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 project 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 understand that my involvement in this study may not be of any direct benefit 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 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my medical history will be divulged to unauthorised third parties and the results of any tests involving me will not be published so as to reveal my identity.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 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 trial doctor in the conduct of the trial.
- 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 TGA Note for Guidance on Good Clinical Practice July 2009 clause 4.8.9 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.