SaxInstitute

Chronic conditions Umbrella Program Linkage (CUPL) Institutional Agreement

Project Title:	Gender based differences in Atrial Fibrillation risk and management: an Australian prospective cohort study.
Lead Research Organisation:	MQ HEALTH PTY LIMITED T/A MACQUARIE UNIVERSITY HOSPITAL
ABN:	46 141 203 125
Address:	3 Technology Place Macquarie University NSW, 2109, Australia
Researchers:	A/Prof Chrishan Nalliah (Lead Researcher) Dr Karice Hyun A/Prof Hari Raju Prof David Brieger

This Agreement is made between the Parties named below:

Parties	The Sax Institute ABN 68 095 542 886, of Level 3, 30C Wentworth Street, Glebe 2037 in the State of New South Wales ("**Institute"**); and The entities whose details are set out on the first page of this Agreement **("Research Organisations")**

Background

A. The Institute manages the 45 and Up Study (Study) which is an open access resource for health research in the public interest.
B. The Institute has auspiced the Chronic conditions Umbrella Program Linkage (CUPL) which comprises the Study Data and linked data sets.
C. The Institute has sought and received Data Custodian and ethics approval for the CUPL.
D. The Lead Research Organisation and Participating Institute wishes to conduct their Research Project using the CUPL.
E. The Research Project will require ethics approval as a sub-study from *The NSW Population and Health Services Research Ethics Committee (PHSREC)* approval before it can commence. This will be facilitated by the Institute.
F. CUPL can only be accessed by researchers via the Institute's purpose-built high powered computing environment called the Secure Unified Research Environment (SURE).
G. The Institute agrees to allow the Lead Research Organisation and Participating Institution(s) to use approved data items available through the CUPL to conduct the Project, subject to the terms and conditions of this Agreement.
H. The Institute reserves the right to refuse access to the CUPL if the proposed Project and/or the relationship of the Researcher with the Research Organisation is in violation or potential violation of the governance requirements or Conditions of Data Disclosure of the Institute or of Data Custodian/s.

1 Definitions and interpretation

1.1 Definitions

In this Agreement unless the context otherwise requires, the following words and expressions have the following meanings:

Access Period means the period set out in item 1 of the Schedule 1 or twelve (12) months from the Effective Date, whichever is earlier if no period is set;

Access Policy means the policy of the Institute that outlines the principles, approval process and requirements that permit a researcher to conduct a research project using Data from the CUPL, which can be found in the governance and ethics section of the Study website;

Agreement means this agreement and all schedules and annexures to it;

Agreements for Data Disclosure means the agreements required by each and every Data Custodian for release and use of data under the CUPL;

Archive means to remove Data from the Workspace and store this Data on tape and/or optical disk which are maintained at a secure facility in an encrypted format for a duration of time usually in keeping with the retention period required by Ethics Approval;

Authors' Guidelines: are the 45and Up Study guidelines prepared by the Institute and available with instructions and conditions for the preparation and publication of papers, reports, abstracts,

presentations and any other publications arising from use of the 45 and Up Study Cohort data, as amended from time to time. These are available on the 45 and Up website here.

Business Day means a day that is not a Saturday, Sunday or a public holiday in New South Wales, Australia;

Chronic conditions Umbrella Program Linkage (CUPL) is an enduring program linkage under the management of the Institute and approved by the Population and Health Services Research Ethics Committee (PHSREC) and relevant Data Custodians.

Conditions of Data Disclosure means:

Conditions of Data Custodian authority under:

(i) Instrument/s of Data Disclosure: and/or,

(ii) Agreement/s for Data Disclosure; and/or,

(iii) Authority/ies for Data Disclosure;

to provide the Institute with access to datasets and data variables for linkage and use under the Chronic conditions Umbrella Program Linkage (CUPL).

Schedule 2 sets out the Conditions of Data Disclosure binding the Lead Research Organisation, Participating Institution/s and Researcher/s in order to authorise the release of Cause of Death Unit Record Files and/or other data sets accessed under CUPL. Schedule 2 must be signed and executed at the same time as this Agreement for access to data to be provided;

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; or

b. is designated by the disclosing Party as confidential; or

c. the receiving Party knows or ought to know is confidential, and,

d. includes unit record data and linked data provided under this Agreement to the Researcher.

The Data is deemed Confidential Information for the purposes of this Agreement.

Confidential information does not include information which:

a. is in the public domain; or

b. is in the recipient's possession prior to the date of this Agreement; or

c. comes into the public domain after the date of this Agreement other than because of a breach of confidentiality obligations under this Agreement; or

d. is already known by the Lead Research Organisation, Participating Institution(s) or the Researcher(s) at the time of disclosure; or

e. has been non-confidentially disclosed to the Lead Research Organisation, Participating Institution(s) or the Researcher(s) by a third party legally entitled to disclose the information;

Credential means a physical or electronic token or information that is used to establish authority to access a User Virtual Machine;

Curator refers to the Institute's data manager who is responsible for curating (reviewing and approving) incoming and outgoing Data flow within the CUPL Workspace and is also responsible for ensuring that any information entering the User's Virtual Machine complies with Ethics Approval and Data Custodians Provider approvals;

Data means in connection with this Agreement:

a. the data which are available in the CUPL, as specified in Item 8 of the Schedule 1; and

b. any linked health information collected or obtained about Participants under clause 4 (where applicable);

Data Custodian is the agency, body or position designated with the custody of a specified data set and holds the overall accountability and responsibility for the data set;

Effective Date means the date the Researcher(s) is provided access to the Project Virtual Machine;

Ethics Approval means approval granted by an ethics committee following review of the ethical acceptability of human research and ensuring compliance with regulatory and legislative requirements, as well as institutional policies relating to human research.

Execution Date means the date that this Agreement has been signed by the last Party;

Fees means the costs charged to the Lead Research Organisation under or with respect to this Agreement as specified in Item 5 of the Schedule 1.

Intellectual Property Rights means all intellectual and industrial property rights and interests throughout the world, whether registered or unregistered, including trade marks, designs, patents, inventions, semi-conductor, circuit layouts and other eligible layouts, copyright and analogous rights, trade secrets, processes, concepts, plant breeder's rights, confidential information and know-how;

Laws means any statute, regulation, order, rule, subordinate legislation or other document enforceable under any statute, regulation, order, rule or subordinate legislation;

Lead Researcher means the lead investigator on the Project as detailed on Page 1 of this Agreement and as per Ethics Approval. The lead investigator has responsibility for the Project and has the authority to sign-off on instructions for SURE access, change of services or data refreshes in relation to their Project;

Lead Research Organisation means the organisation with which the lead investigator on the Project is employed or affiliated, and is specified on the first page of this Agreement. The Lead Research Organisation has responsibility for the compliance of the lead investigator and all other researchers employed by, or affiliated with it, who are named on the Project with all conditions of this Agreement, including those specified in any schedule attached to this Agreement;

Linked Data means information that relates to the same individual, family, place or event from different data sources and which have been anonymised**;**

Participant means a person who is participating in the 45 and Up Study;

Participating Institution refers to a research organisation that is included on Page 1 of this Agreement and has Researchers collaborating on the Project. The Participating Institution has responsibility for the compliance of all researchers employed by, or affiliated with it, who are named on the Project with all conditions of this Agreement, including those specified in any schedule attached to this Agreement;

Parties means a party (or the parties) to this Agreement;

Personal Information has the meaning given to it in the *Privacy Act 1988* (*Cth*);

Policies means the Institute's policies and procedures which will be made available to the Research Organisation/s and Researchers, and with which, the Research Organisation/s is/are required to familiarise itself with. For the purposes of this Agreement, the Research Organisation/s is/are deemed to have read and understood the policies;

Project means the research project as specified in Item 3 of the Schedule 1;

Project Folder means a directory accessible to a discreet and approved User;

Researcher(s) means any investigator who is involved in the Project and is named on the first page of this Agreement and in Item 8 of the Schedule 1 (as varied and amended from time to time in accordance with this Agreement);

Researcher Deed Poll means a deed signed by Researchers in the form used by the Institute;

Research Organisation means any or all of the Lead Research Organisation and Participating Institution/s as specified on the first page of this Agreement and in Schedule 1.

Software for a Virtual Machine means those software products which are approved for use by the Users;

Standards means the standards of research governance, management and practice set out in the following guidelines, codes and statements:

1) National Statement on Ethical Conduct in Research Involving Humans (NHMRC, 2007, as updated in 2018) or any replacement versions;
2) Australian Code for the Responsible Conduct of Research (NHMRC, 2018);
3) Values and Ethics: Guidelines for ethical conduct in Aboriginal and Torres Strait Islander health research (NHMRC, 2003);
4) Guidelines for Genetic Registers and Associated Genetic Material (NHMRC, 1999);
5) Guidelines issued and/or approved under sections 95, 95A or 95AA of the *Privacy Act 1988 (Cth)*;

Study Data means the 45 and Up Study survey data;

Study Partners refers to the organisations that support the Study and may be varied from time to time;

SURE means the service known as the “Secure Unified Research Environment” operated by the Institute;

Term has the meaning set out in clause 13.a;

Termination Date means the date on which this Agreement (as varied and extended in accordance with this Agreement) expires;

Third Party Data Provider/Data Custodian refers to the agency or organisation who has responsibility for Data, including assignment rights;

Users refer to researchers named on Page 1 of this Agreement and employed by or affiliated with the Lead Research Organisation or the Participating Institution(s) who have been approved to access the CUPL data;

Virtual Machines refers to any virtual desktops, project folders, appliances or server within the Workspace; and

Workspace(s) means the virtual workspace in SURE provided under this Agreement in relation to the Project.

1.2 Interpretations

In this Agreement, unless the context indicates a contrary intention:

a. Headings and bold type are for convenience only and do not affect the interpretation of this Agreement.

b. The singular includes the plural and the plural includes the singular.

c. Other parts of speech and grammatical forms of a word or phrase defined in this Agreement have a corresponding meaning.

d. An expression referring to a person includes any company, partnership, joint venture, association, corporation or other body corporate and any government agency as well as an individual.

e. A reference to a clause, Party or schedule is a reference to a clause of, and a Party or schedule to, this Agreement.

f. A reference to any legislation includes all delegated legislation made under it and amendments, consolidations, replacements or re-enactments of any of them.

g. A reference to a document (including Policies) includes all amendments or supplements to, or replacements or novations of, that document.

h. A reference to a Party to a document includes that Party's successors and permitted assignees.

i. A reference to liquidation or insolvency includes appointment of an administrator, liquidator, provisional liquidator, receiver, controller, compromise, arrangement, merger, amalgamation, reconstruction, winding up-, dissolution, deregistration, assignment for the benefit of creditors, scheme, composition or arrangement with creditors, insolvency, bankruptcy, or any similar procedure or, where applicable, changes in the constitution of any partnership or person, or death.

j. A reference to a body, other than a Party to this Agreement (including an institute, association or authority), whether statutory or not, which ceases to exist or whose powers or functions are transferred to another body, is a reference to the body which replaces it, or which substantially succeeds to its powers or functions.

k. Specifying anything in this Agreement after the words 'include' or 'for example' or similar expressions does not limit what else is included.

l. Where the day on or by which any agreed action is to be done is not a Business Day, that action must be done on or by the next Business Day.

2. Research Organisations' obligations

2.1 Access and use terms and obligations

In consideration of the Fees paid by the Lead Research Organisation, the Institute will provide the Research Organisation with access to, and use of, relevant, approved variables from the CUPL data on a non-exclusive basis.

a. Data may only be accessed, viewed or used by the named Users:

1) for the purposes of the Project;

2) subject to and in accordance with appropriate Ethics Approvals;

3) subject to the Execution of the Agreement by the Lead Research Organisation and all Participating Institutions;

4) subject to each and every Researcher having signed the Researcher Deed Poll;

5) during the Access Period;

6) within a SURE Virtual Machine; and

7) in accordance with the Data Custodian Conditions of Data Disclosure, and the Access and Governance policies of the Institute.

b. The Lead Research Organisation must give the Institute the following written reports within the specified period:

Type of report*	Timing
Progress reports	Six (6) monthly following the Effective Date or at any other interval as required for compliance with Conditions of Data Disclosure
Final report	30 days following the end of this Agreement.

*Format of report will be specified by the Institute.

c. The Research Organisation warrants as to the bona fide of their Researcher/s as named on this Project and to the accuracy of information provided to the Institute about the Project including information about the source of funding for this Project and the relationship of its Researcher/s to the funding body;

d. The Research Organisation must immediately (within 24 hours) notify the Institute when the Research Organisation:

i. receives a request for disclosure of Personal Information of Participants and shall refuse any such request, to the full extent permitted by the Laws; or

ii. receives a complaint relating to an alleged breach of any of the obligations contained in or referred to in this Agreement; or

iii. becomes aware of any inappropriate conduct in relation to the CUPL data or the Virtual Machines including (but not limited to) conduct inconsistent with the Australian Code for the Responsible Conduct of Research and notifiable data breaches; or

iv. becomes aware of a serious allegation or sanction for research misconduct against the Researcher/s named on this Project; or

v. terminates its Researcher/s or is notified that the Researcher/s is/are no longer an affiliate or employee of the Research Organisation.

e. The Institute will be responsible for co-ordinating Ethics Approvals for this Project and the Lead Research Organisation undertakes to provide all requisite assistance to enable the Institute to carry out the process to seek ethics approval. Any variation to the Project, ethics approved protocol, personnel or data requirements must be submitted in writing to the Institute for approval before any variation commences.

Copies of all ethics approvals, including the approved protocol and any approved amendments will be provided to each and every data custodian as required under the Conditions of Data Disclosure and schedules to this Agreement.

2.2 Confidentiality and Privacy obligations

a. Each Party must keep the Confidential Information of the other Party confidential and must not disclose that information to any third party without the written consent of the other Party. Each Party must use the Confidential Information of the other Party only for the purpose of complying with its obligations under this Agreement.

b. A Party's obligations of confidentiality in this Agreement do not apply to information which:

1) is or becomes generally known other than through a breach of this Agreement;

2) that Party can prove was developed independently by that Party without reference to the Confidential Information of the other Party;

3) is rightfully received by that Party from a third party without an obligation of confidentiality; or

4) that Party can prove was known to that Party prior to the disclosure of the information by the other Party.

c. If the Parties have earlier executed a separate confidentiality or non-disclosure agreement, then, except to the extent of inconsistency (in which case the terms of this Agreement take priority), the obligations in this Agreement are in addition to and run in parallel with the obligations in that agreement.

d. The Research Organisation must comply with the *Privacy Act 1988 (Cth)*, the Laws, the Standards and the Policies in relation to the use, collection, handling, storage, processing and disclosure of any Personal Information obtained as a consequence of this Agreement.

e. The Research Organisation must notify the Institute of any Data breach within this Project as soon as possible but no later than 24 hours of becoming aware of the breach.

f. The Institute will be responsible for any mandatory data breach reporting requirements in relation to CUPL data. The Research Organisation will provide the Institute with all necessary information within the requested timeframe to enable the preparation of a report for lodgement with the relevant regulatory authorities.

2.3 Authority

a. The Lead Research Organisation acknowledges and agrees that the Institute may act on written instructions provided via the form specified by the Institute given by the Lead Researcher on all matters relating to the Project as if they were instructions given directly by the Lead Research Organisation.

b. The Research Organisation agrees to be bound by all such instructions and must not hold the Institute in any way responsible for any loss or harm occasioned as a result of the Institute following such instructions.

c. Where the Institute gives information or material in relation to the Project or Workspace to the Lead Researcher, that information or material is treated as having been given to the Lead Research Organisation and Participating Institution.

d. The Lead Research Organisation undertakes to notify the Institute as soon as possible (within five Business Days) of any proposed changes in the Lead Researcher. The Institute reserves the right to determine the acceptability of the proposed changed based on the information provided by the Lead Research Organisation, the project status and other relevant matters, including the capacity of the Lead Researcher to comply with all

Conditions of Data Disclosure and the Researcher Deed Poll.

2.4 Amendments to the Project

If the Lead Research Organisation wishes to request addition of Researchers or remove Researchers from the Project or make changes to the Project, the Lead Researcher must provide the Institute with full particulars in the form specified by the Institute of all changes to the Institute for review and to facilitate Ethics amendments. The Institute reserves the right to determine the acceptability of the proposed changed based on the information provided by the Lead Research Organisation, the project status and other relevant matters. The Institute may require the payment of further Fees or specify other conditions to the change of service. The Research Organisation/s acknowledges that no amendments to the Project can take place without appropriate Ethics approval.

If the Lead Research Organisation wishes to request additional services, the Lead Research Organisation must provide the Institute with full particulars of all changes for review, in the form specified by the Institute. The Institute may require the payment of further Fees or specify other conditions to the change of service, including the need for ethics approval via an amendment as detailed in clause 2.1 e.

2.5 Breach of Obligations

a. The Research Organisation/s must work with, consult, assist and cooperate in good faith with the Institute to resolve any breach of any of the obligations contained in or referred to in this Agreement.

b. Failure to comply with any of the obligations listed in this Agreement and schedules to this Agreement may result in the Lead Research Organisation's, Participating Institution's and/or Researcher's access to the Workspace and Data being reviewed, suspended or revoked. It may also preclude publication of any analyses or papers or reports arising out of the Project and may result in Data Custodian restrictions including suspension or removal of data access for the current Project and in the future.

3. Reports, Publications and Acknowledgments

a. The Research Organisation must ensure that publication guidelines as outlined in the Institute's Authors' Guidelines which is available on the Institute's website, are adhered to.

b. Where Cause of Death Unit Record File data is used, the Research Organisation must ensure that the conditions of Schedule 2 are adhered to.

c. The Research Organisation must provide a final draft copy of any article or report, or presentation containing or based on the Data or generated through the Project, to the Institute for review not less than 30 Business Days prior to submission for publication (unless otherwise agreed between the Parties in writing). The Institute will conduct a review based on the Author Guidelines. If the Institute requires changes as a result of the review, the Research Organisation/s must make the required changes and resubmit the draft for approval prior to publication.

d. All data disclosure must comply with the requirements of the Institute and all Data Custodians whose data is utilised in the Project, and must adhere to best practice, including prohibition of release of data with cell sizes < 5, utilisation of other statistical disclosure control techniques as required, and compliance with Conditions of Data Disclosure in the identification and comparison of sites, facilities and centres.

e. The Research Organisation acknowledges and agrees that articles or reports containing data from other Data Custodians may be subject to separate requirements for review and approval. If such requirements apply, they will be detailed in a schedule to this agreement.

f. The Research Organisation must provide a copy of all final published or circulated abstracts, papers, articles or reports or presentations containing or based on the CUPL data or generated through the Project, to the Institute at least 21 days prior to publication of the article or report.

The Research Organisation grant the Institute permission to:

i. publish any publication relating to the Project on the Institute's website; and,

ii. provide a copy of the final publication to Study Partners and Data Custodians.

g. The Research Organisation must acknowledge the contribution of the Institute and the Study Partners (as specified by the Institute), and the NSW Ministry of Health and/or Data Custodians in a form to be specified by the Institute in any relevant correspondence, public announcement, advertising material, research reports, articles or other material produced by, on behalf of or through the Research Organisation in any manner relating to the Project.

4. Special obligations related to Linked Data

4.1 Obligations of the Lead Research Organisation and Participating Institutions

The Lead Research Organisation will ensure that all Participating Institutions and all Researchers are aware of their responsibilities under this Agreement.

The Lead Research Organisation and Participating Institutions:

a. will ensure compliance with all Conditions of Data Disclosure required by Data Custodians for any and all data set/s utilised by their Researcher/s under this Agreement. In some circumstances, the use of certain data sets or data variables will require the execution of a schedule to this Agreement prior to the data being released. Researchers will be advised of this and the schedule included with this Agreement.

b. will ensure that if Cause of Death Unit Record File Data is sought to be used, Schedule 2 of this Agreement is executed and all conditions therein complied with;

c. will ensure that all their Researchers conduct the Project in accordance with the conditions of ethical approval and Standards for the conduct of research;

d. will ensure that the use of Aboriginal and Torres Strait Islander status is subject to the approval of the Aboriginal Health and Medical Research Council (AH&MRC) and AH&MRC Ethics Committee if one or more of the following apply:

- Aboriginality is a key determinant
- data collection is explicitly directed at Aboriginal peoples
- Aboriginal peoples, as a group, are to be examined in the results
- the information may have an impact on one or more Aboriginal communities
- Aboriginal health funds are a source of funding;

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e. will ensure all their Researchers use the Data only for the purposes of the approved Project;

f. will ensure that at the completion of the Project, all data and associated files are stored and/or destroyed in accordance with the Institute and/or NSW Ministry of Health

requirements, and Data Custodian/s Conditions of Data Disclosure;

g. will ensure all their Researchers will not attempt to access any variables that have not been approved by relevant ethics committee, Data Custodians and the Institute;

h. will ensure all their Researchers adhere to the requirements detailed in the Author Guidelines for Researchers issued by the Institute in the preparation for publication and presentation of all papers, reports, presentation and abstracts arising from the Project. This includes submitting all such publications and reports for Technical Review to the Institute at least 30 Business Days prior to submission or release, and submitting all approved final draft publications and papers to the Sax Institute at least 21 days prior to publication or release.

i. will ensure all their Researchers use the required form of words and/or disclaimers when describing the data sets and data variables used in the Project and the limitations on collection, interpretation and related matters. Researchers will be advised of the required form of words on submission of material for Technical Review.

j. will ensure their Researchers appropriately acknowledge the Institute, Data Custodians, the NSW Ministry of Health as appropriate and using the required form of words in all publications, presentations and reports arising from the Project. Researchers will be advised of the required form of words on submission of material for Technical Review.

k. acknowledge that these conditions continue to apply after projects end and/or approvals expire and the Lead Research Organisation, Participating Institution and Researcher will comply with any audit processes required to check the compliance of these and any additional conditions of approval. Such audits may be conducted by the Institute or by the NSW Ministry of Health in accordance with the Conditions of Data Disclosure; and,

l. must not assign or otherwise deal with rights under this Agreement without the Institute's prior written consent.

The Lead Research Organisation:

(i) will ensure that the expected research outputs detailed in item 7 of the Schedule 1 are delivered, or will notify the Institute within five Business Days of the Lead Research Organisation becoming aware that the delivery of research outputs may be delayed or not possible;

(ii) will notify the Institute as soon as possible (within one Business day) if it becomes aware of any breach or potential breach of the conditions of this Agreement;

5. Use of SURE

5.1 Virtual Machines

a. The Lead Researcher may request the Institute to modify, add or delete the Virtual Machines and issue Credentials relating to those Virtual Machines. The Lead Researcher must complete the form specified by the Institute and comply with any procedures listed in the form for modifications, additions or deletions relating to the Virtual Machines and pay any applicable Fees in relation to them.

b. Any request for changes to the Virtual Machines is subject to payment of Fees which are charged in accordance with the Schedule 1 Fees and Charges unless otherwise agreed in writing by the Parties. The Institute can only act on such requests where the specified form(s) and procedures are complied with and all relevant Fees are paid by the Lead Research Organisation.

c. Subject to this clause c, the Lead Researcher may provide Credentials issued to them by the Institute for the establishment of a Virtual Machine to a User. Credentials will only be provided to Users if:

1) they are a Researcher for the relevant project identified on Page 1 of this Agreement and in Item 8 of the Schedule 1 or amendment form for the Virtual Machine or in a change request for the Virtual Machine accepted by the Institute;

2) all relevant ethical and other approvals required in relation to the Project have been obtained and are current in relation to the Researcher;

3) they have signed a Researcher Deed Poll with the Institute relating to access to the Virtual Machine, that Researcher Deed Poll is current, and that Researcher is not in breach of that Researcher Deed Poll; and

4) that Researcher has successfully completed all training requirements specified by the Institute as necessary for access, including any refresher or update courses specified by the Institute.

5) User Guides for using SURE will be provided to all Users

5.2 Maintenance and Support

a. The Lead Research Organisation and Participating Institution acknowledge and accept that the Institute may restrict or prevent access to a Virtual Machine for operational purposes from time to time by providing no less than 24 hours' notice (except in case of emergencies, in which case no notice is required). Such purposes include system upgrades, scheduled maintenance, including maintenance of the underlying infrastructure, and responding to security and other compliance issues.

b. The Institute provides support between 9am – 5pm (Eastern Time), Monday to Friday, excluding public holidays, in NSW. This support involves the Institute making reasonable efforts to resolve issues subject to the availability of the Institute's help desk staff. The Institute has no liability for any failure to provide support or for a failure of that support to reach any particular standard.

5.3 Data Providers

a. Data Custodians may, as a condition of providing access to their data or a part of it through the SURE service, request or require the Lead Research Organisation and/or Participating Institution and/or the Institute to execute a deed, consent or agreement which gives that data provider or a nominated third party rights in relation to the SURE service and the Virtual Machine (Data Provider Rights).

b. The Lead Research Organisation and Participating Institution acknowledge and agree that:

1) the NSW Ministry of Health and/or the NSW Cancer Registry and/or any Data Custodian may revoke access to datasets for linked data or for individual Projects;

2) the NSW Ministry of Health or its appointed representative/s may access all data, records and associated documents for audit purposes;

3) if the Lead Research Organisation has indicated on the Application Form for the Workspace or otherwise notified the Institute that data from a specific Data Custodians Provider may be stored in the Virtual Machine, or has used data from a specific data provider, the Institute may:

A. suspend access to the Virtual Machine at any time if it receives a written

notice requesting such suspension from the relevant Data Custodians Provider and, if it receives such a suspension request, the Institute may disclose to the Data Custodians Provider:

i. the name and contact details of the Lead Researcher for the Virtual Machine;
ii. the name of each file in the Virtual Machine.

B. suspend a person's access to the Virtual Machine as requested by that Data Custodians Provider;

4) without limitation, Data Provider Rights may include rights for the Data Custodians Provider to access, delete or modify files within the Virtual Machine or to require suspension or limitation of access to the Virtual Machine;

5) the Institute is released from its obligations to the Research Organisation in relation to the Virtual Machine and SURE service to the extent necessary to give full effect to the Data Provider rights;

6) the Institute will not be liable to the Research Organisation for any loss, cost, damage or expense of any kind suffered due to any actions taken by the Institute in accordance with this clause.

5.4 Third Party Software

a. In order to access the SURE service, any computing hardware used to access SURE must meet the system requirements published or advised from time to time by the Institute. These requirements may include the installation of third party software or specific configuration requirements for software. It is the Research Organisations' responsibility to ensure that these third party dependencies are properly met, installed, configured and licensed, as appropriate. The Institute has no liability to the Research Organisation or any other person for any inability to access or use any part of the SURE service as a result of these requirements not being met.

b. Except where expressly stated to the contrary:

1) the Software is subject to licence terms provided by third parties;

2) all use of such Software is subject to those licence terms;

3) the Institute does not guarantee that all Software will remain available for the entire Term or that the pricing in relation to the Software will be set for any period of time;

4) the availability and pricing of each of the applications comprising the Software is dependent on their continued availability and support from the third party suppliers of that software and on the pricing imposed by such suppliers;

5) in the case that the Lead Research Organisation requests Software installed for which it has a licence and can show evidence of licence, the Institute bears no liability or responsibility in relation to the installation or usage of such Software, nor that the Software will work in the SURE environment and the Research Organisation agrees to indemnify and keep indemnified the Institute against any loss, cost, expense, claim or liability of any kind resulting from or associated with the installation, attempted installation or usage of such Software;

6) the Institute may choose to charge separately for any Software; and

7) subject to the Lead Research Organisation's prior written approval, the Institute will provide system support or maintenance associated with Software use or installation at the Institute's then current time and materials rates

5.5 End Use of Virtual Machine

a. The Virtual Machine may be terminated or suspended when:

i. the licence to the Virtual Machine expires;

ii. the relevant Fees for the current use or an approved extension to the use of the Virtual Machine are not paid in accordance with Clause 8; or

iii. the Lead Research Organisation provides notice in writing of not less than fourteen (14) days, advising that they wish to cease access to the Study and request the Institute to close its Virtual Machine.

iv. The Institute will close the Virtual Machine in compliance with the Lead Research Organisation's request and any applicable policies of the Institute.

b. After the closure or expiration of a Virtual Machine the Institute will prepare an archive of the Data (but not any Software). The archive will be in a format determined by the Institute in its discretion. The Institute will retain each such archive for seven (7) years following the closure of the CUPL data. The Institute may engage third party service providers to have custody of such archives.

c. The Institute may provide access to Data archived under clause 5.5b on a basis to be agreed. The Institute may charge the Lead Research Organisation Fees for such access.

d. The Institute will provide one (1) month's written notice prior to the destruction or deletion of any archive.

e. The Lead Research Organisation:

1) is solely responsible for and must ensure that the Institute has all rights necessary to enable the Institute to archive the Data and comply with clause 5.5b, including any intellectual property rights or licences required to permit the Institute to copy the material included in the archive;

2) agrees to carry out all necessary actions to ensure that the Institute has a licence to use and keep a copy of the Data for the Institute's use; and

3) must indemnify the Institute against any and all loss resulting from any breach of this clause and any and all loss resulting from any third party claim that the performance by the Institute of an obligation under this Agreement resulted in an infringement of any third party right. This clause survives the expiry or termination of this Agreement.

6. Intellectual Property Rights

a. All Intellectual Property Rights in, and ownership of, the Study Data remain at all times and without exception vested in the Institute.

b. Except as expressly granted under this Agreement, the Research Organisation and Researchers have no right, title or interest, including Intellectual Property Rights, in or to the Data or other materials provided by the Institute. Except where expressly set out to the contrary, nothing in this Agreement grants the Research Organisation any rights over any intellectual property rights (including copyright, patents, and rights to the registration of such rights) held by the Institute at any time during the term of this Agreement. Where Intellectual Property Rights arise as a result of the performance of this Agreement by or on behalf of the Institute, those rights vest on creation in the Institute.

c. The Institute retains all Intellectual Property Rights not expressly granted to the Research Organisations and Researchers under this Agreement.

d. Subject to clauses 6a, 6b and 6c, the Research Organisation retains Intellectual Property Rights in all materials developed by the Research Organisation in a SURE Virtual Machine or with respect to the Project.

e. The Research Organisation may not make any commercial use of the Data unless a separate agreement has been reached between the Parties in relation to such commercial use, including the sharing of the financial or other benefits from such commercial use.

7. Insurance

7.1 Insurances to be Maintained by the Research Organisation

The Research Organisation must:

a. maintain at all times with respect to the Term a professional indemnity insurance policy with a limit of not less than $20 million for any claim with an insurance company approved to operate in Australia; and

b. maintain at all times with respect to the Term all necessary workers compensation insurance and public and general liability insurance; and

c. provide certificates of currency to the Institute upon execution of this Agreement.

8. Fees

8.1 Payment Terms

a. The Fees for the Project identified in item 5 of the Schedule 1 are payable unless waived by the Institute.

b. In the event of any changes relating to Virtual Machine after establishment, the Lead Research Organisation is responsible for the payment of any Fees associated with the changes. The Lead Research Organisation must pay each of the Institute's invoices in full in accordance with the Payment Terms and, where no time is set out in the Payment Terms, within 30 days of the date of the invoice.

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c. The Institute's Fees for use of the Data and the Virtual Machines are as published or advised from time to time by the Institute (including on the Institute's website, through any fee estimate provided by the Institute or in any fee schedule or similar published by the Institute). Unless stated otherwise, all Fees are payable in advance.

d. The Institute may charge additional fees associated with any Virtual Machine upgrades requested by the Lead Research Organisation.

e. Where the Institute incurs expenses or disbursements in the course of carrying out its obligations under this Agreement, the Institute may pass those expenses or disbursements on to the Lead Research Organisation. Prior to incurring such disbursements or expenses, the Institute will seek the Lead Research Organisation's express written consent.

f. Except where the Parties agree in writing to the contrary, or where the context requires otherwise:

1) all amounts quoted by the Institute are exclusive of GST and all other taxes and duties;

2) where applicable, the Institute will charge GST at the prevailing GST rate;

3) where no price or other method of calculation of Fees has been agreed in writing, the Institute may invoice the Lead Research Organisation for work performed at the Institute's then current time and materials rates; and

4) to the extent permitted by law, and except in the event of a total failure by the Institute to provide the relevant goods or services in breach of this Agreement, all payments made under this Agreement are non-refundable.

g. Where the Lead Research Organisation disputes any invoice, the Lead Research Organisation must pay the full amount of the invoice and, if the dispute is resolved in the Lead Research Organisation's favour, the Institute will credit the relevant amount to the Lead Research Organisation.

9. Audit Rights

a. The Lead Research Organisation must provide to the Institute such information relating to the Project as the Institute may reasonably request for the purpose of auditing and evaluating the Project including but not limited to the outcome or impact of the Project.

b. The Lead Research Organisation and Participating Institution(s) must:

1) upon reasonable notice of not less than fourteen (14) days given by the Institute; and,

2) at times agreed to by the Parties during the performance of, or up to five (5) years after the completion of, the Project;

make itself available for visits by officers of the Institute, or any other person nominated by the Institute, including the NSW Ministry of Health, for the purpose of auditing and evaluating the Project.

c. The Lead Research Organisation agrees that in accordance with clause 9 b, it will permit all Data Custodians, or their representative, access to relevant Project materials for the

purpose of audit upon request by the NSW Ministry of Health. Any such access will occur during business hours at a mutually agreed time, and subject to reasonable conditions relating to occupational health and safety, security and confidentiality.

d. The Lead Research Organisation agrees to pay the Institute's reasonable costs of audit and evaluation if such audit or evaluation shows the Research Organisation or the Researchers were not in compliance with a material term of this Agreement.

10. Suspension of Performance

a. Where an obligation of the Institute under this Agreement is dependent upon the Research Organisation providing information or assistance or performing an obligation under this Agreement, that obligation of the Institute is automatically suspended until the Research Organisation have provided that information or assistance or performed that obligation. Any other obligations of the Institute under this Agreement are extended by a reasonable period as a result of the Research Organisations' delay.

b. The Institute may suspend the performance of any or all of its obligations under this Agreement to the extent it is unable to comply with them as a result of a cause beyond the reasonable control of the Institute. The Institute will promptly notify the Lead Research Organisation upon such an event occurring. The Research Organisation acknowledges that causes beyond the reasonable control of the Institute includes actions taken by telecommunication companies and other utilities, hosting providers and other subcontractors to the Institute.

11. Warranty & Indemnity

11.1 Warranty

a. The Institute makes no warranty pertaining to the granting of approval or the timing of the provision of Linked Data by Data Custodians or Data Linkage Units to access Linked Data;

b. The Research Organisation represents and warrants to the Institute that they have obtained all necessary rights and licences as set out in 5.5e.1 above for all material, Data or information stored in the Virtual Machine; and

c. The Research Organisation warrants that the Researchers associated with the Project are appropriately and suitably qualified to participate in the Project.

d. The Research Organisation acknowledges and agrees that:

   a. the Institute has played no part in the Research Organisations' choice of, or decision to implement, any Software under this Agreement;

   b. it represents and warrants that it has evaluated the appropriateness of all Software to be installed by the Institute under this Agreement. Such Software is licensed by the relevant third party to the Research Organisation or individual researchers by virtue of a separate licence agreement; and

   c. the Institute has no liability to the Research Organisation for any failure of any part of the Software made available in a Virtual Machine under this Agreement or under the broader relationship between the Institute and the Lead Research Organisation including with respect to:

      i. failures of the Software to perform in the manner expected, anticipated or understood by the Research Organisation;

ii. failures by the Software to interoperate with any other Software or device; and,

iii. failures of the Software to comply with any documentation relating to the Software (including documentation produced or provided by the Institute.

11.2 Indemnity

The Research Organisation must indemnify and keep indemnified the Institute at all times against any loss, damage, claims, actions, liability, penalty or payment (including legal costs and expenses) which the Institute suffers, incurs or is liable for in connection with:

(i) a material breach by the Research Organisation of their obligations under this Agreement, or any negligent act or wilful omission of the Research Organisation or its employees or agents in the performance or non-performance of any of the Research Organisations' obligations under this Agreement;

(ii) any negligent act or wilful omission on the part of the Research Organisation, its employees or agents or the Researcher/s in the course of, or in connection with, this Agreement or in application of any procedure or protocol for the purposes of this Agreement (including with respect to the Project); and

(iii) any data security or privacy breach and any breach of clause 2.2 of this Agreement (with respect to Participants or otherwise);

except to the extent caused by the negligence or wilful misconduct of the Institute or its agents, officers and employees.

12. Liability

a. To the extent permitted by law, the Institute excludes all warranties, guarantees and conditions that would otherwise be implied into this Agreement by law. Where the Institute is not able to exclude such a warranty, guarantee or condition, the Institute limits, to the extent permitted by law, its liability for a breach of that warranty, guarantee or condition to one or more of the following at its option:

   1) in the case of goods, any one or more of the following:
      A. the replacement of the goods or the supply of equivalent goods;
      B. the repair of the goods; and

   2) in the case of services, to the Institute supplying the services again.

b. The Institute has no liability to any person arising under or in relation to this Agreement (whether in tort, contract, equity or otherwise) for any loss in the nature of consequential or economic loss. In particular, the Institute has no liability to any person for any: lost profits; loss of savings, income or revenue; revenue not meeting targets or certain levels; uptime or availability of internet connectivity or of the ability of third parties to access a website; loss of opportunity; or the use of SURE. The exclusions in this clause apply even in respect of loss or damage that was foreseeable or about which either or both of the Parties were aware was likely to arise.

c. The total aggregate liability of the Institute for all loss or damage in respect of all claims arising out of or in relation to this Agreement or out of or in relation to the relationships contemplated by this Agreement whether arising in tort (including negligence), contract, equity or otherwise is limited to the total of all Fees received by the Institute in the twelve

(12) months immediately preceding notice of the of the alleged loss, damage, claim or dispute.

d. Nothing in this Agreement is intended to exclude, restrict or modify rights which either Party may have under the *Competition and Consumer Act 2010 (Cth)* or any other legislation which may not be excluded, restricted or modified by Agreement.

13. Term and Termination

a. This Agreement commences on the Execution Date and expires on the Termination Date (the "**Term**"), unless terminated earlier or extended in accordance with this Agreement.

The Access Period begins on the Effective Date of the service and continues for the specified term.

b. The Lead Research Organisation may request, in writing, that the Access Period be extended for a specified period. The approval for the extension of the Access Period is subject to the discretion of the Institute and will become effective upon execution of a written variation by the Parties. Extensions to the Access Period are subject to payment of annual Fees as specified by the Institute, unless waived by the Institute.

c. A Party may terminate this Agreement immediately by written notice where:

1) the other Party commits a material breach of a term of this Agreement and that breach is not remedied within fourteen (14) days of written notice of that breach from the first Party; or

2) the other Party becomes insolvent or unable to pay its debts when they fall due; or

3) the other Party fails to pay (in full and in cleared funds) money due under this Agreement by the time that payment is due.

d. On termination or expiry of this Agreement:

1) all rights granted to the Research Organisation and Researchers terminate immediately;

2) the Lead Research Organisation is not entitled to any refund of any amounts paid;

3) the Lead Research Organisation must pay to the Institute within five (5) Business Days any amount due and payable and outstanding at the date of termination or expiry; and

4) the Research Organisation and Researchers must immediately cease using the Data and, within five (5) Business Days return, erase or destroy any Confidential Information and all documents and other property belonging to the Institute as instructed by the Institute.

e. Clauses 2, 3, 4, 5.3, 5.4, 5.5, 6, 7, 9 and 11 through 16, and all Schedule 2 clauses (if applicable) survive expiration or earlier termination of this Agreement. Termination or expiry of this Agreement is without prejudice to the rights and remedies of the Parties arising before the date of termination or expiry.

14. Dispute resolution

a. Disputes between the Parties will be resolved, as far as possible, between the Lead Researcher of the Lead Research Organisation and nominated representative of the Institute. Where the dispute is unable to be resolved within seven (7) days, a senior representative of the Institute will meet with a senior representative of the Lead Research Organisation to attempt to resolve the dispute in good faith.

b. If any dispute is not resolved by consultation under sub clause (a) above within fourteen (14) days, the Institute and the Lead Research Organisation expressly agree to endeavour in good faith to settle the dispute by arbitration administered by the Australian Disputes Centre (ADC) with costs shared equally by both Parties to this Agreement and the decision reached shall be binding upon the Parties and regarded as final. This clause shall not apply where a Party seeks urgent interlocutory or equitable relief.

15. Notices

a. A notice or other communication under this Agreement must be in writing and delivered by hand or sent by pre-paid post or email to a Party at the address or email address specified by that Party.

b. A notice sent by post is regarded as given and received on the fifth (5th) Business Day following the date of posting.

c. An email is regarded as given and received within 30 minutes after the time of sending by the sender unless the sender receives an automated message that the email has not been delivered.

d. A notice delivered or received after 4.00pm (recipient's time) or on a day other than a Business Day is regarded as received at 9.00am on the following Business Day and a notice delivered or received before 9.00am (recipient's time) is regarded as received at 9.00am.

16. General Clauses

a. This Agreement may be executed in any number of counterparts.

b. This Agreement is governed by the law in force in New South Wales. Each Party irrevocably submits to the non-exclusive jurisdiction of courts exercising jurisdiction in New South Wales.

c. Nothing in this Agreement imposes any fiduciary duties on a Party in relation to any other Party.

d. Except as set out in this Agreement to the contrary, nothing in this Agreement gives either Party the ability to act or incur liability on behalf of the other Party or creates a relationship of joint venturers, principal and agent or employee and employer between the Parties.

e. If any provision of this Agreement is invalid under the law of any jurisdiction the provision is enforceable in that jurisdiction to the extent that it is not invalid, whether it is in severable terms or not.

f. No Party to this Agreement may rely on the words or conduct of any other Party as a waiver of any right unless the waiver is in writing and signed by the Party granting the waiver.

g. A variation of any term of this Agreement must be in writing and signed by the Parties.

h. Words used in this clause which have a defined meaning under *A New Tax System (Goods and Services Tax) Act 1999 (Cth)* have the same meaning as in that Act unless the Agreement otherwise specifies. Fees and other payments referred to in this Agreement exclude GST unless otherwise specified.

i. The Research Organisation/s must not assign or otherwise deal with its rights under this Agreement without the Institute's prior written consent.

j. Each Party must, at its own expense, do all things and execute all documents necessary to give full effect to this Agreement and the transactions contemplated by it.

k. This Agreement states all the express terms of the Agreement between the Parties in respect of its subject matter. It supersedes all prior discussions, negotiations, understandings and agreements in respect of its subject matter.

l. The Research Organisation must provide all assistance as is reasonably necessary for the Institute to carry out its obligations under this Agreement. This may include, but is not limited to, provision of any necessary information or support by the Research Organisation as required by the Institute to enable it to deliver the services under this Agreement.

Executed by an authorised signatory of The Sax Institute ABN 68 095 542 886

Signature	
Name	
Position	
Date	

Executed by an authorised signatory of MQ Health Pty Limited ABN 46 141 203 125

Signature	
Name	
Position	
Date	

(print name and position) who warrants they have the authority to bind the Research Organisation.

Schedule 1

Item 1.	**Execution Date:**	Date the last Party signed this Agreement
	Termination Date:	12 months from the Effective Date
	Access Period:	12 months
	Archive Period:	7 years
Item 2.	**PHSREC Approval Date:**	8 August 2022
Item 3.	**Project Title:**	Gender based differences in Atrial Fibrillation risk and management: an Australian prospective cohort study.
	Folder Name:	CVDGENDER
Item 4	**Lead Researcher:**	A/Prof Chrishan Nalliah Clinical Cardiologist and Electrophysiologist Con-joint Professor
Item 5.	**Fees**	The fees for licensing of the datasets and the SURE workspace have been waived for the Access Period stated in item 1 of Schedule 1.
Item 6.	**Contacts for Parties**	

The Sax Institute

Name	Dr Martin McNamara
Position	Head, Research Assets
Address	Level 3, 30C Wentworth Street, Glebe, NSW, 2037
Phone	+61 2 9188 9502
Email	martin.mcnamara@saxinstitute.org.au
Enquiries	45andUp.research@saxinstitute.org.au

Lead Research Organisation

Name	A/Prof Chrishan Nalliah
Position	Clinical Cardiologist and Electrophysiologist Con-joint Professor
Address	3 Technology Place Macquarie University NSW 2109
Phone	0415316498
Email	chrishan.nalliah@mqhealth.org.au

Lead Researcher

Name	A/Prof Chrishan Nalliah
Position	Clinical Cardiologist and Electrophysiologist Con-joint Professor
Address	3 Technology Place Macquarie University NSW 2109
Phone	0415316498
Email	chrishan.nalliah@mqhealth.org.au

Item 7. **Expected Research Outputs**

During the period of the Agreement, using the templates provided by the Institute, submit the following to the Institute:

- A six (6) monthly report within 30 days of the agreed date; and
- A final report within 30 days from the end of this Agreement.

Where the duration of the Project is 12 months, the Research Organisation need only submit a Progress Report and a Final Report.

Have produced at least one research output within the first 12 months of the Project.

Item 8. Services

A Datasets licensed or provisioned for named users

Researcher name	Data provisioned	Licence commencement date	Licence end date	Value*
Chrishan Nalliah	• *CUPL Data (approved variables)*	TBA	12 months from TBA	Waived
Karice Hyun	• *CUPL Data (approved variables)*	TBA	12 months from TBA	Waived

B SURE workspace

Item	Qty	SURE access commencement date	SURE access end date	Value*
Annual storage and operation	1	TBA	12 months from TBA	Waived
1 x Power Virtual Machine (per annum) (with Licensed Software) • Chrishan Nalliah	1	TBA	12 months from TBA	Waived
1 x VM Sharing Fee (per user, per annum) • Karice Hyun	1	TBA	12 months from TBA	Waived
Study Archiving Fee for up to 10 Years	1	N/A	N/A	Waived

* The value of these services have been waived for the 12 months referred to above.

Schedule 2

CONDITIONS FOR USE OF CAUSE OF DEATH UNIT RECORD FILE (COD-URF)

The Research Organisations named in the CUPL Institutional Agreement acknowledge and accept the conditions listed below for the use of Cause of Death Unit Record File.

1. All terms in this Schedule have the same meaning as in the Agreement to which this Schedule is attached;

2. The data are to be used only for the project entitled 'Gender based differences in Atrial Fibrillation risk and management: an Australian prospective cohort study by the Researcher/s named in the Institutional Agreement to which this Schedule is appended;

3. The Project is carried out in accordance with the approved ethics application and all subsequent amendments. A copy of the ethics approval and any subsequent amendments must be supplied to the Sax Institute for forwarding to the Australian Coordinating Registry (ACR) prior to the execution of this Schedule;

4. The Project is conducted and the data used in compliance with the Conditions for Data Disclosure. This includes conditions detailed in the Agreement to which this Schedule is attached relating to data access, use, disclosure, auditing and reporting;

5. The Researcher will provide a quarterly report on the status of the Project to the Institute for the duration of the Project. The status report must include the name of the project, the name, title, role and contact details of all Researcher/s and the affiliated or employing Research Institution, and information as to the Project progress, and copies of any approved changes to the protocol and ethics approval. A proforma template will be supplied for completion by the Researcher;

6. The source of the data is to be stated as detailed in the Sax Institute' Author Guidelines and in Clause 10 (below);

7. The data will not be matched with information on individuals from another source [other than the datasets specified in the Schedule/s;

8. The data are to be destroyed after seven years and its disposal notified to the ACR in accordance with clause 11 (below);

9. Where data are being provided in the future as they become available, the authority for data disclosure provided under this Agreement continues until and unless it has been revoked in writing;

10. Any publication, report, presentation or data output will include:

    (i) the following source: "Source: Cause of Death Unit Record File held by the NSW Ministry of Health Secure Analytics for Population Health Research and Intelligence"; and

    (ii) the following acknowledgement: "The Cause of Death Unit Record File (COD URF) is provided by the Australian Coordinating Registry for the COD URF on behalf of the NSW Registry of Births, Deaths and Marriages, NSW Coroner and the National Coronial Information System."

    (iii) any statistical tables, or figures derived from statistical tables, using records from the COD URF must **not** show cell counts less than five.

11. Data will be securely destroyed and the ACR notified within the timeframe specified in the ethics application or earlier as to the destruction (unless approval for extension or indefinite retention has been provided by the ACR/Data Custodians). Notification should be to the ACR, emailed to BDM.CODURF@justice.qld.gov.au, and to the NSW Ministry of Health, emailed to moh-cee@health.nsw.gov.au;

12. These conditions continue to apply after projects end and/or approvals expire and Researchers will comply with any audit processes required to check the compliance of these and any additional conditions of approval; and,

13. A breach of any of these conditions may result in further data access being restricted or current access being revoked.

Executed on behalf of MQ Health Pty Limited T/A Macquarie University Hospital ABN 46 141 203 125 by its authorised representative:

Signature:

Name:

Position:

Date:
