## Appendix C Sample Informed Consent Form

The following sample is provided as a skeleton developed to assist the Principal Investigator in the design of their informed consent forms (ICF). It is important that Principal Investigators adapt their own ICFs to the outline and requirements of their particular study.

The length of the final ICF should not exceed more than 2-3 pages. Investigators are reminded to keep the level of language in the Informed Consent Form to around the reading level of an 8th to 10th Grade school student. Long technical terms should be avoided or explained in detail. Every effort to ensure the language is clear and simple should be made.

[YOUR INSTITUTIONAL LETTER HEAD]

**STUDY INFORMATION**

**Title of Research:** (a summarised version of your protocol title, that is simple to understand)

**Principal Investigator:** (only one person may be named as principal investigator)

**Participant's Printed Name:** _____

**Study Population and Indication:** [If the study involves different consent forms for different populations, identify the population group as the subtitle of the study.]

**Study Sponsor:** If applicable. Delete if this is an investigator-led study without specific Grant funding.

**Introduction**

I am [name of investigator], working for [name of organization/affiliation]. You are being invited to take part in this research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully, and discuss it with others if you wish.

You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign the consent form. You will be given a copy of the consent form to take home with you.

## PART I: INFORMATION SHEET

**Why is this study being done and why have I been selected? (Purpose of the research)**

Explain in layman's terms the purpose of the study.

You are invited to participate in a research study designed to look at [state what the study is designed to discover or establish]. You have been asked to participate because we feel that your experience as (state why the individual was selected – inclusion criteria for the study) can contribute much to our understanding and knowledge of _____ [state the benefits of the research].

**How many people will take part in this study? (Number of study participants)**

Approximately ___ people will take part in this study at ___ [if multicenter, add number of hospitals/medical facilities] different hospitals and medical facilities.

**What will this research involve? (Type of Research Intervention)**

This research will involve your participation in a [state the type of research method – questionnaire, interview, drug/device study etc] that will take about [state how long the data collection/ what the study duration will be].

If biological samples will be taken:

Any samples of tissues, blood and/or body fluids obtained during the course of this study will be stored and analysed only for the purposes for a period not exceeding *(insert duration of storage)*, and will be destroyed after completion of the study.

**What will I have to do? (Procedures)**

Describe the procedures chronologically using simple language, short sentences and short paragraphs. The use of subheadings helps to organize this section and increases readability. Medical and scientific terms should be defined and explained. The more invasive the procedures, the more detail should be provided.

If you agree to participate in this study, you will be asked to: [describe the study procedures clearly, roughly in the order that they will be done.]

Explain to the participant:

- What will happen at each visit including the specifics of any procedures, tests, questionnaires or interviews
- What is being done as part of the research vs. what is being done as part of standard care/routine practice
- The frequency of the procedures/tests
- The length of time for each visit
- The procedure for collecting any biological samples, if applicable.

If participants will be randomised to study groups:

| |
|---|
| If you agree to take part in this study, you will be randomised to receive (expand with details of study as necessary). Randomisation means assigning you to one of (insert number of study groups) groups by chance, like tossing a coin or rolling dice. |

Your participation in the study will last (insert length of time subject will be required for the study). You will (undergo an interview/ answer a questionnaire/ take the study medication / use the study device) for about (insert number of times study intervention will be performed) and be followed up for (state length of time of follow-up within the study). You will need to visit the doctor's office (state number of times) times in the course of the study.

A tabular format of the visit schedule is usually preferable:

| *Study visit* | *What you will have to do* |
|---|---|
| Visit 1 (Day 1) | Screening<br>Blood test<br>Administration of drug/device<br>Observation |

## How long will I be in this study? (Study Duration)

The research will take place over ___ (number of) days/ or ___ (number of) months in total at _____ [number of study sites/ name of the study centre (if single centre)]. [If applicable, indicate how many times the participant will have to visit the study site, if transportation will be provided, etc.]

### Do I have to stay in the study? (Voluntary Participation)

Taking part in this study is entirely voluntary. It is your choice whether to participate or not. *If you choose not to participate all the services you receive at this Centre will continue and nothing will change. OR The choice that you make will have no bearing on your job or on any work-related evaluations or reports.* You may change your mind later and stop participating even if you agreed earlier.

Your doctor, the Principal Investigator and/or the Sponsor of this study may stop your participation in the study at any time for one or more of the following reasons: (You may use these reasons and/or add some of your own.)

- Failure to follow the instructions of the Principal Investigator and/or study staff.
- The Principal Investigator decides that continuing your participation could be harmful.
- Pregnancy (if applicable.)
- You need treatment not allowed in the study.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

**What are the possible risks I could experience while being a participant? (Risks)**

There are risks, discomforts and inconveniences associated with any research study. These deserve careful thought.

- Describe the discomforts and inconveniences reasonably expected.
- Describe the expected adverse outcomes (to exclude what is possible but unexpected).

Risks of blood sampling, if applicable:

Having a blood (or tissue sample) taken may cause some discomfort or bruising. Sometimes, the blood vessel may swell, or blood may clot in the blood vessel, or the spot from which tissue is taken could become inflamed. Rarely, there could be a minor infection or bleeding. If this happens, it can be easily treated.

Risks related to conception, pregnancy or breast-feeding [if women of child-bearing potential are enrolled in an interventional study]:

The effects of [insert name of intervention] on the unborn child and on the newborn baby are not known. Because of this, it is important that study participants are not pregnant or breast-feeding and do not become pregnant during the course of the research project. You must not participate in the research if you are pregnant or trying to become pregnant, or breast-feeding. If you are female and child-bearing is a possibility, you will be required to undergo a pregnancy test prior to commencing the research project. If you are male, you should not father a child.

Both male and female participants are strongly advised to use effective contraception during the course of the research and for a period of [insert number] months after completion of the study. You should discuss methods of effective contraception with your doctor. [For female participants]If you do become pregnant whilst participating in the study, you should advise your treating doctor immediately. Your doctor will withdraw you from the study and advise on further medical attention should this be necessary. You must not continue in the research if you become pregnant. [For male participants] You should advise your treating doctor if you father a child while participating in the research project. Your doctor will advise on medical attention for your partner should this be necessary.

Concluding statement, if applicable:

There may be additional risks that the researchers do not expect or do not know about. Tell a member of the research team immediately about any new or unusual symptoms that you get.

**What are the benefits of my being a participant? (Benefits)**

The information collected may not benefit you directly, but your participation is likely to help us find out more about [explain the usefulness of your research].

OR

We cannot guarantee or promise that you will receive any benefits from this research, however, possible benefits may include [describe any likely benefits to participants or other people in the future].

**If I do not want to take part in the study, are there other choices? (Alternatives to participation)**

It is important for you to know that you can choose not to take part in the study. There are other choices such as [specify choices]. Your study doctor will discuss these with you.

OR

An alternative to the procedures described above is not to participate in the study and continue on just as you do now. Your study doctor will discuss this alternative with you.

Describe how you would care for a participant who is not part of this research study or describe the options that you would normally offer a person who did not participate in the study. If applicable, include supportive care as an option.

**What are the costs to take part and will I be paid? (Reimbursements)**

There are no costs for participating in the study. You will not be provided any incentive to take part in the research. However, we will give you [provide a figure, if money is involved] for your travel expense (if applicable).

**Will my information be kept confidential? (Confidentiality)**

We will not be sharing information about you to anyone outside of the research team. The information that we collect from this research project will be kept private. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except [name who will have access to the information, such as research sponsors, your clinician, etc].

**Will the results of this study be published and will I get a copy? (Sharing the Results)**

The knowledge that we get from this research will be shared with you before it is made widely available to the public. Each participant will receive a summary of the results. We intend to publish the results so that other interested people may learn from the research.

**Whom should I call if I have questions or problems? (Who to Contact)**

If you have any questions, you can ask them now or later. If you wish to ask questions later, you may contact any of the following: [name, address/telephone number/e-mail]

**This proposal has been reviewed and approved by the Bahrain MOH Health Research Committee [and name of the institutional REB, if applicable], which are committees whose task it is to make sure that research participants are protected from harm.**

## PART II: STATEMENT OF CONSENT
## [If written consent will be taken *(recommended)*]

I have been invited to participate in research about [state research topic].

**I have read the abovementioned information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have been asked have been answered to my satisfaction. I consent voluntarily to be a participant in this study.**

**Print Name of Participant_____**

**Signature of Participant _____**

**Date _____**

**Day/month/year**

**<u>Statement by the researcher/person taking consent</u>**

**I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:**
**1.**

**2.**

**3.**

**I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.**

**A copy of this ICF has been provided to the participant.**

**Print Name of Researcher/person taking the consent_____**

**Signature of Researcher /person taking the consent_____**

**Date _____**

**Day/month/year**