PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT FORM

1. Title of study: Factors Associated with blood pressure control among hypertensive patients in Klinik Kesihatan Seri Tanjung Melaka

2. Name of investigator and institution:

1. Dr A'qilah Baharudin, Family Medicine Department, Universiti Putra Malaysia
2. Associate Professor Dr Aneesa Binti Abdul Rashid, Family Medicine Department, Universiti Putra Malaysia

3. Name of sponsor: Servier Malaysia Sdn Bhd

4. Introduction:

You must 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 want more information. After you are properly satisfied that you understand this study and wish to participate, you must sign this informed consent form.

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 any time. If you decide to withdraw from the study midway, you can exit the site freely, and no measures will be used to preserve the data you have filled in; thus, all data will be destroyed. Your refusal to participate or withdraw will not affect any medical or health benefits to which you are otherwise entitled.

The Medical Research and Ethics Committee, Ministry of Health Malaysia, has approved this study.

5. What is the purpose of the study?

The purpose of this study is to determine the factors associated with Uncontrolled blood pressure among Hypertensive patients in Klinik Kesihatan Seri Tanjung Melaka.
This research will be conducted for 32 months. Data collection will be commenced in three months. The expected number of participants is 475 individuals.

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

You will be given a self-administered questionnaire to be answered. The survey will take about 10 minutes to complete. This survey contains four sections that will enquire regarding factors associated with uncontrolled blood pressure. The four sections include your demographics, clinical characteristics, medication adherence, and home blood pressure monitoring practice.

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

Participation in this study involves minimal risk. You are free to decline to answer any of the questions that you feel uncomfortable with.

8. 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 us understand your disease better. Study findings shall potentially provide a better understanding of the factors associated with uncontrolled blood pressure and aid in improving treatment outcomes.

9. Who is funding the research?
This study does not receive any external funding. You will not be paid for participating in this study.

10. Will my medical information be kept private?
All your information obtained in this study will be kept and handled confidentially following applicable laws and/or regulations. Your identity will not be revealed without your consent when publishing or presenting the study results. Individuals involved in this study, qualified monitors, and auditors, and governmental or regulatory authorities may inspect the study data where appropriate and necessary.

11. Who should I call if I have questions?
If you have any questions about the study or want more information about this study, please contact the study doctor, Dr. A'qilah Baharudin, at qilla.bahar@gmail.com. or phone number (019-6215259)
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 03-3362 8407/8205/8888.

12. Please indicate your response after reading the following:

13. Title of study: Factors Associated with Blood Pressure control among Hypertensive Patients in Klinik Kesihatan Seri Tanjung Melaka

By signing below, I confirm the following:

- I have been 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 freely withdraw from the study without giving a reason and this will in no way affect my future treatment. 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 to make sure that the study is conducted correctly and the data are recorded correctly. All personal details will be treated as STRICTLY CONFIDENTIAL

Please indicate your response by choose one of the options below:
• I hereby agree to participate in this study:

- ☐ Agree
- ☐ Not Agree

Sign:

……..
Name:
Identification number:
Date: