Informed Consent Process and Documentation Policy

The Principal Investigator submits a proposed informed consent procedure and written form with his/her HREC application prior to initiation of research, except in situations such as: research proposals that meet exempt criteria (although informed consent(s) may be included), and research proposals that include a request for waiver of informed consent or waiver of documentation of informed consent. The investigator indicates in the HREC application the individuals who will be participating in the informed consent process from the research team or individuals who are authorized to obtain informed consent on behalf of the Principal Investigator.

1. At a minimum, the proposed consent process and form include the following eight required elements and additional elements where appropriate:

   - Research Statement: a statement that the study involves research, an explanation of the purpose of the research, an explanation of the expected duration of participation, a description of the procedures involved, and identification of any procedures that will be experimental.

   - Reasonably Foreseeable Risks or Discomforts: a statement that describes any foreseeable risks or discomforts associated with the research, the likelihood of their occurrence and the ramifications associated with the risks (e.g., decreased blood count may result in need for a blood transfusion).

   - Reasonably Expected Benefits to Subjects or Others: a statement that describes any benefits to subjects or others that may be reasonably expected from the research including no benefit, if this is applicable. Payment for participation in a research project is not considered a benefit.

   - Appropriate Alternatives: a statement that describes with enough detail any alternative procedures or course of treatment that may be advantageous to the subject. If no alternatives exist, the consent form must state that there are no alternatives except to not participate.

   - Extent of Confidentiality: a statement that describes the extent to which confidentiality of records identifying the subject will be maintained or not maintained ,describes how the research team will protect subjects' private records during and after the conclusion of proposed research studies. Any research that is subject to audit or inspection must identify who will have access to the subject's record (e.g., study sponsors, contract research organizations, UnitingCare Health Human Research Ethics Committee).

   - Compensation or Treatment for Injury: for studies with greater than minimal risk, a statement obtaining explanations regarding: any compensation and an explanation of any medical treatments available if injury occurs or where further information may be obtained.

   - Contact Information: a statement that describes contact information details, including telephone numbers, and whom to contact for the following situations: questions about the research (e.g., investigator and other team members), questions about subjects' rights, comments/suggestions (e.g., the UnitingCare Health HREC) and in the event of a research-related injury (depending on the nature of the research, the Principal Investigator or a physician on the research team).

   - Voluntary Participation Statement: a statement that describes clearly: participation in the research is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

- Additional Elements Where Appropriate: The Uniting Care Health HREC requires the additional elements unless the item(s) does not apply given the nature of the research or the proposed procedures (e.g., subjects will not be paid for participation).
- Unforeseeable risks to subjects, embryos, or fetuses: a statement warning subjects that some risks are currently not known or foreseeable should be included when applicable;
- Investigator-initiated termination of participation: a statement that describes the instances an investigator may terminate a subject's participation (e.g., subject non-compliance, subject not benefiting from research, etc);
- Additional costs: a statement that describes any additional costs a subject may encounter such as: transportation, time away from work, parking, health costs, etc.;
- Early withdrawal/procedures for termination: a statement that describes a subject's right to withdraw from research and any procedures that may be necessary after an early withdrawal for subject's safety;
- Significant new findings: a statement that subjects will be told of any new findings which may affect willingness to continue in the research;
- Approximate number of subjects: a statement that explains the approximate number of subjects to be enrolled in the study worldwide nationwide and locally;
- Disposition of subjects' blood samples: DNA testing, cell lines, development of future products;
- Payment: a statement that includes all information concerning the amount and schedule of payment for participation.

2. If the research involves vulnerable populations or sensitive issues, the investigator addresses additional regulatory and/or institutional requirements. The vulnerable populations and sensitive issues include, but are not limited to:

- Research involving the participation of children;
- Research involving decisionally challenged/impaired subjects;
- Research involving HIV screening and/or AIDS research;
- Research involving DNA Banking, Genetic Research, or Gene Therapy;
- Research activities directed toward pregnant women;
- Research involving prisoners.

3. The investigator also needs to address the following issues, if applicable, to the proposed research:

- Inform the subject in the purpose that the study includes evaluation of both safety and effectiveness of investigational drugs, devices, or biologics and state the test article is investigational, and, if applicable, not approved by the Therapeutic Goods Authority in Australia;
- The process of dose escalation;
- The possibility of risk for an unborn child, a man or woman's ability to procreate or a woman's ability to conceive or carry a child.

4. If the research involves genetic testing or DNA banking the Principal Investigator must address, in the informed consent process and form, the applicable issues discussed in Chapter 3.5: Human Genetics within the National Statement on Ethical Conduct in Human Research (2007).

5. If the research involves establishing a specimen/tissue repository, the Principal Investigator must address, in the informed consent process and form, the applicable issues discussed in Chapter 3.4: Human Tissue Samples within the National Statement on Ethical Conduct in Human Research (2007).

6. The HREC assesses the PI's description of the informed consent process to ensure that the process meets the general requirements of informed consent (ie consent be obtained from the subject or subject's legally authorized representative; be in language understandable to the subject; be obtained under circumstances that provide the subject with the opportunity to consider whether or not to participate, and that minimize coercive influences; does not include language through which the subject is made to waive his/her legal rights or releases the investigator, sponsor, or institution from liability for negligence).

7. The HREC determines whether disclosure of any investigator conflict of interest is warranted in the informed consent process and document.

8. The investigator is responsible for ensuring that informed consent is obtained from each research subject or his/her legally authorized representative after the subject or the subject's legally authorized representative has had an adequate opportunity to read the form and before that subject participates in any part of the research study, using the process and form approved by the HREC.