PATIENT INFORMATION SHEET AND ICF (ENGLISH TEMPLATE)

PATIENT INFORMATION AND INFORMED CONSENT FORM

TITLE OF STUDY : _____

SPONSOR : **_(if applicable)_____**

NAME OF PRINCIPAL INVESTIGATOR: _____

IMPORTANT: PLEASE READ THE ENTIRE DOCUMENT. DELETE ALL TEXTS IN RED BEFORE SUBMITTING TO THE RERB FOR REVIEW.

This template serves as a guide and may be modified according to your research requirements. This document is for a prospective participant who may not be familiar with scientific/medical terms therefore it is suggested not to use them, if possible, in this document. Use a language that is simple and understandable. Use at least a 12pt font for the entire document.

1. Introduction

Briefly state that you are inviting them to participate in the research you are doing.

I am doing a study about (Describe what the study is about). I would like to invite you to join this study because you (Explain why they are being considered/chosen to participate in the study).

Before you can take part in this study, it is important that you understand what the study involves. Please take time to read the following information carefully and ask any questions that you might have.

2. Purpose of the Study

Explain why you are doing the research in lay terms. The language used must clarify rather than confuse. Do not use technical terms. If you must, then provide an explanation of the technical term in a simple language can be easily comprehended. Use local and simplified terms.

The purpose of this study is to _____.

3. Approximate Number of Participants and the Expected Duration of Your Participation in the Study

The study will take place at Chinese General Hospital and Medical Center (if outside state the place). About (write in numbers not in words) or more participants will be enrolled to participate in the study. Participants must meet all the qualifications to be included. If you are enrolled, the duration of your participation is (Include a statement about the time commitments of the research for the participant including both the duration of the research and follow-up, if relevant.).

4. Procedures (Type of Research Intervention)

Briefly state the type of intervention/ procedure that will be undertaken. (e.g. research involves interview, a questionnaire or collection of data/ medical records) Describe research procedures step by step in the simplest way understandable to a lay person. Avoid using scientific/medical terms. If not possible, define or describe such terms so that the participant may understand. It may be helpful to the participant if you use drawings or props to better illustrate the procedures. Do not copy paste study maneuver of the protocol.

During your stay some information collected about you in the course of standard care provided to you by the medical staff may be used for this study. This information includes your medical history, laboratory tests, medications and other chart information. You will be asked to answer a set of questions that would inquire on your medical condition which would last approximately __ mins. Data /information collected is primarily for research purposes. (for observational studies).

Also include follow-up intervals (if relevant)

You will be asked to fill out a survey/ questionnaire which will be provided by your study doctor. This will approximately last for _____ mins. You may answer it by yourself or it can be read to you (if applicable)

(for questionnaire/surveys)

5. Benefits

Describe the benefits the PARTICIPANT may gain by joining the study and not those to which they are entitled regardless of participation. You may include benefits to the individual, benefits to the community in which the individual lives, and benefits to society as a whole as a result of finding an answer to the research question. If there is no direct benefit, you may say so, but there should at least be a benefit to the society.

There will be no additional direct medical benefit to you from taking part in this study. However, with your participation, you will be able to contribute to a better knowledge in the management of _____ in the Philippines. (or the information learned from this study can be used in the future to benefit other people with _____.)

6. Risk

Describe the risk/s or discomfort the study may bring to the participant, what will be done to minimize it. Provide enough information about the risks so that the participant can make an informed decision.

This study is only observational and does not involve drugs, laboratory, medical or surgical procedures outside of the treatment that you are receiving from your attending physician. As such, there will be no additional direct risk to you from your participation much as the same way if you do not participate. for observational studies

7. Compensation If there is no compensation, the standard line is

You will not be paid for joining this study.

8. Voluntary Participation / Withdrawal from the Study

Your participation in this study is entirely voluntary. It is up to you to decide whether to take part or not. If you choose not to participate in this study, you are free to refuse and it will not interfere with your future care. If you join the study and change your mind later, you may withdraw from the study at anytime in the future by informing the study doctor, there will be no penalty or loss of benefits to which you are otherwise entitled, and your future medical care will not be affected.

9. Permission for Review of Records, Confidentiality and Access to Records

Your study doctor will collect information. This information, called data, will be entered without your name, on a data collection form. In all of these data collection forms, a code will replace your name. All the data collected will be kept confidential and will be used only as permitted by this consent form or as required by law.

10. Questions/Information

- If you or your representative(s) have any questions regarding the study (or in case of study related injuries, if study involves any form of intervention or procedures), you should contact your study doctor: Study Doctor's name in BOLD letters , Phone number: _____

- If you or your representative(s) have any questions/ concerns regarding your rights as a research subject, you should contact **Dr. Bernice T. Ong-Dela Cruz,** Chair of the Research Ethics Review Board (RERB) of Chinese General Hospital and Medical Center, Manila, Philippines, Tel: 711-4141 1oc. 418.

11. Consent Signatures

Please remove "side effects" and "research medication" if there is no research medication to be given as part of the study.

Please read this section carefully and if in agreement please sign and date at the bottom of the page.

- I have had sufficient time to consider the information provided and to ask for advice if necessary
- I have had the opportunity to ask questions and have received satisfactory responses to my questions.
- I have been provided the details of the known or foreseeable side effects and risks of the research medication and study procedures that I may receive.
- I understand that I am free to accept or refuse my participation at any time without giving a reason. My decision to accept or refuse my participation will have no effect on my continuing treatment. I understand that I am free to discontinue my participation at any time without giving a reason. My decision to discontinue my participation will have no effect on my continuing treatment. I will keep all my rights to treatment and alternative therapy.
- I agree that the data collected for the study will be used for the purpose described above.
- I understand that I'm not waiving any of my legal rights as a result of signing this consent form.
- I have read and understood this patient information and Informed Consent Form and that I freely give my consent to participate in this study.
- I will receive a signed and dated copy of this Informed Consent Form.

12) I FREELY ACCEPT TO PARTICIPATE IN THIS STUDY

Sign and date at the same time, all party:

Printed Name of Participant _____

Date (to be entered by participant) _____

Signature _____

Printed Name of Study Personnel _____

Obtaining Consent

Date _____

Signature _____

Distribution: original for study doctor, copy to _____(name of participant)

For emergency situations where consent of the participant cannot be obtained the following signature line must be signed:

Printed Name of Participant's Legally Authorized Representative _____

Date (to be entered by participant's Legally Authorized Representative) _____

Signature _____

Relationship to Participant _____

If the participant's legally authorized representative cannot read, the following signature line should be signed:

Printed Name of Witness _____

Date (to be entered by the witness) _____

Signature _____

At any given time an incapacitated adult (e.g. intubated patients, unconscious patients, or patients in emergency situations, or patients with impairment in decision making) may explicitly refuse to participate in or request to be withdrawn from the study. The Investigator must respect the request. Wherever possible, the patient will be informed as soon as possible and his/her consent will be requested for the continuation of participation to the study.