

BELLBERRY LIMITED: PARTICIPANT INFORMATION SHEET – SAMPLE

(Consent Form **MUST** accompany this document)

1. **Study Title:-** _____

2. **Investigators:-** _____

3. **Introduction:-**

The following information describes the study and your role as a participant.

Your study doctor will answer questions you may have about the study. The information contained in this Information Sheet will help you to understand the possible risks and benefits involved in the study, what alternatives are available and what would happen. Also your rights and responsibilities will be outlined. Please note you *cannot* receive any reward for being a part of this study.

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:-**

Included the following, if relevant:

- In the event you become pregnant during the course of the study, you will be immediately withdrawn from the study.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.
- 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**

This research study involves exposure to ionising radiation. As part of every day living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 to 3 millisieverts (mSv) each year. The effective dose from this study is aboutmSv.

Choose one of the following:

1. Effective doses less than 2 mSv- At this dose level, no harmful effects of radiation have been demonstrated and the risk is negligible or

2. Effective doses between 2 and 20 mSv - At this dose level, no harmful effects of radiation have been demonstrated and the risk is low. The dose from this study is comparable to that received from routine diagnostic medical x-ray and nuclear medicine procedures or

3. Effective doses between 20 and 50 mSv – The dose from this study is comparable to that received from several computed tomography (CT) x-rays procedures. The benefits from the study should be weighed against the possible detrimental effects of radiation, including an increased risk of cancer.

In this particular study, the risk is moderate and the theoretically calculated risk of contracting fatal cancer in the future is considered acceptable.

The possible detrimental effects of radiation should be weighted against the benefits from the study which are (*state benefits to the patient or to society*). If there are no perceived benefits from participating then state this.

4. Effective doses greater than 50 mSv - This research study involves exposure to a significant amount ionizing radiation. The benefits from the study should be weighed against the possible detrimental effects of radiation, including an increased risk of cancer. In this particular study, the risk is moderate and the calculated risk of such harm is about 1 in.... (Calculate using the ICRP risk coefficient for fatal cancer in the general population of 5×10^{-2} per Sv. For studies in children or for persons over the age of 50, the risk of radiogenic cancer should be calculated using age- and sex-specific risk factors. The possible detrimental effects of radiation should be weighted against the benefits from the study which are (*state benefits to the patient or to society*). If there are no perceived benefits from participating then state this.

If you would like to discuss your exposure to radiation with a radiation safety officer (or relevant state personnel) you may contact the Environmental Protection Agency (EPA) on (08) 8130 0700 or (relevant local agency).

8. Tissue Donation:- _____

9. Possible Benefits: _____

10. Alternative Treatments:- _____

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.

13. Adverse Events:-

The sponsoring drug company abides by the Medicines Australia "Guidelines for Compensation for Injury Resulting from Participation in a Company Sponsored Clinical Trial". A copy of these guidelines is available upon request from the researcher or via the Medicines Australia website www.medicinesaustralia.com.au. Please note you retain all your legal rights in relation to this study.

If you should suffer any injury from participating in this study, you will be given appropriate medical treatment however, in the event you do not have private health insurance and you require hospitalisation, you will be admitted to a public hospital.

14. Payment /Costs

You may be reimbursed for study-related visits, blood or urine tests, study medications, ECG, chest X-ray and other specific assessments. 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.

15. Compensation for Injury

This study is being conducted subject to the 'Guidelines for Compensation for Injury resulting from Participation in a company sponsored Clinical Trial' published by Medicines Australia. Information on compensation can be obtained from the Human Research Ethics Committee listed below or at the Medicines Australia website at www.medicinesaustralia.com.au

Compensation for medical expenses shall not be deemed an admission of fault or liability by the Sponsor or any other person or institution. By signing the Consent Form, you are not waiving any of the legal rights which you otherwise would have as a participant in a research study, and you are not releasing anyone involved in this research study from liability or negligence.

16. 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.

17. 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.

18. 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 this study. 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 Chairman, Bellberry Human Research Ethics Committee on 08 8297 2323.

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