**PATIENT/PARTICIPANT INFORMATION SHEET & CONSENT FORM**

The information sheet is the basis of your contract with the patient, it is all that they have to retain and record what they have agreed to

Potential recruits to your research study need to be given sufficient information to decide whether or not they want to take part.

The patient information sheet and the consent form should be written in simple, non-technical terms and easily understood by a lay person; as majority of lay people are not accustomed to reading heavy pages of texts. To facilitate this, you may consider using

* Short words, sentences, paragraphs
* Headings in question format
* Highlight the significant and important words by making it bold
* Active voice
* Do not use “I understand that…..”
* Font size at least Times New Roman 12 point. Studies with elderly subjects and those with visual impairments may require larger fonts.
* Page numbering

The patient information sheet should be dated and given a version number (when applicable). It is a good practice to give the patient a copy, stapled to a copy of their consent form. This should also be retained by you and a copy has to be filed in the hospital (patient’s) notes.

The patient information sheet should contain information under the following headings (You may adapt the ones that are appropriate to your study):

1. **Study Title**

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

1. **Invitation Paragraph**

This should explain that the patient is being asked to take part in a research study.  The following is a suitable 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 others 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.  Thank you for reading this”.*

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

The background and aim of the study should be given here. The following may be considered while describing the purpose

* + Purpose of the study
	+ Reasons why the trial is important at this time
	+ Why the suggested treatment/procedure is being tested at this time
	+ Evidence from other studies regarding the effectiveness of the drug or procedure to be investigated.

If different patients in the trial are to receive different treatment schedules, a brief overview of what each patient group will receive should be provided. Detail whether the study will take place at other hospitals and if so give an approximate total, if known. Include the total number of patients that will be included in the study. Also mention the duration of the study.

1. **What is the duration of the study?**

State the participant’s time commitment in terms of the length of the time required for completion, number of visits required, and time for other activities (e.g., diaries, telephone follow-up).

1. **Why have I been chosen?**

You should explain how the patient was chosen i.e. their suitability and eligibility for the study and how many other patients will be studied. The following paragraph may be used:

You are asked to take part in this study because…

……you have (a certain illness or condition)

……you are already scheduled to undergo (a standard of care procedure)

……you are part of a (some organization) from which the research study is seeking

 information

……you are a healthy person who will be used as a control subject

1. **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.  A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive now or in the future”.*

1. **What will happen to me if I take part?**

A breakdown of all clinical procedures that will take place, highlighting any procedures that will be over and above that which would be carried out during normal clinical management of the patient if they do not agree to take part in the trial. The reason for tests being performed that are over and above normal clinical management should be given.

* 1. You should say how long the patient will be involved in the research
	2. How long the research will last (if this is different)
	3. How often they will need to visit the clinic (if this is appropriate) and how long these visits will be.
	4. You should explain if the patient will need to visit the clinic more often than for his/her usual treatment and if travel expenses are available.
	5. What exactly will happen? e.g. blood tests, genetic tests, x-rays or any other laboratory investigations (over and above those involved in standard diagnosis and treatment) interviews, etc.?
	6. Whenever possible, you should draw a simple flowchart or plan indicating what will happen at each visit.
	7. What are the patient’s responsibilities?  Set down clearly what you expect of them.
	8. If patients within the trial are to receive very different treatment schedules then the researcher should split this section into:
		1. What will happen to patient that are allocated to receive treatment/Procedure A
		2. What will happen to patients that are allocated to receive treatment / procedure B
		3. What will happen to all patients?
	9. For Medical/dental studies, explain about the medications being given, the amount of blood drawn, invasive and/or non invasive procedures, length of hospital stay, follow-up procedures and the like.

You should set out the research methods you intend to use – the following simple definitions may of help to you

**Randomized 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 patients what chance they have of getting the study drug/treatment e.g. a one in four chances.**

**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).

**Cross-over trial:**

In a cross-over 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*.*

1. **What do I have to do?**
2. Are there any lifestyle restrictions?
3. You should tell the patient if there are any dietary restrictions.
4. Can the patient drive? Drink? Take part in sport?
5. Can the patient continue to take their regular medication?
6. Should the patient refrain from giving blood?
7. What happens if the patient becomes pregnant?
8. Any other specific requirements from the patient, such as completion of quality of life questionnaires and their frequency, collection of samples at home, return of tablets if they have not been taken, etc.
9. **What is the drug / treatment 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 with details of the trial they are in.  They should be asked to carry it at all times

1. **What are the alternatives for diagnosis or treatment?**

For therapeutic research, the patient should be told what other treatments are available. Alternative treatments must be detailed in the information sheet and not just discussed verbally with the patient.

1. **What are the side effects of any treatment received when 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 name and number of the person to contact in the event of an emergency (if that is different) should also be given**.

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

1. **What are the possible disadvantages and risks of taking part?**

Provide full details of all known side effects and explain in simple language understandable by a lay person. All information should be prioritized in terms of seriousness, severity and frequency which a participant would understand.

Detail any disadvantages or risks for the patient if they choose to participate in the study. This should include discomfort and inconvenience. Provide details of how patients will be monitored for side effects and what action will be taken in the event of such side effects occurring.

Additional points one may have to consider are:

* Potential behavioral and psychological risks, such as triggering bad memories, learning disturbing things about one’s self, nervousness about being observed, etc.
* Legal or social risks, if any (e.g. discovery of criminal behavior, or loss of status)
* Economic risks (such as loss of wages/job, non-payment by insurance), if any
* If the subject may know conditions that increase the risk for them and/or make them ineligible for the study, e.g., allergies, pregnancy, medical conditions, use of certain medications, etc. they should be included in this session. (Note: the risk of pregnancy is not an acceptable reason to exclude women of child-bearing potential. Contraceptive measures and pregnancy testing can be used to ensure the appropriate inclusion of women in studies).

The fact that the effectiveness of the treatment/procedure is under investigation and is therefore unknown must be mentioned including the fact that the treatment/procedure may not benefit the patient directly.

Ionizing Radiation

If use of additional radiation is required as part of the study then information on the additional amount of radiation must be given, in simple lay person’s language

For women

For studies where there could be harm to an unborn child if the patient was pregnant or became 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 therefore not take part in this study. Women will have a pregnancy test before taking part to exclude the possibility of pregnancy. Women who plan to become pregnant during the study should not take part. Women who could become pregnant must use an effective contraceptive during the course of this study*”.

Use the pregnancy statement carefully. In certain circumstances (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 fetus.

If **insurance** status could be affected by taking part this should be stated if e.g. high blood pressure is detected. If the patients have private medical insurance you should ensure that they 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 patient was unaware. What might be uncovered? Is it treatable? What are you going to do with this information?

1. **What are the possible benefits of taking part?**

List any direct benefits to the subjects or to others which may reasonably be expected from the research.

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 similar to:

“*We hope that both (all) the treatments will help you.  However, this cannot be guaranteed.  The information we get from this study may help us to treat future patients with (name of condition) better”.*

**Costs:**

Any additional costs that may result from participation in the study must be listed. If there are no costs – including no charges passed on the insurance or other third party payers, the consent form should say, “There is no cost to you to participate in this research study”.

For medical/dental studies that include **standard care with research**, the following wording may be used:

“*How much you will have to pay depends on whether or not you have insurance and what costs your insurance will cover. You or your insurance carrier will be responsible for the costs of clinic visits, study drugs, any hospital admissions, laboratory tests, X-rays and other tests. Insurance coverage cannot be guaranteed for tests and treatments related to this study”.*

(Note: if charges will be made to third parties, the details must be explained in the DSREC application form for review. Charges are not allowed for items/services that are paid for by a grant/contract or provided free by the sponsor. If drugs, other therapies and tests are to be provided at no cost as part of the study, specify what will be provided.)

**Payments:**

If subjects are to be paid for participation, reimbursed for expenses or given other incentives for participation, specify the amount, schedule and type of payment/incentive, and conditions for payment. Payment should be prorated for participation. This means that the payments are earned/given as the study progresses and that subjects do not have to complete the entire study to receive a payment.

1. **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 the necessary 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’*.

For minimal risk studies that have no alternatives (e.g., some surveys), you may delete this section, if it does not add information needed to decide about participation.

1. **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 stop it.  If this is the case the reasons should be explained to the patient.

List the circumstances, if any, under which the subject’s participation may be terminated without their consent. The following are examples of acceptable wording:

*“If you do not keep appointments for study visits or can not complete study activities, e.g. taking study medications or completing forms”.*

*“If you do not follow the instructions you are given” (Note: do not use the phrase “fail to follow the protocol or research procedures” as subjects do not have this information.)*

1. **What will happen if I don’t want to carry on in the study?**

In a clinical trial, the patient may wish to withdraw from treatment but be willing to continue to be followed up. If there are any restrictions on withdrawal, e.g. a single intervention will take place but they may withdraw from any other data collection, this should be made clear. If continuing follow-up is genuinely in the participant’s own interests or an ‘exit’ check up will be needed, then this should be stated. The participant, however, retains the right to decide if data from this visit can be used. The position on retention/destruction of data/samples on withdrawal must be made clear. You may use the following texts:

*“If you withdraw from the study, we will destroy all your identifiable samples, but we will need to use the data collected up to your withdrawal”*

OR

*“You can withdraw from treatment but keep in contact with us to let us know your progress. Information collected may still be used. Any stored blood or tissue samples that can still be identified as yours will be destroyed if you wish”.*

1. **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 happening during or following their participation in the trial i.e. a reportable serious adverse event.

In researches that carry 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, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, you can contact Dubai Scientific Research Ethics Committee, DHA on 800 342 or email on* *DSREC@dha.gov.ae*

*OR*

 *‘Compensation for any injury caused by taking part in this study will be provided by the sponsor\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. This applies in cases where it is likely that such injury results from giving any new drug or any other procedure carried out in accordance with the protocol for the study.  ‘The sponsor’ will not compensate you where such injury results from any procedure carried out which is not in accordance with the protocol for the study.  Your right at law to claim compensation for injury where you can prove negligence is not affected”.*

1. **Will my taking part in this study be kept confidential?**

If the study is international or involving an international pharmaceutical company and patient information may be given to other organizations in other countries, this information must be provided.

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 drug 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 organizing) the research for purposes of analyzing 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 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 will have your name and address removed so that you cannot be recognized from it”.*

1. **What will happen to any samples I give?**

Details of any tissue/fluid samples to be taken, what will happen to these where they will be stored and for how long they will be stored? It should be clear to the participant, in the description of study procedures, whether

1. New samples will be taken (e.g. blood, tissue, specifically for this study)
2. Samples excess to a clinical procedure will be asked for
3. Access to existing stored samples will be asked for.

The same type of information, as for data, is needed. This should include:

1. Who will have access?
2. The level of identifiability (for this study and for storage for future studies)
3. Provision for destruction
4. Procedures for possible feedback of individually significant information from their use.
5. Whether samples will be transferred outside the country.
6. **Will any genetic tests be done?**

Details of any genetic tests that will be undertaken must be explained to the patient. The DSREC recommends that for genetic studies information on possible individual implications, feedback, counseling etc. should be clearly explained.

1. **What will happen to the results of the research study?**

You should be able to tell the patients what will happen to the results of the research.  If the results of the study are to be used to inform clinical decision making or the development of another trial this should be mentioned. You might add that the results of this research study may be presented at meetings or in publications; however, the name of the participant will be kept private.

1. **Who is organizing and funding the research?**

The answer should include the organization or company sponsoring or funding the research (e.g. Sheikh Hamdan Award, a pharmaceutical company).

The patient should be told whether the doctor conducting the research is being paid for including and looking after the patient in the study.  This means 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 or research fund) for including you in this study”*

OR

*‘Your doctor will be paid for including you in this study.’*

1. **Who has reviewed the study?**

Provide the name of Dubai Scientific Research Ethics Committee, DHA

1. **Contact for Further Information**

It is very important that you should give the patient a contact point for further information or in cases of any adverse event to be reported. The information should clearly mention who can be contacted in cases of such emergencies. Also, it should be ensured that this person is available round the clock. This can be your name or that of another doctor/nurse involved in the study.

1. **Signatures**

In situations where signature of a witness is required, the signature of the witness on the consent form attests to the fact that

* The form was read by or read to the subject
* An explanation of the research was given
* Questions from the subject were solicited and answered to the subject’s satisfaction
* In this person’s judgment, the subject voluntarily agreed to participate.

When obtaining Informed Consent from a mentally deficient or incompetent person, prisoner, non-English speaking subject, or a subject to whom the Informed Consent must be read (including children), a witness must be present and must sign the Consent document. The witness is verifying that the subject was fully informed and that the subject voluntarily agreed to participate. For non-English speaking subjects, the witness must be fluent in both English and the language of the subject.

**(*Form to be on headed paper)***

**PARTICIPANT CONSENT FORM**

*(NB: This is a sample consent form, to provide you an overview of the basic content required. Please adapt the content and language of the form for your study and ensure that it is appropriate for your participants. You are welcome to use a different lay-out that may suit you and your participants better. Also, please ensure that there is consistency between the content of your application and your consent forms)*

|  |
| --- |
| **Prospective Research Subject**: you are requested to read the patient information sheet carefully before you sign this consent form. You are free to ask questions at any time before, during or after your participation in this research.  |

|  |
| --- |
| Project Title: |
| Project Number: | Site / Center Number: |
| Patient Identification Number:(for this trial) | Sponsor: |
| Principal Investigator: | Organization: |
| Location: | Phone: |

1. I confirm that I have read and understand **the information sheet/contents of the consent form** dated ............................   (version ............) for the above study
2. I have had the opportunity to ask questions and have received answers.
3. 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.
4. 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.
5. I agree to take part in the above study.
6. A copy of this consent form will be provided to me after I sign it.

**Signatures**

**Participant**:

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Legally authorized representative**

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Witness**

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Person obtaining the consent:**

*(I have read this patient information sheet/consent form to the subject and/or the subject has read this form. I have provided the subject with a copy of the form. An explanation of the research was given and questions from the subject were solicited and answered to the subject’s information. A copy of the signed consent form has been provided to the participant).*

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**Investigator     Date  Signature**

*Copies: 1 for participant; 1 for researcher; 1 to be kept in hospital notes*