

Bellberry accepts the NHMRC Participant Information Sheet/Consent Form (PICF). Please refer to the "Instructions for Creating a Participant Information Sheet/Consent Form" that accompanies the NHMRC template. We also encourage you to consider incorporating the following statements into your PICF when applicable.

General considerations

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.

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 BA G5 sample participant information sheet available at www.bellberry.com.au for additional information.*

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.

Introduction (*interventional NHMRC PICF template section 1*)

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.

What does participation in this research involve? (*interventional NHMRC PICF template section 3*)

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 any tests or treatments that are considered standard care in the usual way (health insurance, Medicare and your personal contribution depending on your circumstances). All study-related tests and treatments 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 be met by reimbursement, such as reimbursement of petrol costs, parking costs or the use of taxi vouchers.

Please refer to BA G10 participant payment and reimbursement guidance and BA G5 sample participant information sheet available at www.bellberry.com.au for additional information.

What do I have to do? (*interventional NHMRC PICF template section 4*)

'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.'

Refer to BA G5 sample participant information sheet available at www.bellberry.com.au for additional information.

What are the possible risks and disadvantages of taking part? (*interventional NHMRC PICF template section 9*)

Please consider including the following statements when applicable to the protocol:

In the event you become pregnant during the course of the study, you will be immediately withdrawn from any ongoing study treatment. 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 BA G14 pregnancy and sexual health guidance, BA F14.1.1 standard clauses – pregnancy and sexual health, and BA G5 sample participant information sheet available at www.bellberry.com.au for additional information.

Emergency contact

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.

What will happen to information about me? (*interventional NHMRC PICF template section 16*)

Please consider including the following statement:

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.'

Data sent overseas

'Participants should note that, some data from your participation in this study will be sent overseas or shared with persons outside Australia; the regulatory regimes governing data access and use in other countries may not be the same as those that are in place in Australia. If you have any questions about this direct them to the Principal Investigator.'

Please refer to BA G11 researcher data storage and retention guidance and BA F11.1.1 standard clauses – confidentiality and privacy available at www.bellberry.com.au for further information.

Compensation for injury

Please refer to BA F5.1.6 Compensation for injury standard clauses available at www.bellberry.com.au.

GP notification (*interventional NHMRC PICF template section 3 and consent form*)

Please include a statement in the PICF and/or the Consent Form "I consent to my treating Doctor/s being notified of my participation in this study and of any clinically relevant information".

Who has reviewed this research project? (*interventional NHMRC PICF template section 19*)

Please include the following statement below the section:

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.

Additional considerations

Photographs

If photography is non-identifying the Participant Information Sheet must state that 'photographs will be used for research purposes only.'

If photography is identifying include the following section in the consent form:

Photographic release

Please check the appropriate "Yes" or "No" box below in order to indicate what you will allow your photographs to be used for. Once publication has occurred the images will be in the public domain, and thus you will have a very narrow window for revocation of consent.

Yes No

Education

Scientific publication

Purposes of research associated with this study

By signing this release, I do not forfeit any of my legal rights. At any time, I may revoke this authorisation for future use.

Signature of participant

date

Printed name of participant

Please refer to BA F5.1.1 photographic release consent for further information (available at www.bellberry.com.au).

Extension/further studies

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

Consent form

For adult PICFs please include a declaration that the participant is aged 18 years or over.