Consent Form Requirements

Bellberry Limited expects the following points to be addressed. The Consent Form should state clearly to which study it relates and include the following:

- A statement to the effect that the participant may freely withdraw from the project at any time without prejudice to further treatment.
- Where applicable, a statement informing the participant that there may be no direct clinical benefit to him/her as a result of the trial.
- A statement that information collected will be kept confidential, however consent for access for specific purposes such as quality assurance, auditing, research and in the event of a serious adverse event must be obtained.
- Ensure that the written consent form is signed and personally dated by the participant or Legally Authorised Representative and by the person who conducted the informed consent discussion.
- Notification of their participation in the study and that any clinically relevant information noted by the trial doctor during the conduct of the trial will be given to treating Doctor/s.
- I have read, or have had read to me, and I understand the Participant Information Sheet, Version x, dated x.

The participant must be given ample time and opportunity to ask whatever questions occurred to them during the consent process. These must be answered to the satisfaction of the participant or the participants Legally Authorised Representative.

Researchers must renegotiate or confirm participants consent when significant trial related events occur that may affect a participant's willingness to continue to participate in the trial. (per National Statement 2.2.8)

There should be a signed declaration by the researcher confirming a verbal explanation of the research project, its procedures and risks has been given to the participant and understood by them.

If it is intended to seek permission for use of optional tissue samples (either residue from obligatory tests or fresh tissue sought), a separate Participant Information Sheet and Consent Form must be included for this secondary purpose. Refer Sample Participant Information Sheet for further details.

Consent Form Requirements for Children and Adolescents

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 now 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.

A separate information sheet for children and adolescents is required.

The Committee requires reassurance that any participant turning 18 years of age during the study will be re-consented. This is legally necessary because the young person is then legally an adult and parental consent is no longer operative.