ATTACHMENT 3 PARTICIPANT INFORMATION SHEET – SAMPLE

Manual: Policies
Section: Attachments
No. Pages: 4
Date Created: Jul 04
Review Date: Nov 17
Future Review Date: Nov 19

(Consent Form MUST accompany this document) Refer to Section 5.2.16 of the National Statement on Ethical Conduct in Human Research (2007) – incorporating all updates.

1. Study Title:— __________________________________________________

2. Investigators:— _______________________________________________

3. Introduction:—

Please insert a standard introduction regarding the generic information of clinical trials. For example;

“You have been asked to take part in a clinical research study. This is because you have…. The research project is testing a potential new treatment/investigational product for .... The potential new treatment/investigational product is called ....

This Participant Information Sheet and Consent Form tells you about the research project. It explains the purpose of the research, procedures and risks involved. It also describes information about you that will be obtained, how that information will be used and with whom it will be shared. Knowing what is involved will help you decide if you want to take part in the research. Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor. Participation in this research is voluntary. If you don’t wish to take part, you don’t have to. You will receive the best possible care whether or not you take part. If you decide you want to take part in the research project, you will be asked to sign the Consent Form.

By signing it you are telling us that you;
- Understand what you have read
- Consent to take part in the research project
- Consent to have the tests and treatments that are described
- Consent to use of your personal and health information as described

You will be given a signed and dated copy of this Participant Information Sheet and Consent Form to keep.”

4. Purpose of the Study:—

You are invited to participate in a research study, which is being conducted in order to:

______________________________________________________________

Explain the proposed duration of the study.
5. **Study Procedures:**

5.1 **Treatment Schedule**

5.2 **Length of Treatment Time Including Length of Each Visit**  
(*this information may be provided in a table form):**

6. **Risks and Discomforts:-**

To also include the following:

- In the event you become pregnant during the course of the study, you will be immediately withdrawn from the study. You will be invited to give consent to allow access to information regarding any pregnancy and its outcome for the purpose of determining any effects from the study. *Please refer to Pregnancy and Sexual Health Policy PI013 available at www.bellberry.com.au for sample clauses.*

- You will be counselled by the examining medical officer during the course of your pre study evaluation if blood screening is to be performed for Hepatitis B, Hepatitis C and/or HIV.

7. **Ionising Radiation**

*See sample clauses available in the Bellberry Ionising Radiation Policy PI007 available at www.bellberry.com.au*

8. **Possible Benefits:**  
__________________________________________________

9. **Alternatives to participation:-**  
________________________________________

10. **Tissue Samples:-**

All tissue samples (blood, tumor samples, urine, saliva etc.) are to be treated as falling in to one of two named categories:

1. **OBLIGATORY:** this relates to analyses on samples necessary for the conduct of the research; refusal to provide them is a sufficient condition for exclusion from the trial. These need to be explained in the PIS but no separate consent of any kind is required for them. In the PIS explanation it is important to specify the ultimate destruction date for samples.

2. **OPTIONAL:** this category covers everything else irrespective of the origin of the tissue (be it residue from the obligatory tests or fresh tissue that is sought via blood draws or biopsies). Since none of these are obligatory they are all therefore voluntary and of the nature of donations for either (i) specified testing regimes, or (ii) unspecified future uses.

   Both 2(i) and 2(ii) require brief separate PIS/CF documents. It is important to specify ultimate destruction dates for samples in 2(i).

11. **Voluntary Participation/Right to Refuse or Withdraw:-**

   There is no obligation for you to be involved in this study. If you do not participate your normal treatment plan will be followed. If you decide to participate in the study and later feel that you no longer wish to be part of it, you may withdraw from the study at any time without prejudice to any current or future medical treatment.
12. Confidentiality: -
Your records relating to this study and any other information received will be kept strictly confidential. However staff participating in your care, the sponsor and other agencies authorised by law, may inspect the records related to the study. In the event you are admitted to hospital as a result of an adverse event resulting from this study, your treating doctor may require access to your study records.

Your identity will not be revealed and your confidentiality will be protected in any reviews and reports of this study which may be published. However, results may be suppressed for commercial reasons as the sponsor of the project retains the rights to the data.

Your treating Doctor/s will be notified of your participation in this study and of any clinically relevant information noted by the trial doctor in the conduct of the trial.


13. Costs
Some of the tests or treatments used in this study may be part of standard care used to maintain your health even if you did not take part in the study. You will be responsible for the cost of this standard care in the usual way (health insurance, Medicare and your personal contribution depending on your circumstances). All medication and study-related tests will be provided at no cost to you. You should ask the study doctor to explain any payments for which you may be responsible.

The cost of travel can either be met by reimbursement of petrol costs or the use of taxi vouchers. Reimbursement of parking is also provided.

14. Illness or Injury
If, as a result of being in this study, you become ill or are injured, please immediately contact your study doctor. She or he will then give you all necessary information and treatment and will inform the trial sponsor.

15. Compensation for Injury
See sample clauses available in the Bellberry Compensation Policy PI014 available at www.bellberry.com.au

16. Termination of the Study
This research project may be stopped for a variety of reasons. These may include the following:
Unacceptable side effects, the drug being shown not to be effective, the drug being shown to work and not need further investigation and decisions made in the commercial interests of the sponsor.

17. Investigators Benefits
Your study doctor is being remunerated to conduct this study. He/she will not allow a conflict of interest to compromise their position or this research study.

18. New Information Arising During the Project
During the research project, new information about the risks and benefits of the project may become known to the researchers. If this occurs, you will be told about this new information. This new information may mean that you can no longer participate in this research. If this occurs, the person(s) supervising the research will stop your participation. In all cases, you will be offered all available care to suit your needs and medical condition.
19. **Results of Project**

State how participants will be informed of the results when the research project is completed.

20. **Consent**

Your study doctor is required to provide you with all information regarding the nature and purpose of the research study, risks/benefits and the possibility of alternative treatment and you should be given the opportunity to discuss these. It must be stated that you are free to withdraw anytime and that if you do not participate you will not suffer any prejudice.

21. **Advice and Information**

If you have any further questions regarding this study, please do not hesitate to contact Dr(s) ________________________ on ________________________________.

The Bellberry Human Research Ethics Committee has reviewed and approved this study in accordance with the National Statement on Ethical Conduct in Human Research (2007) – incorporating all updates. This Statement has been developed to protect the interests of people who agree to participate in human research studies. Should you wish to discuss the study or view a copy of the Complaint procedure with someone not directly involved, particularly in relation to matters concerning policies, information or complaints about the conduct of the study or your rights as a participant, you may contact the Operations Manager, Bellberry Limited on 08 8361 3222.

All study participants must be provided with a signed and dated copy of the Participant Information Sheet and Consent Form for their personal records.