PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT FORM

(for adult subjects and interventional studies)

1. **Title of study**: Vaccine Hesitancy: A Cross Sectional Survey of The Knowledge, Atitude and Practice (KAP) among Parents

2. **Name of investigator and institution:** Dato' Dr Ahmad Farouk Musa, Dr Trived Soni, Prof Rusli Nordin (Monash University Malaysia)

3. **Name of sponsor**: Jefferey Cheah School of Medicine & Health Sciences, Monash University Malaysia.

4. **Introduction:**

   You are invited to participate in a research study to look into the behavior on vaccination. 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. MREC: NMRR-16-2508-33624[IIR].

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

   The purpose of this study is to assess parental knowledge, attitude and practice (KAP) towards the Ministry of Health (MOH) free vaccination programme and factors predicting vaccine hesitancy (uptake) of the free vaccines among parents. This research is necessary to appreciate the prevalence of vaccine hesitancy and find the predictors to it. The whole study will last about 6 months and your participation will be about 10-15 mins.

6. **What kind of study products will I receive?**

If you agree to participate in the study, the investigator will hand you an explanatory and consent form to give written consent. Following that, a self-administered questionnaire and pen will be given for you to fill. may need to perform some tests and examinations to determine if you are suitable for the study.

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

a. A written consent form is to be filled in full after reading the explanatory statement
b. The given questionnaire is to be filled and submitted to the investigator on site upon completion
c. All personal information will be kept securely to maintain patient confidentiality

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

It is important that you answer all of the questions asked in the self-administered questionnaire honestly and completely. If in any condition or circumstances, you may withdraw from the study at any time by informing the investigator and returning the incomplete questionnaire.

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

There is no treatment received throughout the study.

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

There are no potential risk or side effects to the study as it is a self-administered questionnaire-based study.

11. 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 understanding of prevalence and possible predictors of vaccine hesitancy among different subgroups in Malaysia.

12. What if I am injured during this study?

If you are injured at any point of this study, there will be medical assistance from health care providers in Klinik Tanglin to aid you. 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 investigator or the study site or any third parties. You do not lose any of your legal rights to seek compensation by signing this form.

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

You do not have to participate in this study if you do not agree and consent to it.

14. Who is funding the research?

This study is sponsored by Jefferey Cheah School of Medicine and Health Sciences, Monash University Malaysia who will pay for all study materials and procedures. There will be no reimbursement to the participants as it is solely on a voluntary basis.

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

Participants may withdraw from the study at any time by informing the investigators.

16. 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 will be kept safely by the primary author for the purpose of analysis, but your identity will not be revealed at any time.

17. 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, Dato' Dr. Ahmad Farouk Musa at telephone number +6012-232-1939.

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: Vaccine Hesitancy: A Cross Sectional Survey of The Knowledge, Attitude and Practice (KAP) among Parents.

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.

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: