

Undertaking by Investigators

Project Title:

I/We, the investigators identified below, undertake:

- To observe the principles laid down in the most recent NHMRC Statement on Human Experimentation and The Declaration of Helsinki. (See Appendix 1 for a summary of these documents)
- Not to commence this research project until approval is obtained from the Austin Health Human Research Ethics Committee
- Not to commence this research project unless adequate funding and expertise are available to enable the study to be undertaken in accordance with the principles of good research practice and in an ethical manner
- To provide additional information as requested by the Human Research Ethics Committee
- To provide annual reports to the Human Research Ethics Committee in the required format
- To maintain the confidentiality of all data collected from study participants
- To notify the Human Research Ethics Committee in writing immediately if any changes to the protocol are proposed and await approval before proceeding with the proposed change
- To notify the Human Research Ethics Committee in writing promptly if any serious adverse events occur after the approval of the committee has been obtained
- To act promptly upon advice of a serious adverse event to ensure the safety and well being of study participants
- To agree to an audit as required by the Human Research Ethics Committee
- That data and any tissue samples collected will be used only for the study for which approval has been given
- That security procedures will be applied to maintain confidentiality (in general this will involve removal of personal identifying information from data collection forms and computer files. Codes linking individuals to data will be stored in a locked cabinet. Access to identifying data on computer should be under password control).
- That access to data will be only to appropriately authorised persons
- That no data capable of identifying a particular individual will be published without the specific written consent of the participant

As the Principal Investigator, I additionally declare that:

- I will take responsibility for the confidential maintenance of records for 15 years after completion (or 7 years in the case of non-drug trials).

Signature (Principal Investigator)

Name (in block letters)

Date

We, the undersigned investigators, confirm the undertakings detailed on the previous page:

Signature (Investigator)

Name (in block letters)

Date

Signature (Investigator)

Name (in block letters)

Date

Signature (Investigator)

Name (in block letters)

Date

Signature (Investigator)

Name (in block letters)

Date

Acknowledgment of Supervisor (if student project)

I am satisfied with the scientific integrity and validity of the proposal:

Signature (Supervisor)

Name (in block letters)

Date

Acknowledgment of notification to Head of Department at Austin Health

I am aware that this research is being undertaken in my Department and am satisfied that processes are in place to assure the scientific integrity of this proposal:

Signature (Head of Department)

Name (in block letters)

Date