherence program (DMTAC) on the clinical outcomes, Quality of life, Cost of treatment and progression of diabetic complications of diabetes in different hospitals of Malaysia

2. **Name of investigator and institution:** Dr Amer Hayat Khan From Universiti Sains Malaysia & Dr Muhammad Zahid Iqbal from Aimst University Malaysia
   Expected duration of study: September 2018- September 2019

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

4. **Introduction:**

   You are invited to participate in a research study because you have Diabetes mellitus with or without diabetic complications that requires continuous treatment. The details of the research 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 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 Primary objective of the study is to assess the progression of diabetic complications with and without involvement of pharmacists (DMTAC), in a Malaysian hospital setting.

Specific Objectives

1. To observe the progression of diabetic complications in diabetes mellitus patients with and without involvement of DMTAC clinics in selected hospitals.

2. To observe and compare the clinical outcomes (HbA1c, FBS, BMI, CV incidences, BP measure, and lipid profile) on patients of Diabetes mellitus with and without intervention of DMTAC clinics in selected hospitals.

3. To observe and compare Quality of life (QOL) of patients in diabetes mellitus with and without involvement of DMTAC clinics in selected hospitals

4. To determine and differentiate the cost of treatment (hospital bearing cost) in diabetes mellitus patients with and without intervention of DMTAC clinics in selected hospitals.

A total of 600 subjects like you from three different hospitals in Malaysia will be taken. The whole study will last about 12 months and your participation will be required about 4 times.

6. What kind of study products or procedures will I receive?

Study process:

After the approval of the study, to recruit the patients, 3 to 4 month time capsule frame will be set which actually depends on the patient's inflow in the hospital. Initially total of 150 patient's hospital IDs will be listed as control group and similarly as interventional group. Then from this list 100 patients will be selected as control group and 100 as intervention group randomly. Randomization process will be as follows:

Randomization process: This study is prospective randomized open-label study. In Malaysia the patients are referred by the specialist, doctors or identified by the pharmacists during their routine clinical follow-up depend on the condition and disease control of the patient. The selected patients then either refer to the Diabetic Clinics or DMTAC in hospital.

Once the patients referred to clinics or to DMTAC their hospital record number will be noted in list of control group and similarly in list of intervention group. Upon completion of 150 record numbers of patients in each control and intervention group in each hospital that list will be entered in to Microsoft Excel and randomization will be carried out to select randomly 100 from each 150 record numbers.

Then the selected patients will be given the informed consent form once the patients sign the informed consent form then only they will be considered as participant of the study.

Note: As this study is observational study so all the participants' medical hospital files will be accessed and their disease and treatment outcome information will be taken only on validated data collection form. Only data in the form of information is required from the patient's medical files in hospitals. No other sampling will be taken from patients in the form of blood, biospecimen or any other biological sampling.

Quality of life evaluation: To determine the patients quality of life validated and well developed EQ 5D 5L will be used which is available in all major languages in Malaysia i.e. Malay, Chinese and Tamil languages. Approval to use this instrument has already been taken by researcher from concern authorities. Once the patient agreed to participate in study and upon sign the consent

form the patient will be given EQ 5D 5L questionnaire in their preferred language to self-write the quality of life. No other sampling will be taken from patients either blood or any other biological sampling.

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

a) Some of the important information about your disease will be taken from you on data collection form by researcher himself.
b) Your response about the quality of life will be taken from you on validated EQ 5D 5L in your preferred language (Malay, English or Chinese)

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

You will be given the study questionnaire at each study visit throughout the treatment period of the study. The study staff will instruct you on how the questioner must be answered.

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

As this study is observational study so all the participants' medical hospital files will be accessed and their disease and treatment outcome information will be taken only on validated data collection form. Only data in the form of information is required from the patient's medical files in hospitals. No other sampling will be taken from patients in the form of blood, biospecimen or any other biological sampling.
Only the data in the form of information is required from you. 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 researcher.

10. What kind of information will I receive after my participation in the study?

At the end of the study, the results of this study will be published with the permission of concern authorities in Malaysia.

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

Only the data in the form of information is required from you. There is no risk involve in this study. It is a survey kind of study you need to share the treatment information with the researchers only.

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

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

13. What are the compensation and/or treatment in the event of study-related injuries?

Only the data in the form of information is required from you. There is no risk of injuries involved in this study as no drug or treatment will be given by researcher. So no compensation and/or treatment are required. It is a survey kind of study you need to share the treatment information with the researchers only.

14. What are the anticipated prorated payments for reimbursement will be given?

Only the data in the form of information is required from you. There is no risk of injuries involved in this study and also this study is not funded by any research institute so no anticipated prorated payments for reimbursement will be given

15. What if I am injured during this study?

Only the data in the form of information is required from you. You cannot injure by this study, because this is a survey kind of research where only information about your disease will be taken from you.

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

Your participation in this research project is completely voluntary. You may decline altogether, or leave blank any questions you don't wish to answer. There are no known risks involve if you don't Want to participate in this study. Your responses will remain confidential and anonymous.

17. Who is funding the research?

This study is not sponsored by any institution. This study is self-sponsored by researchers.

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

Your participation in this research project is completely voluntary. You may terminate early, or leave blank any questions you don't wish to answer. There are no known risks involve if you don't want to participate in this study. Your responses will remain confidential and anonymous.

19. Will I be informed of the study findings?

At the end of the study you can take information on the findings of this study by using researcher contact details given at the end of this form. Similarly after finishing of this research all findings will be published online (after getting approvals for authorities) and all participants can get information about the findings.
Furthermore all the subjects will be informed if new information became available relevant to consent.

20. 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.

21. Who should I call if I have questions?

If you have any questions about the study and you want any information, please contact the researcher, **Dr Zahid Iqbal** at telephone number ***016-9729584***.

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.

INFORMED CONSENT FORM

Title of Study: Effect of pharmacist involvement in Diabetes medication therapy adherence program (DMTAC) on the clinical outcomes, Quality of life, Cost of treatment and progression of diabetic complications of diabetes in different hospitals of Malaysia

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 anytime 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 participant information sheet is orally communicated to subject)*

Signature: I/C number:

Name: Date: