



**Institutional Review Board of
The University of Hong Kong /
Hospital Authority Hong Kong West Cluster**



香港大學及醫院管理局港島西醫院聯網研究倫理委員會

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**HKU/HA HKW IRB
GUIDANCE NOTES FOR THE
PREPARATION OF PATIENT/SUBJECT INFORMATION SHEET
&
PATIENT/SUBJECT CONSENT FORM**

Approved by:

Professor Albert Chan, Chairman, HKU /HA HKW IRB

Name / Title

Signature / Date

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INTRODUCTION

This document is designed to assist the investigator in the preparation and submission of a Patient/Subject Information Sheet and Patient/Subject Consent Form for a review by the HKU-QMH-IRB.

This description should be followed for clinical trials of Investigational New Drug (IND), Device or Diagnostic Test, and for other clinical studies when requested by the HKU-QMH-IRB. The guidance that follows applies primarily to studies that must comply with the ICH Good Clinical Practice (GCP) guidelines. However, the principles and much of the content will be of use to researchers Patient/Subject Information Sheet and Patient/Subject Consent Form in their particular fields, for trials involving patients, patient volunteers and healthy volunteers.

Patient/Subject Information Sheet

Potential recruits to your research study must be given sufficient information to allow them to decide whether or not they want to take part. A Patient/Subject Information Sheet should contain information under the headings given below where appropriate, and in the order specified. It should be written in simple, non-technical terms and be easily understood by a lay person. Use short words, sentences and paragraphs.

Patient/Subject Consent Form

The study patient/subject should sign this form and confirm that he/she (a) has read and understood the information sheet and have had the opportunity to ask questions, (b) had understood that the participation is voluntary and that he/she is free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected, (c) have understood that sections of any of my medical notes may be looked at by responsible individuals where it is relevant to my taking part in research, and (d) agrees to participate in the study.

Adapted from:

Study Site Standard Operating Procedures Manual
Clinical Trials Centre
Faculty of Medicine
The University of Hong Kong

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PATIENT INFORMATION SHEET

The guidance which follow applies primarily to studies that must comply with the ICH Good Clinical Practice Guideline. However, the principles and much of the content will be of use to researchers writing information sheets in their particular fields, for research involving patients, patient volunteers and healthy volunteers.

During an IRB review and also during trial inspections the patient information sheet is the most frequent source for discussion.

Potential recruits to your research study must be given sufficient information to allow them to decide whether or not they want to take part. A Patient/Subject Information Sheet should contain information under the headings given below where appropriate, and in the order specified. It should be written in simple, non-technical terms and be easily understood by a lay person. Use short words, sentences and paragraphs.

Use the headed paper of the hospital/institution where the research is being carried out. Plain un-headed paper is not acceptable.

1. STUDY TITLE

Is the title self-explanatory to a lay person? If not, a simplified title should be included.

2. INVITATION PARAGRAPH

This should explain that the subject/patient is being asked to take part in a research study. The following is a typical example:

"You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your family doctor if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part."

3. WHAT IS THE PURPOSE OF THE STUDY?

The background and aim of the study should be given here. Also mention the duration of the study.

4. WHY HAVE I BEEN CHOSEN?

You should explain how the subject/patient was chosen and how many other patients will be studied.

5. DO I HAVE TO TAKE PART?

You should explain that taking part in the research is entirely voluntary. You could use the following paragraph:

"It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This will not affect the standard of care you receive."

6. WHAT WILL HAPPEN TO ME IF I TAKE PART?

You should say how long the subject/patient will be involved in the research, how long the research will last (if this is different), how often they will need to visit a clinic (if this is appropriate) and how long these visits will be. You should explain if the patient will need to visit their family doctor (or clinic) more often than for his/her usual treatment and if travel expenses are available. What exactly will happen e.g. blood tests, x-rays, interviews etc.? Whenever possible you should draw a simple flowchart or plan indicating what will happen at each visit. What are the patient's responsibilities? Set down clearly what you expect of them.

You should set out simply the research methods you intend to use; the following simple definitions may help:

Randomised trial

"Sometimes because we do not know which way of treating patients is best, we need to make comparisons. People will be put into groups and then compared. The groups are selected by a computer which has no information about the individual, i.e. by chance. Patients in each group then have a different treatment and these are compared".

You should tell the subject/patient what chance they have of getting the study drug/treatment e.g. a one in four chance.

Blind trial

"In a blind trial you will not know which treatment group you are in. If the trial is a double blind trial, neither you nor your doctor will know in which treatment group you are (although, if your doctor needs to find out he/she can do so)".

Crossover trial

"In a crossover trial the groups each have the different treatments in turn. There may be a break between treatments so that the first drugs are cleared from your body before you start the new treatment"

Placebo:

"A placebo is a dummy treatment such as a pill which looks like the real thing but is not. It contains no active ingredient".

7. WHAT DO I HAVE TO DO?

Are there any lifestyle restrictions? You should tell the subject/patient if there are any dietary restrictions. Can the subject/patient drive/drink/take part in sport? Can the subject/patient continue to take their regular medication? Should the patient refrain from giving blood? What happens if the subject/patient becomes pregnant?

Explain (if appropriate) that the subject/patient should take the medication regularly.

8. WHAT IS THE DRUG OR PROCEDURE THAT IS BEING TESTED?

You should include a short description of the drug or device and give the stage of development.

You should also state the dosage of the drug and method of administration. Patients entered into drug trials should be given a card (similar to a credit card) with details of the trial they are in. They should be asked to carry it at all times.

9. WHAT ARE THE ALTERNATIVES FOR DIAGNOSIS OR TREATMENT?

For therapeutic research the patient should be told what other treatments are available.

10. WHAT ARE THE SIDE EFFECTS OF TAKING PART?

For any new drug or procedure you should explain to the patients the possible side effects. If they suffer these or any other symptoms they should report them next time you meet. You should also give them a contact name and number to phone if they become in any way concerned.

The known side effects should be listed in terms the patient will clearly understand (e.g. "damage to the heart" rather than "cardiotoxicity"; "abnormal liver tests" rather than "raised liver enzymes"). For any relatively new drug it should be explained that there may be unknown side effects.

11. WHAT ARE THE DISADVANTAGES AND RISKS OF TAKING PART?

For studies where there could be harm to an unborn child if the patient were pregnant during the study, the following (or similar) should be said:

"It is possible that if the treatment is given to a pregnant woman it will harm the unborn child. Pregnant women must not therefore take part in this study, neither should women who plan to become pregnant during the study. Women who are at risk of pregnancy may be asked to have pregnancy test before taking part to exclude the possibility of pregnancy. Women who could become pregnant must use an effective contraceptive during the course of this study. Any woman who finds that she has become pregnant while taking part in the study should immediately tell her research doctor."

Use the pregnancy statement carefully. In certain circumstance (e.g. terminal illness) it would be inappropriate and insensitive to bring up pregnancy.

There should also be an appropriate warning and advice for men if the treatment could damage sperm which might therefore lead to a risk of a damaged foetus.

If future insurance status could be affected by taking part this should be stated. If the patients have private medical insurance you should ask them to check with the company before agreeing to take part in the trial. They will need to do this to ensure that their participation will not affect their medical insurance.

You should state what happens if you find a condition of which the patients was previously unaware. Is it treatable? What are you going to do with this information? What might be uncovered (e.g. high blood pressure, HIV + status)?

12. WHAT ARE THE BENEFITS OF TAKING PART?

Where there is no intended clinical benefit to the patient from taking part in the trial this should be stated clearly.

It is important not to exaggerate the possible benefits to the particular patient during the course of the study, e.g. by saying they will be given extra attention. This could be seen as coercive. It would be reasonable to say something like:

"We hope that both/all the treatments will help you. However, this cannot be guaranteed. This information we get from this study may help us to treat future patients with [name of condition] better."

13. WHAT IF NEW INFORMATION BECOMES AVAILABLE

If additional information becomes available during the course of the research you will need to tell the patient about this. You could use the following:

"Sometimes during the course of a research project, new information becomes available about the treatment/drug that is being studied. If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw your research doctor will make arrangements for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form."

"Also, on receiving new information your research doctor might consider it to be in your best interests to withdraw you from the study. He/She will explain the reasons and arrange for your care to continue".

14. WHAT HAPPENS WHEN THE RESEARCH STUDY STOPS?

If the treatment will not be available after the research finishes this should be explained to the patient. You should also explain to them what treatment will be available instead. Occasionally the company sponsoring the research may halt the study. If this is the case the reasons should be explained to the patient.

15. WHAT IF SOMETHING GOES WRONG?

You should inform patients how complaints will be handled and what redress may be available. Is there a procedure in place? You will need to distinguish between complaints from patients as to their treatment by members of staff (doctors, nurses etc.) and something serious which occurs during or following their participation in the trial i.e. a reportable serious adverse event.

Where there are no Association of the British Pharmaceutical Industry (ABPI) or other no-fault compensation arrangements, and the study carries risk of physical or significant psychological harm, the following (or similar) should be said:

"If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal health service complaints mechanisms may be available to you."

16. WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?

You will need to obtain the patient's permission to allow restricted access to their medical records and to the information collected about them in the course of the study. You should explain that all information collected about them will be kept strictly confidential. A suggested form of words for company sponsored research is:

"If you consent to take part in the research any of your medical records may be inspected by the company sponsoring (and/or the company organising) the research for purposes of analysing the results. They may also be looked at by people from the company and from

regulatory authorities to check that the study is being carried out correctly. Your name, however, will not be disclosed outside the hospital or your family doctor's surgery".

Or for other research,

"All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital/surgery will have your name and address removed so that you cannot be recognised from it."

You should explain that for studies not being conducted by a GP, the patient's own GP will be notified of their participation in the trial. This should include other medical practitioners not involved in the research who may be treating the patient. You should seek the patient's agreement to this. In some instances agreement from the patient that their GP can be informed is a precondition of entering the trial.

17. WHAT WILL HAPPEN TO THE RESULTS OF THE RESEARCH STUDY?

You should be able to tell the subjects/patients what will happen to the results of the research. When are the results likely to be published? Where can they obtain a copy of the published results? Will they be told which arm of the study they were in? You might add that they will not be identified in any report/publication.

18. WHO IS ORGANISING AND FUNDING THE RESEARCH?

The answer should include the organisation or company sponsoring or funding the research (e.g. Medical Research Council, pharmaceutical company, charity, and academic institution).

The patient/subject should be told whether the doctor conducting the research is being paid for including and looking after the patient in the study. This refers to payment other than that to cover necessary expenses such as laboratory tests arranged locally by the researcher, or the costs of a research nurse. You could say:

"The sponsors of this study will pay [name of hospital department/research fund] for including you in this study" or "Your doctor will be paid for including you in this study."

19. WHO HAS REVIEWED THE STUDY?

You may wish to give the name of the Institutional Review Board or Research Ethics Committee(s) which reviewed the study (you do not however have to list the members of the Committee).

20. CONTACT FOR FURTHER INFORMATION

You should give the subject/patient a contact point for further information. This can be your name or that of another doctor/nurse involved in the study.

Remember to thank your patient/subject for taking part in this study!

The Patient/Subject Information Sheet should be dated and given a version number.

The Patient/Subject Information Sheet should state that the subject/patient will be given a copy of the information sheet and a signed consent form to keep.

PATIENT/SUBJECT CONSENT FORM

[Form to be on headed paper of the department involved]

Centre Number:
 Study Number:
 Patient Identification Number for this trial:

Title of Project:

Name of Researcher:

Please initial box

1. I confirm that I have read and understood the information sheet dated ___/___/___ for the above study and have had the opportunity to ask questions.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
3. I understand that sections of any of my medical notes may be looked at by responsible individuals from [company name] or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records.
4. I agree to take part in the above study.

<i>Name of patient / Legal Guardian</i>	<i>Date</i>	<i>Signature</i>
<i>Name of Witness (if applicable)</i>	<i>Date</i>	<i>Signature</i>
<i>Name of person taking consent (if different from researcher)</i>	<i>Date</i>	<i>Signature</i>
<i>Researcher</i>	<i>Date</i>	<i>Signature</i>

Copies to:

- Patient/Subject
- Researcher's File
- Hospital Record