

## PATIENT INFORMATION SHEET AND INFORMED CONSENT FORM

*(for adult subjects and interventional studies)*

1. **Title of study:** *[Insert title of study as stated in protocol]*
2. **Name of investigator and institution:** *[Insert name of investigator and site where study is conducted]*
3. **Name of sponsor:** *[Insert name of organization or institution sponsoring study]*
4. **Introduction:**

You are invited to participate in a research study because you have *[insert disease/condition]* that requires *[insert treatment/procedure/intervention]*. 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 you 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 *[insert purpose/objective/aim of study]* for the treatment of *[insert disease state / condition]*. This research is necessary because *[state the experimental aspects and rationale of the study]*.

*[If study is a comparison of current and new interventions, state what is the current standard intervention and what is its limitation that necessitates the development of the new intervention. State what advantages are offered by the new intervention. If relevant, state briefly the mode of actions of the 2 interventions]*

A total of *[insert total number of subject for global studies]* subjects like you from various parts of the world will be participating in this study; in Malaysia, there will be about *[insert total number of Malaysian subjects]* subjects. The whole study will last about *[insert*

*expected duration of whole study]* and your participation will be about *[insert expected duration of each subject's participation]*. *[Modify accordingly if this is only a local study]*

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

If you agree to participate in the study, the doctor may need to perform some tests and examinations to determine if you are suitable for the study. If you are deemed suitable, you will be randomly (by chance, like flipping a coin) assigned to one of the treatment groups below *[modify accordingly if there is no randomization or there is only 1 treatment group]*. You have equal chance of being assigned to each of the groups *[change accordingly]*. Neither you nor the doctor will know which group you are assigned to but in case of emergencies, this information is available to your doctor.

The study products do not contain porcine, bovine or animal components *[modify where appropriate]*.

Group 1: *[State names of the investigational products or procedures being studied, dosages and frequencies, how administered, etc]*

Group 2: A placebo at *[state dosage and frequencies, how administered]*. A placebo looks like the study treatment but has no active medication.

*[Add more groups if appropriate]*.

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

*[List the following where applicable:*

- a) All study procedures, especially invasive ones, for screening, washout, intervention/treatment, follow-up, withdrawal, study termination, etc.*
- b) Types and frequencies of tests done; types and frequency of physical examinations and measurements taken; number of visits; and actions to take prior to study visits (such as fasting); etc.*
- c) Types, frequencies and amount of biospecimens taken (for blood, state in mls and teaspoons/tablespoons) for whole study and per visit.*
- d) Instructions on how to take or administer study product/procedure and frequency. List any special precautions needed.*
- e) Types and frequencies of data that subject have to record personally (e.g. readings of self monitoring glucose meters); how and where to record.*
- f) Current medications or treatments that need to be stopped or modified, or allowed to continue to be taken while in study.*
- g) Any optional or non-optional collection of biospecimens for genetic or biomarker research, and whether related or unrelated to the study disease/condition or product; state expected duration of storage of specimens, who has access, will specimens be*

*anonymized and how, can subject withdraw consent later and how specimen will be disposed off.*

*[The information above may be listed as per visit or in general for the whole study duration]*

**8. When will I receive the trial product and how should it be kept?**

You will be given the study product at each study visit throughout the treatment period of the study. You must not give the product to anyone else. The study staff will instruct you on how the product must be handled and stored. Please ensure that you keep your used and partly used study products after you have finished with them. For some visits you will need to bring back all study products (partly used, unused and empty packaging material) to your study site. *[Change where necessary]*

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

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 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. *[Change where necessary]*

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. *[Change where necessary]*

**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. *[Change where necessary]*

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

*[List any known risks and side effects of the study products (including placebo) and procedures from pre-clinical and other clinical trials. Where possible, indicate level or frequency of occurrence of risks.]*

The risks for subjects on placebo are *[insert risks]* but the risks will be managed by *[insert procedures for managing risks]*

The effect of the study product on an unborn child is not known. You should not become pregnant or father a child while in this study. Women subjects should not breast feed a child while in the study as the study product may be present in the breast milk. Women who are able to

become pregnant will be given a pregnancy test to confirm they are not pregnant. While in the study, if you are able to have a baby or father a child, it is important you use highly effective birth control methods consistently and correctly; the study doctor will discuss these methods with you. Notify your study doctor immediately if you think that you or your partner has become pregnant during the study. If you are pregnant, the study therapy will be discontinued immediately and you will be removed from the study. If you or your partner becomes pregnant while taking part in the study, the sponsor would like to follow the pregnancy until term to gather information regarding the pregnancy and the health of your infant. *[Modify where necessary]*

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 product which may affect your health or willingness to continue in this study. Where necessary, you may be asked to reconsent 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. *[Modify where necessary]*

## **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 doctor. 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. *[Modify where necessary. Replace 'sponsor' with name of hospital, if this is a MOH investigator initiated study]*

## **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. Alternate treatments which are available are *[list alternate treatments]*. The study doctor will discuss in more details the benefits and risks of those treatments with you. *[Modify where necessary]*

## **15. Who is funding the research?**

This study is sponsored by *[insert name of sponsor]* who will pay for all study drugs and procedures. All other drugs and procedures that are not required by the study but are part of your routine medical care will have to be paid by you or your insurance. The sponsor will financially compensate the time spent by the study staff, use of facilities, etc., for including you in the study.

You will be reimbursed RM *[insert amount]* for your travel expenses for each study visits. *[Modify where necessary]*

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

The study doctor or the sponsor 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. *[Modify where necessary]*

#### **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. *[Modify where necessary]*

Your biospecimens may be sent to laboratories in other countries for testing. If this is required, your biospecimens will be coded and information that can identify you will be removed. Only your study doctor and study staff will be able to link the code with you. *[Modify where necessary or delete if not applicable]*

Some of your biospecimens may be stored by the sponsor for *[insert number]* years for future testing. Your biospecimens will be coded and information that can identify you will be removed. Only your study doctor and study staff will be able to link the code with you. The sponsor may share those biospecimens with other researchers. A separate optional consent will be obtained from you for the storage and use of those biospecimens. You can withdraw your consent and the specimens will be destroyed. The sponsor will still use any information obtained from the biospecimens up until the time you withdraw consent. *[Modify where necessary or delete if not applicable]*

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. *[Modify where necessary or delete if not applicable]*

With your permission your family doctor will be informed of your participation in the study. *[Delete if not applicable]*

#### **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 study doctor, *[insert name of site investigator]* at telephone number *[insert telephone number of site investigator]*.

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: *[insert title of study as stated in protocol]*

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 patient information sheet is orally communicated to subject)*

Signature:

I/C number:

Name:

Date: