

DEED OF CONFIDENTIALITY

This Deed is made on

Parties **THE INVESTIGATOR** (Investigator)

THE RESEARCH INSTITUTE named in Item 2 of the Schedule
(Research Institute)

THE SAX INSTITUTE ACN 095 542 886 of Level 8, University of
Technology, 235 Jones Street, Ultimo in the State of New South
Wales (**Sax Institute**)

Background

- A. The Sax Institute manages the 45 and Up Study. Investigators through the Research Institute can apply to use the Sax Institute to approach participants of the Study to be participants in their own sub-studies, provided certain requirements are met.
- B. The Research Institute wishes the Sax Institute to approach participants for the purpose of conducting a sub-study and has satisfied the Sax Institute's requirements.
- C. The Sax Institute has agreed to approach participants on the terms and conditions set out herein.
- D. The Sax Institute requires the Research Institute to cause the Investigator to enter into this deed for the benefit of the Sax Institute before access to data from the 45 and Up Study is made available to the Investigator.
- E. The Investigator has agreed to keep confidential the material disclosed to the Investigator by the Sax Institute in connection with the sub study.

Operative Parts

1. Definitions and interpretation

1.1 Definitions

In this Deed unless the context otherwise requires the following words and expressions shall have the meanings ascribed thereto:

Baseline Data means the Study questionnaire data, including identifying details, collected at baseline, and does not include any data collected at follow-up, or Project Data or, Linkage Data.

Confidential Information Means:

- (a) Any information which by its nature or by the circumstances of its disclosure, is or could reasonably be expected to be regarded as confidential to:
 - the Sax Institute; or
 - any third party with whose consent or approval the Sax Institute uses that information is designated by the disclosing party as

confidential; or

- (b) is designated by the disclosing party as confidential
- (c) the receiving party knows or ought to know is confidential,

and includes without limitation:

- (d) the terms of this Agreement
- (e) the Baseline Data, including the Data Set
- (f) information received from Study Participants as a result of executing this Agreement
- (g) Specimens received from Study Participants as a result of executing this Agreement
- (h) results of tests undertaken on Specimens taken from Participants as a result of executing this Agreement
- (i) all information about the disclosing party, its employees, agents, research, property, policies and operations which is made available or which becomes known during the term of this Agreement or as a result of executing this Agreement

but does not include information:

- (j) in the public domain, or in the recipient's possession prior to the date of this Agreement;
- (k) which comes into the public domain after the date of this agreement;
- (l) already known by the Research Institute or the Investigators at the time of disclosure other than as a result of an unauthorised disclosure;
- (m) non-confidentially disclosed to the Research Institute or the Investigators by a third party legally entitled to disclose the information.

Data

means Participant information held by the Study, including, but not limited to:

- (a) the Data Set
- (b) Health Data
- (c) Baseline Data

and excluding the Project Data.

Data Set

means any version, edition or release, current or otherwise, by the Sax Institute, of the de-identified Baseline data for the purposes of health-related research.

Health Data

includes any of the following data:

- (a) hospital, pathology and death records;
- (b) NSW Health and Departments of Veterans' Affairs data;
- (c) hospital waiting times, surgical procedures and emergency department information;
- (d) ambulance services data and Roads and Traffic Authority Information on accidents;
- (e) Medicare and general practice information;
- (f) Pharmaceutical Benefits Scheme and Repatriation Pharmaceutical Benefits Scheme;
- (g) aged care, mental health and hearing services information;
- (h) special disease or treatment record systems, including diabetes and cancer registers;
- (i) infectious diseases notifications;
- (j) disability information;
- (k) radiotherapy, injury, midwives and birth defects data;
- (l) dialysis and transplant register, and
- (m) breast, breast cervical, prostate and bowel cancer screening records.

Specimen

means any human biological specimen. This term is to be interpreted broadly and given its full meaning to include the full range of human specimen types including, but not limited to:

- (a) Sub-cellular components such as DNA or RNA
- (b) Cells or tissues from any part of the human body
- (c) Organs
- (d) Gametes
- (e) Exhaled air
- (f) Bodily products such as teeth, hair, nail clippings, sweat, urine, faeces
- (g) Blood and blood fractions: plasma, serum, buffy coat, red blood cells
- (h) Saliva and buccal cells

Study

means the 45 and Up Study.

Sub-study

means a nested study which recruits study participants from the 45 and Up Study cohort.

1.2 Legislation

A reference to legislation or a provision of legislation includes any change or reenactment of the legislation or a legislative provision substituted for and legislation and statutory instruments and regulations issued under, the legislation.

1.3 Singular to include plurals

Words denoting the singular include the plural and vice versa; words denoting individuals or persons include bodies corporate and trusts and vice versa; and headings are for convenience only and will not affect interpretation.

1.4 References to clauses

A reference to a clause, paragraph or schedule is a reference to a clause, paragraph or schedule of this Deed; and a reference to a document or agreement includes reference to that document or agreement as changed, novated or replaced from time to time.

2. CONFIDENTIALITY

2.1 Maintain Confidentiality

Subject to clause 2.3, the Investigator agrees:

- (a) to keep the Confidential Information confidential and to ensure that it does not disclose or permit the disclosure of the Confidential Information to any person without the prior written consent of the Sax Institute; and
- (b) to take all steps and do all things that are necessary or prudent or desirable in order to safeguard the confidentiality of the Confidential Information.

2.2 Disclosure of Confidential Information

The Investigator must:

- (a) only disclose Confidential Information to agents or advisors who need to receive the Confidential Information for the purpose of the Sub Study and provided that the Sax Institute has consented to such disclosure under clause 2.1;
- (b) before disclosing any of the Confidential Information (other than this Deed) to any agents or advisor associated with the Sub Study, supply a copy of this Deed to that person and require the person to execute a Deed in like terms as if they were the Investigator.

3. DISCLOSURE

3.1 Notification

The Investigator must:

- (a) notify the Sax Institute immediately if it becomes aware of a suspected or actual breach of this Deed; and
- (b) take all reasonable steps, at its own expense, required to prevent or stop the suspected or actual breach.

3.2 Compelled Disclosure

If the Investigator is or may be required by law or court order to disclose any of the Confidential Information, the Investigator must immediately notify the Sax Institute and the Research Institute in writing of the requirement. The Investigator must, as directed by the Sax Institute:

- (a) assist or permit the Sax Institute to oppose or restrict disclosure; or
- (b) to the extent practicable, make disclosure on terms which will preserve the confidentiality of the Confidential Information.

4. RETURN OF CONFIDENTIAL INFORMATION

4.1 Return

The Investigator agrees to deliver to the Sax Institute or otherwise as the Sax Institute may direct, all documents and other materials, or copies of such documents or materials, in its possession, power or in the possession, power or control of any of the Investigator's agents or advisors which contain any Confidential Information and which were supplied to the Investigator by the Sax Institute or the Research Institute, on the earlier of:

- (a) written demand by the Sax Institute; and
- (b) the time the Confidential Information embodied in the documents and other materials is no longer required for the Sub Study.

4.2 No Release

Return of the documents and other materials referred to in clause 4.1 does not release the Investigator or its agents or advisors from their obligations under this document.

5. General

5.1 Amendment

No variation or waiver of, or any consent to any departure by a party from, a provision of this Deed is of any force or effect unless it is confirmed in writing signed by the parties and then that variation, waiver or consent is effective only to the extent for which it is made or given.

5.2 Waiver

The failure, delay, relaxation or indulgence on the part of any party in exercising any power or right conferred upon that party by this Deed does not operate as a waiver of that power or right, nor does any single exercise of any power or right preclude any other or further exercise of it or the exercise of any other power or right under this Deed.

5.3 Severance

If any provision of this Deed is invalid and not enforceable in accordance with its terms, other provisions which are self-sustaining and capable of separate enforcement without regard to the invalid provision, are and continue to be valid and enforceable in accordance with their terms.

5.4 Counterparts

This Deed may be executed by any number of counterparts and all of those counterparts taken together constitute one and the same instrument.

5.5 Governing law and jurisdiction

This Deed is governed by, and is to be construed in accordance with, the laws of New South Wales and the parties submit to the non-exclusive jurisdiction of the courts of New South Wales and any court hearing appeals from those courts.

Schedule 1

Item 1: Name of Investigator

Item 2: Name of Research Institute

Item 3: Details of Sub Study

Signed as a Deed

SIGNED SEALED AND DELIVERED by)
the **INVESTIGATOR** in the presence of:)

Signature of witness

Signature

Name of witness:

Address of witness:

EXECUTED by the **RESEARCH INSTITUTE**)
in accordance with section 127 of the)
Corporations Act:)
)
)

Signature

Signature

Name:

Name:

Office held:

Office held:

EXECUTED by **THE SAX INSTITUTE**)
ACN 095 542 886 in accordance with)
section 127 of the Corporations Act:)

Signature

Signature

Name:

Name:

Office held:

Office held: