

Participant Information and Consent Form Requirements for Site Governance Review

Please ensure the PICF for use at ACT Health sites contains the following item

- ACT Health and or TCH logos (as appropriate)
- reference to ACT law, legislation or ACT Health policy
- Clear statement that participation is voluntary and there will be no adverse effect on treatment or relationships due to non-participation
- Clear statement that participants may withdraw from the study at any time
- Clear statement on how data (including tissue) will be managed post withdrawal:
 1. All data destroyed; or
 2. All data up until point of withdrawal retained and used in analysis/publication; and
 3. No new data to be collected or used
- Clear statement on how tissue samples will be managed (as per National Statement)
 1. Specific – current study only
 2. Extended – current study and future similar studies (eg, same disease/indication)
 3. Unspecified – current study and any future study
- Clear statement on how study is funded
- Clear statement that participants will not be paid for research participation
- Clear statement that research participation will not carry any cost burden to the participant
- Clear statement that benefit to the individual participant is not guaranteed
- Description of study and study procedures
- Information on drug side effects (if applicable) and any other risks of participation
- Information on birth control and pregnancy related risks (if applicable)
- Clear statement on compensation, including reference to Medicines Australia Guidelines for Compensation for Injury Resulting from Participation in a Company-Sponsored Clinical Trial
- Contact information for study doctor/coordinator at ACT Health
- Contact information for LifeLine etc (if applicable)
- Contact details for ACT Health Ethics and Gov Office
- Footer showing study name/reference, site name, version and date

Consent Form

Must contain the following information

- Study title
- Local PI name and contact details
- Name and location of site (eg Medical Oncology, Canberra Hospital, Building 19)
- Where applicable, separate check box for:
 1. Genetic testing
 2. Digital recording

Name: _____ Signature: _____ Date: _____