Purpose and Scope

The purpose of this document is to outline Bellberry-specific requirements for inclusion in Participant Information Sheets and Consent Forms (PICFs) where relevant to the research project. These requirements apply regardless of the template used (CT:IQ InFORMed, NHMRC, sponsor-developed, or other).

Adhering to these requirements will assist investigators in preparing PICFs that are more likely to meet approval without extensive revision.

Template Guidance

- Bellberry HRECs review and accept all PICF templates.
- Investigators are encouraged to use the CT:IQ InFORMed PICF, a simplified national template.
- Please refer to any user guides associated with templates.
- Bellberry inclusions outlined in this document must be incorporated into all PICFs where relevant, regardless of the base template.

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1. Structure, Formatting and Language

- Each PICF must have a version number and date.
- Include the Study title, Principal Investigator, Sponsor and Site on the first page.
- Use plain English, suitable for the participant population.
- Use “participant” instead of “patient” or “subject.”
- Use the term “invited” instead of “asked” (e.g., “You are invited to take part in a clinical research study. This is because you have…”).
- Avoid terms such as “eligible”, “qualify”, or “screen failure”. Use neutral alternatives, e.g., “to see if a study is suitable for you”.
- Avoid persuasive language suggesting merit, good fortune, or opportunity.
- The consent form must be incorporated in the same document as the PICF, not as a separate document.
- Include page numbers.

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2. Special Participant Groups

2.1 Participants unable to provide consent

- Where decision-making capacity is impaired, a “Person Responsible” PICF is required unless precluded by jurisdictional law.
- Alternative processes may be submitted for HREC review.
- Investigators are responsible for compliance with relevant jurisdictional laws.
- Review Chapter 4.5 of the National Statement before submission.

2.2 Participants under 18 years of age

- Age-appropriate child/young person PICFs (assent/consent) and a Parent/Guardian PICF are required.

- Consent/assent is generally expected from the child or young person wherever they have capacity, in addition to parental/guardian consent (National Statement 4.3.4).
- The term “assent” may be used, defined as agreement by a minor to their enrolment in research.
- Research involving children should be designed with close attention to the guidance provided by the National Statement Chapter 4.3. The guidance regarding capacity to consent reflects the mature minor test accepted in Australian law since 1992.

2.3 Non-English speaking participants

- If translated PICFs are used, they must be submitted to the HREC for approval with a translation certificate from a nationally accredited vendor referencing the approved English version. The use of AI for translating PICFs, questionnaires, or surveys is not acceptable or appropriate. These documents must be translated by an accredited translator to ensure accuracy, cultural suitability, and clarity.
    - If translated PICFs are used, they must be submitted to the HREC for approval with a translation certificate referencing the approved English version.
    - The translated PICF requires its own version and date.
    - Back-translated English versions should not be submitted.
- Interpreters: 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.

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3. Bellberry-Specific Inclusions

3.1 What am I being invited to do?

- Use appropriate language: e.g., “You are invited to take part in a clinical research study. This is because you have…”

3.2 What is the purpose of this study?

- State how many participants are expected to take part in the study in Australia and additionally, at the local site.
- Registration of trial: If the PICF includes reference to a registry, the following text is required (noting this may be a combination of both sentences, as appropriate):

  A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. In addition, where required, information and results from this study will be posted on other local registries as required by law. These websites will not include information that can identify you. At most, this Web site will include a summary of the results. You can search this Web site at any time.

  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.

  Please note: the FDA has issued guidance regarding the first paragraph. The exact statement must be included in the informed consent documents of applicable clinical trials where applicable.

3.3 Do I have to take part and can I change my mind?

- Include that the study doctor is required to provide all information regarding the nature and purpose of the research study, risks/benefits and the possibility of alternative treatment and the participant should be given the opportunity to discuss these.
- Example wording:
  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.

You can change your mind at any time

- Include that the participant is free to withdraw anytime and that if they do not participate, they will not suffer any prejudice.

The project might stop for other reasons

- Include the potential reasons for stopping the project and what will happen to the participant.
- Example wording:

  During the study, new information about the risks and benefits of the study 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 study. If this occurs, the person(s) supervising the study will stop your participation. In all cases, you will be offered all available care to suit your needs and medical condition.

  This study may be stopped for a variety of reasons. These may include unacceptable side effects, the study drug being shown not to be effective, the study drug being shown to work and not need further investigation and decisions made in the commercial interests of the sponsor.
  When the study is stopped, you will no longer have access to the study drug even if you are responding to the treatment. Your treating doctor will discuss ongoing care with you, however there may be no further treatment options available to you.

3.4 What do I have to do if I take part?

- Include that the participant will be counselled by the examining medical officer during their pre-study evaluation if blood screening is to be performed for Hepatitis B, Hepatitis C and/or HIV.

3.5 Your time and expenses

- Advise participants that they ‘will’ be reimbursed rather than ‘may’ be reimbursed. Any conditions relating to the reimbursement, such as dollar limits or presentation of receipts, must be included in the PICF.
- Participants should be advised of any payment variation due to withdrawal from the research.
- See document BA G10 Participant Payment & Reimbursement Guidance.
- Required wording:

  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.

3.6 What are the benefits of taking part?

- Required wording:
  By providing your specimen to < > you are gifting your rights to the data or samples. This means that you will not receive any benefit from this use of your data or samples, for example if the research leads to a new treatment.

3.7 What are the risks and discomforts of taking part?

Risk of study intervention

- Where participants are being prescribed an approved drug for an approved indication, Adverse Events should not be listed in the PICF.
  Required wording: *Some drugs you will be taking for this study are already approved by the Australian Therapeutic Goods Administration for your condition. They have side effects and these are described in the Consumer Medicines Information (CMI) for each drug. You should read the CMI for the drug, or each drug if there are more than one, before reaching a decision about your participation in the study and before signing the consent form.*
- If participants are being prescribed an unapproved drug or approved drug for an unapproved indication, Adverse Events should be listed in the PICF and the CMI not used.
- In the paragraph referring to reporting serious side effects include instructions for seeking medical assistance in an emergency i.e. by ringing 000.

Risks for unborn and newborn babies

- Include clauses for pregnancy testing, withdrawal, and counselling if relevant.
- Bellberry provides non-denominational contraception wording and recommends this wording is used rather than Catholic and non-Catholic options.
- Include that any follow up of a child will be for a minimum of 12 months.
- See Bellberry documents BA G14 Pregnancy & Sexual Health Guidance and BA F14.1.1 Pregnancy & Sexual Health Standard Clauses.

Risks if you are taking other medicines

- Refer to template wording.

Risks from exposure to radiation

- Use Bellberry standard clauses as relevant.
- See Bellberry documents BA G13 Ionising Radiation Guidance and BA F13.1.1 Ionising Radiation Standard Clauses.

Breach of confidentiality

- Include the potential risk of breach of privacy associated with any unauthorised release of personal information.
- Insert Bellberry standard wording.
- See Bellberry documents BA G11 Researcher Data Retention & Storage Guidance and BA F11.1.1 Confidentiality & Privacy Standard Clauses.

3.8 How will my information and/or samples be used and shared?

Use of information and/or samples:

- Biospecimen donation from archived tumour samples may mean that there will be less (if any) remaining for any future studies, this should be made clear in the PICF

- All data and biospecimen samples (blood, tumour samples, urine, saliva, etc.,) are to be treated as falling into one of two categories:
    - 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. Provide an explanation and specify the ultimate destruction date for samples.
    - Optional: Includes data and biospecimens that can be residue from the obligatory tests or fresh biospecimens that is sought via blood draws or biopsies. They are voluntary donations for either specified testing regimes for the biospecimen or unspecified future uses. A brief separate PICF document is required for optional collection of data and/or samples.

Keeping information and/or samples safe:

- Sharing your information with others: Include Bellberry standard wording, including when data is sent overseas.
- Publishing project information: State how participants will be informed of the results when the research project is completed.
- See BA G11 Researcher Data Retention & Storage Guidance and BA F11.1.1 Confidentiality & Privacy Standard Clauses.

3.9 Who is running and paying for this project?

- Include information about remuneration for the Principal Investigator.
- If a conflict of interest exists for the PI or study team, the nature of the interest and the management plan must be disclosed.
- See Bellberry document BA G7 Conflict of Interest Guidance.

3.10 What happens if something goes wrong?

- Required wording:
  If, as a result of being in this study, you become ill or are injured, please immediately contact your study doctor. They will then give you all necessary information and treatment and will inform the study 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.
- Insert standard Bellberry Compensation clause. See document BA F5.1.6 Compensation for Injury Standard Clauses.

3.11 Who has reviewed and approved this project?

- Required wording:
  The Bellberry Human Research Ethics Committee has reviewed and approved this study in accordance with the National Statement on Ethical Conduct in Human Research (2025). 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 Director of Operations, Bellberry Limited on 08 8361 3222.

3.12 Consent form and signature page

- See Appendix Consent Form Template.

3.13 Additional circumstances

- Extension studies: State that any extension study/further studies will be subject to relevant regulatory approvals being obtained prior to participant enrolment.
- Photography: Include required clauses or provide a separate PICF as appropriate.
- Digital scribes: Where digital scribes are used to analyse or interpret clinical conversations they are regulated as a medical device. Where a digital scribe is to be used the PICF should clearly state this and provide participants with information about the technology and any potential implications for their privacy. For further information refer to TGA guidance: Digital scribes | Therapeutic Goods Administration (TGA).

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4. Other Requirements

Obtaining consent:

In accordance with ICH GCP E6(R3) and the National Statement on Ethical Conduct in Human Research (2025):

- GCP 2.8.7 states: Prior to trial participation, the informed consent form should be signed and dated by the participant or by the participant's legally acceptable representative and, where appropriate, by an impartial witness and by the investigator or delegated investigator site staff who conducted the informed consent discussion.
- The National Statement on Ethical Conduct in Human Research (2025) further specifies: Participation in the clinical trial can only commence when the participant, or the participant's legally acceptable representative, has received a copy of the signed and dated written informed consent form. These requirements confirm that no trial-related procedures may occur—including behavioural requests such as fasting—until full written informed consent has been obtained.

Electronic consenting (ePICF):

- Bellberry reviews only the content of a document, not the platform it is provided on.

  Sites are responsible for privacy and confidentiality and must document processes in a Data Management Plan. Specific technological practices do not necessitate a separate review by the HREC, as they primarily pertain to administrative processes rather than ethical considerations. The HREC review is limited to ethical considerations of the participant-facing content and subsequent data management. Therefore, participant consenting platforms and electronically verified signature platforms do not require submission to the Bellberry HREC.
- Sites have responsibility for maintaining privacy and confidentiality of participant information and these details should be included in a Data Management Plan. Site specific recruitment strategies and consenting processes should be detailed in the HREC application.

Optional Objective

- When seeking consent for optional objectives in a research project, Bellberry requires that the related information and consent be presented either as an appendix to the main PICF or as a separate PICF. This approach ensures that optional objectives are clearly distinguished from the main study.

  When using an appendix, standard information already covered in the main PICF does not need to be repeated, allowing for a more concise format than would be required in a standalone document. Please refer to the table below for the specific requirements that apply to each type of optional objective. Where both an appendix and a separate document are acceptable, researchers may choose the format they consider most appropriate.

Optional Objective	Appendix to Main PICF	Separate PICF	Notes / Requirements
Optional samples	✓	✓	Either format acceptable
End of treatment biopsies	✘	✓	Consent should be obtained when decision has been made to discontinue treatment
Future research (specified or unspecified)	✓	✓	Either format acceptable
Genetic/genomic testing	✓	✓	Either format acceptable
Long-term extension study	✘	✓	Must be a separate PICF, consent should be obtained when the participant becomes eligible for entry to the LTE study
Identifying photography/ videography	✓	✓	Either format acceptable

For other optional objectives, tick boxes may be used; however, the HREC will determine their acceptability on a case-by-case basis.

Use and Release of Imagery Content

Where photographs or video footage are to be obtained for research purposes, the Participant Information Sheet should include a description of the nature of the required images, including any plans for their use in publications or education.

Where images are **non-identifying**, include the statement “Photographs/video footage will be used for research purposes only” in the Participant Information Sheet.

Images need to be non-identifying unless consent has been received from the participant approving the photographic or video footage release.

Where images are **identifying**, a separate consent form is required. Identifying information includes facial features, tattoos, scars or other body markings. Where identifying images may be used for marketing purposes, this must be stated.

Where a study makes identifying photography or video footage obligatory, the purpose for use must be clearly stated. Where there are multiple optional purposes, a tick-box approach may be suitable. Examples may include for education, scientific publication or purposes of research associated with this study.
Please see the following example clauses:

I, the undersigned:

- Voluntarily consent to the use of my image(s) as described in the Participant Information Sheet and according to my preferences indicated in the points above.
- Understand that by signing this release, I do not forfeit any of my legal rights.
- Understand that once any of the image(s) referred to above have been published, the researchers have no control over subsequent use and disclosure of the images; the images will be in the public domain, and it will not be possible to revoke consent.
- Understand that I can withdraw permission for the further use of my image(s) at any time.

References

- National Statement on Ethical Conduct in Human Research (2025)
- *ICH GCP E6(R3)*
- Bellberry Guidance, Standard Clauses and Templates:
  - BA F5.1.3 Third Party Consent Form Template
  - BA F5.1.4 Withdrawal of Consent Form Template
  - BA F5.1.6 Compensation for Injury Standard Clauses
  - BA G10 Participant Payment & Reimbursement Guidance
  - BA G11 Researcher Data Storage & Retention Guidance
  - BA F11.1.1 Confidentiality & Privacy Standard Clauses
  - BA G13 Ionising Radiation Guidance
  - BA F13.1.1 Ionising Radiation Standard Clauses
  - BA F13.1.3 Radiation Standard of Care Declaration Template
  - BA G14 Pregnancy & Sexual Health Guidance
  - BA F14.1.1 Pregnancy & Sexual Health Standard Clauses
  - BA F14.1.2 Pregnancy & Pregnant Partner Data Release Template

APPENDIX – Consent Form Template

Protocol Title:

(Participant Information Sheet MUST be attached)

I _____, the undersigned hereby voluntarily consent to my involvement in the research project titled: _____

_____

I acknowledge that the nature, purpose and risks of the research study and alternatives to participation have been fully explained to my satisfaction by Dr. _____

Specifically, the details of the procedure(s) proposed and the anticipated length of time it will take, the frequency with which the procedure(s) will be performed and an indication of any discomfort that may be expected have been explained to me.

- I freely agree to participate in this research project according to the conditions in the Participant Information Sheet which I confirm has been provided to me.
- I have been given the opportunity to have a member of my family or another person present while the study is explained to me.
- I understand the purposes, procedures and risks of the research described in the information sheet.
- I have been told that no information regarding my medical history will be divulged to unauthorised third parties and the results of any tests involving me will not be published so as to reveal my identity.
- I understand that my involvement in this study may not be of any direct benefit to me.
- I give permission for long-term storage and use of my data or samples for health-related research purposes and donate my rights to these samples. I understand that I will not receive any benefit from this use of my data or samples, for example if the research leads to a new treatment.
- I understand that access may be required to my medical records for the purpose of this study as well as for quality assurance, auditing and in the event of a serious adverse event and I consent to this access.
- I understand that I am free to withdraw from the study at any stage without prejudice to future treatment. If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.
- I am 18 years of age or over.
- I consent to my treating Doctor/s being notified of my participation in this study and of any clinically relevant information noted by the study doctor in the conduct of the study.
- I declare that all my questions have been answered to my satisfaction.
- I have read, or have had read to me, and I understand the Participant Information Sheet, version x, dated x.

Name of study participant:_____

Signature of study participant:_____ **Date:**_____

Declaration by Principal Investigator (PI) or Co-Investigator (CI):

A verbal explanation of the research project, its procedures and risks has been given to the participant and I believe that the participant has understood that explanation.

Name of PI or CI:_____

Signature of PI or CI: _____ **Date:** _____

The Principal Investigator or Co-Investigator must provide the explanation and provision of information concerning the research project.

Use this section only if required

Refer to ICH GCP E6(R3) clauses 2.8.7 and 2.8.9 outlining when an impartial witness is required.

Signature of witness: _____ **Date:** _____

Full name of witness: _____ **Date:** _____

Address: _____

I declare that I have been present when the research was explained to the above-named participant and to the best of my observation and belief was understood and the consent freely given.