Bellberry recommends use of the *national participant information sheet and consent form (PICF)* template available at www.nationalpicf.com.au/.

General considerations

Consent form

A 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).

Participants under the age of 18

Where participants under the age of 18 are to be included, Child PICFs (including assent or consent) relevant for the age group/s will be required along with a Parent/Guardian PICF.

Bellberry generally requires specific consent/assent to a child's or young person's participation in research from the child or young person whenever he or she has the capacity to make this decision and either one or both parents (depending on the risk involved) or, where applicable, the guardian or person required by law. (per National Statement 4.2.7)

Bellberry will accept the term 'assent' for children as long as it is defined to mean agreement by a minor to their enrolment in research. The Mature Minors Standard supports the use of this term.

Consideration should also be given to participants under the age of 18 having rights to compensation once they turn 18 above and beyond what was promised to their parents. (refer to BA F5.1.6 Standard clauses – compensation for injury guidance document.)

Registrations

If the PICF requires a reference to a registry, please use the following (as appropriate):

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. In Australia any interventional research project must be prospectively registered on a publicly accessible register such as http://www.ClinicalTrials.gov, as required by the Australian National Statement on Ethical Conduct in Human Research."

Optional objectives

Where a study includes any optional objectives (e.g. tissue sample), a separate optional participant information sheet and consent form must be provided. Refer to item 10 below for additional information.

Language and terminology

Please refer to the patient/subject as a 'participant' throughout the PICF.

Please refer to the study product as either the 'investigational product' or 'potential new treatment' throughout the PICF.

Recruitment

Researchers must ensure they consider the *National Statement on Ethical Conduct in Human Research* 3.1.18 (a-e) & ICH GCP guideline 4.8 when developing any recruitment strategy and obtaining informed consent.

Extension studies

Please indicate any extension study/further studies will be subject to relevant regulatory approvals being obtained prior to participant enrolment.

Translation for non-English speaking participants

If non-English speaking participants are to be recruited, the PICF should be translated by a registered translation service in accordance with the National Statement 5.2.17 (b). Consent discussions and any ongoing communication with the participant throughout the study should take place with an accredited interpreter. The interpreter must countersign the PICF to confirm their involvement in the discussion.

In a situation where a potential participant needs to be consented in a timely manner and a translated PICF is not immediately available, an amendment must be submitted requesting approval from the HREC. This should occur on a case-by-case basis. A detailed discussion about the study should be conducted with the participant, their carer/family member and an accredited interpreter. A family member cannot act as an interpreter or translator for a potential participant. A translated PICF should then be sought and provided to the participant for referral throughout the study.

All translated PICFs should be submitted to the Committee for approval. A Translation Certificate must be provided that includes the version number and date of the approved English document the translated version is based on. The translated PICF should have its own version number and version date and the footer should state which English PICF it is translated from. Back-translated English versions of the document/s should not be included in the submission.

eConsent requirements

All electronic and paper-based forms should be submitted to the HREC for review. It is preferred that a link be provided to access the ePICF so that the HREC can review the usability to ensure that it is easy to navigate. The HREC will need to review the contents in the order that the participants will view it to determine if the information is accurate and appropriate. Screenshots may also be provided.

If the ePICF is based on a previously approved paper version, a Letter of Attestation will need to be provided and an Interpretation Document to outline any deviations between the paper PICF and the ePICF. If videos are being used a link to the video, drop-box details or video storyboards can be included in the application.

Any subsequent modifications to the ePICF need to be submitted to the HREC for review on an amendment form. If submitting an amendment to a previously approved ePICF, please make this clear on the amendment form.

Privacy considerations extend to:

(1) How information about a person is collected and stored.

(2) Confidentiality, including the identity of persons participating in a study.

Information regarding how a person's consent to participate via the electronic consent form will be recorded and stored, and how privacy will be protected from unnecessary disclosure must be clearly outlined in the application for the Committee's consideration.

Information will need to be provided about what system/platform will be used to store participant data and what security systems are in place to ensure privacy and confidentiality. If the system used is based in a

country outside of Australia the data will be held in that country. The regulatory regimes governing data access and use in these countries may not be the same as those that are in place in Australia. This issue will need to be addressed and the participant informed if this is the case. (Refer to BA F11.1.1 Standard clauses – confidentiality and privacy).

Please ensure the following information is provided in the submission regarding the process for how the ePICF will be used for consenting:

- Include details regarding the location, i.e. in the clinic or remotely.
- How will study personnel answer questions?
- Will paper copies still be available for those participants who prefer this method?
- How will the ePICF be made available to the potential participants?
- What are the timelines for the participant to consider whether to consent or not?
- How will the participants receive a copy of the signed PICF?

Following are the type of items Bellberry expect to see included in a PICF. This list is by no means exhaustive.

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."

Please include a statement referring to the number of participants that will potentially be recruited at the local site or insert a placeholder (<<insert>>) for the number of participants in a multi-site master PICF template.

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 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. *For additional information, please refer to the Standard Clauses - Pregnancy and Sexual Health (BA F14.1.1) available at www.bellberry.com.au*.
- You will be counselled by the examining medical officer during your pre study evaluation if blood screening is to be performed for Hepatitis B, Hepatitis C and/or HIV.
- In the paragraph referring to reporting serious side effects there needs to be included instructions about seeking medical assistance in an emergency i.e. by ringing 000. Refer to section 14 for example wording.

7. Ionising Radiation

Please refer to the Bellberry Ionising Radiation Sample Clauses (BA F13.1.1).

8. Possible benefits_____

9. Alternatives to participation_____

10. Tissue samples and data_____

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

1. OBLIGATORY: this relates to use of data or 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 data, and tissue irrespective of the origin (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 for the tissue, 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.

(This will apply in most cases, use where relevant).

For further information, please refer to the Confidentiality and Privacy Standard Clauses (BA F11.1.1) available at www.bellberry.com.au.

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. In the case of a serious and rapidly escalating adverse reaction contact emergency services on 000. Ensure that you have your emergency card with you so the study doctor can be contacted as necessary.

15. Compensation for injury

Please refer to BA F5.1.6 Compensation for injury standard clauses 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.

References

National Statement on Ethical Conduct in Human Research (2007 incorporating all updates)

BA F5.1.1 Photographic release consent

BA F5.1.2 Sample consent form

BA F5.1.3 Third party form

BA F5.1.4 Revocation of consent

BA F5.1.5 NHMRC PICF – Bellberry requirements

BA F5.1.6 Standard clauses – compensation for injury

BA G10 Participant payment and reimbursement

BA G11 Researcher data storage and retention

BA F11.1.1 Standard clauses - confidentiality and privacy

BA G13 Ionising radiation

BA F13.1.1 Standard clauses – ionising radiation

BA F13.1.2 Standard imaging - definitions

BA F13.1.3 Standard of care declaration – template

BA G14 Pregnancy and sexual health

BA F14.1.1 Standard clauses – pregnancy and sexual health

BA F14.1.2 Pregnancy/pregnant partner data release - template

BA G15 Standard clauses – pregnancy and sexual health