

**Registry Agreement**

**St John of God Health Care Inc.**

**[*insert*]**



St John of God Health Care Incorporated

Level 1, 556 Willington Street, Perth WA 6000

Telephone +61 8 6116 000 Facsimile +61 8 6116 0800

www.sjog.org.au

Ref: XXX

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This **Agreement** is made on between the following parties:

**1 St John of God Health Care Inc**ARBN 051 960 911
an incorporated association with limited liability, incorporated in Western Australia under the Associations Incorporation Act 1987 (WA) of Level 1, 556 Wellington Street, Perth WA 6000

(**SJGHC**)

**2 [*Insert*]**

ABN [***insert***]
of [***insert***]

(**Coordinator**)

**3 Note: Delete this item if PI is employed by SJGHC or under a contract of services which encompasses the PI
[*Insert*]**

ABN [***insert***]
of [***insert***]

(**Principal Investigator**)

**Recitals**

1. The Coordinator is responsible for creating the Registry to [***insert***] as more clearly described at Annexure A. The nature of the Registry is to [***insert***].
2. SJGHC operates the St John of God [***insert***] Hospital. The Principal Investigator is [employed at/ accredited at/ contracted to provide services to] the Hospital by SJGHC.
3. This Agreement sets out a framework of cooperation between the Coordinator and SJGHC [and the Principal Investigator – NB: delete if PI is not a party] to facilitate data collection, data management and reporting.

**The parties agree** in consideration of among other things, the mutual promises contained in this Agreement:

# Definitions and interpretation

## Definitions

In this agreement:

### **Agreement** means this agreement including its Schedules and Annexures (if any) and any purchase orders issued pursuant to it;

### **Item** means an item in the Schedule to this Agreement;

### **Parties** means the Coordinator and SJGHC and Party means either one of them;

### **Personnel** means officers, employees, contractors, agents and/or authorised representatives;

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

### **Protocol** means the protocol for the study andis attached atAnnexure A but includes amendments as made from time to time with the written agreement of the parties;

### **Principal Investigator** is the person responsible for the conduct of the Study at the Study Site as described in the Schedule;

### **Registry** means the Coordinator’s clinical database containing health-related personal data of Study Subjects;

### **Regulatory Authority** means any government body which has jurisdiction over the conduct of the Study at the Study Site and includes any overseas regulatory authorities who may require to audit any part of the Study or Study Materials;

### **Relevant Privacy Laws** means the *Privacy Act 1988 (Cth), the My Health Record Act 2012 (Cth), Healthcare Identifiers Act 2010 (Cth) and* any other legislation, principles, industry codes and policies, or guideline which applies in Western Australia and which relates to the collection, use, disclosure, storage or granting of access rights to Personal Information;

### **Responsible HREC** means the Human Research Ethics Committee reviewing the Study on behalf of SJGHC and identified at the Schedule;

### **Study** means the Registry to be conducted in accordance with the Protocol;

### **Study Materials** means all the information created for the Study or required to be submitted to the Coordinator including all data, results, Case Studies in whatever form held, conclusions, discoveries, inventions, know-how and the like, whether patentable or not relating to the Study which are discovered or developed as a result of the Study;

### **Case Study** means a printed, optical or electronic document or database designed to record all of the information, required by the Protocol, to be reported to the Coordinator on each Study Subject;

### **Study Site** means the location(s) under the control of SJGHC identified at the Schedule where the Study is actually conducted;

### **Study Subject** means a person recruited to participate on the Registry and the Study;

### **Term** is described at the Schedule.

## Interpretation

In this agreement, unless the context requires otherwise:

### words importing the singular include the plural and vice versa, words of one gender include any gender, and words importing persons include corporations and any other entity recognised by law;

### a reference to this agreement includes the schedules and any annexures to this agreement;

### a reference to a clause, part, Schedule or Annexure is a reference to a clause in or a part, schedule or annexure to this agreement;

### a covenant, agreement representation or warranty on the part of 2 or more persons binds them jointly and severally;

### a reference to a statute or ordinance includes all regulations, by-laws, requisitions or orders under and amendments to that statute or ordinance, whether by subsequent statute or otherwise, and a statute or ordinance passed in substitution for the statute or ordinance referred to or incorporating any of its provisions;

### the words “including”, “for example” or “such as” are not used as, nor are they to be interpreted as, words of limitation and, when introducing an example, do not limit the meaning of the words to which the example relates; and

### Australian dollars, dollars, $, A$ or AUD is a reference to the lawful currency of Australia.

# SJGHC and Principal Investigator Responsibilities

### The Principal Investigator will provide patient data to SJGHC and the Coordinator in a timely and accurate fashion in accordance with the Protocol and related procedures, of which SJGHC and the Principal Investigator will be provided prior to commencement of data collection.

### SJGHC will conduct the Study in accordance with the following requirements, in order of precedence:

#### any requirements of relevant Commonwealth or State or Territory laws or of Regulatory Authorities ;

#### any condition of the Responsible HREC; and

####  the Protocol.

### The Study is purely observational wherein the Coordinator will be provided with data from the Registry. SJGHC will provide Study Subjects and patients not participating in the Study with the same standard of care. The Study Protocol does not require a direct involvement with the Study Subjects by way of additional treatments, investigations or experiments. Participation in the Study creates no additional risk for the Study Subject.

### [***Where the Principal Investigator is employed by SJGHC or is under a contract for services***] SJGHC has authorised the Principal Investigator as the person responsible on a day-to-day basis for the conduct of the Study and, as an [***employee/ contractor***] of SJGHC, SJGHC accepts that the Coordinator may pursue SJGHC for any loss, damage or otherwise resulting from the actions of the Principal Investigator.

### [***Where the Principal Investigator is an accredited VMO***] The Principal Investigator is responsible on a day-to-day conduct of the Study and is solely responsible for the provision of clinical care. The Principal Investigator is not employed by SJGHC and no liability for the actions of the Principal Investigator will attach to SJGHC.

### The Principal Investigator does not have authority to act on behalf of SJGHC to amend this Agreement or the Protocol.

### If the Principal Investigator [***leaves SJGHC or otherwise ceases to be available/ is no longer accredited***] at the Study Site then:

#### SJGHC must consult with the Coordinator and use reasonable endeavours to nominate as soon as practicable a replacement reasonably acceptable to both parties; and

#### If the parties are unable to reach agreement then any party may terminate the Agreement by notice in writing to the other party/ parties.

# Coordinator Responsibilities

### The Coordinator will:

#### provide the Principal Investigator and SJGHC and the Responsible HREC with all current and relevant information as reasonably required to justify the nature, scope and direction of the Study;

#### provide the Principal Investigator with the relevant tools for data collection and storage;

#### liaise with the Principal Investigator and SJGHC Personnel and provide technical support and disseminate information, training and respond to queries as they arise;

#### ensure that the Registry database, including back-ups, is securely maintained;

#### maintain the confidentiality of all data provided by the Principal Investigator or SJGHC for use on the Registry including avoiding the release of information that may publicly identify an individual Study Participant;

#### provide SJGHC and the Principal Investigator with [insert type of reports and frequency of reports] relating to the Registry and the information collected from the Study Site and throughout Australia at other sites;

#### implement and maintain quality assurance and quality control systems with written standard operating procedures to ensure that the Study can be conducted and data generated, documented, recorded and reported in compliance with all the documents referred to in clause 2; and

#### designate appropriately qualified personnel to advise on Study-related questions or problems.

# Fees

## [*No fees are to be paid under this Agreement]/*

## *[The Coordinator will pay fees to [SJGHC/ SJGHC and the Principal Investigator] in accordance with the Schedule]/*

## *[SJGHC will pay fees to the Coordinator in accordance with the Schedule]*].

# Privacy

### The parties must ensure that any Personal Information arising from the Study regarding Study Subjects or Personnel, is collected, stored, used and disclosed in accordance with the following requirements, in order of precedence:

#### any requirements of relevant Commonwealth, State or Territory laws or of Regulatory Authorities;

#### any condition of the Responsible HREC; and

#### the Protocol.

### The Principal Investigator and the Coordinator must each not do anything with the Personal Information that will cause SJGHC to breach its obligations under the Relevant Privacy Laws.

### The Coordinator acknowledges that it may be given access to Personal Information in relation to patients. The Coordinator must at all times:

#### comply with all Privacy Laws by which it is bound;

#### keep all Personal Information confidential and use the Personal Information only for the purpose of fulfilling its obligations under this Agreement and the Protocol;

#### ensure that it does not disclose any Personal Information to a third party without the prior written consent of SJGHC, unless the third party is the individual to whom the Personal Information relates;

#### take all reasonable steps to ensure that the Personal Information is protected against misuse and loss, or unauthorised access, modification or disclosure, including:

##### (i) undertaking any staff training as may be required; and

#### (ii) obtaining written agreement from any third party to whom the Personal Information is disclosed, to comply with this clause and the Relevant Privacy Laws by which the Coordinator is bound;

#### provide all reasonable assistance immediately required to assist SJGHC in complying with its obligations under any Relevant Privacy Law; and

#### notify SJGHC immediately if it becomes aware that a disclosure of Personal Information:

#### (i) has been made in breach of this agreement or any legislation, principle, industry code or policy by which either party is bound relating to the collection, use, disclosure, storage or granting of access rights to the Personal Information; or

#### (ii) is or may be required by law.

# Indemnity

The Coordinator shall be liable for and shall indemnify SJGHC and its officers, servants, employees or agents [***including the Principal Investigator – remove if not employed***] against all claims, demands, losses, actions, damages, costs (including legal costs), liabilities and expenses arising at common law and under statute suffered or incurred by SJGHC resulting from or in connection with this Agreement or the Study **PROVIDED THAT** the Coordinator’s liability will be reduced proportionately to SJGHC’s own negligence or act of fraud or wilful misconduct.

# Term

## This Agreement commences from the dates specified in the Schedule and will run for the Term.

## Either party may terminate this Agreement with 30 days prior written notice or such shorter time period as is reasonably required in the circumstances.

# General

## Assignments and sub-contracting

### Neither party may assign or sub-contract its rights or obligations under this agreement without the prior written consent of the other party.

## Further action

Each party must do all things and execute all further documents reasonably required by the other party to give full effect to this agreement.

## Entire agreement

This agreement supersedes all previous agreements in respect of its subject matter and contains the entire agreement between the parties.

Schedule – Items

|  |  |
| --- | --- |
| **Item** |  |
| 1. **SJGHC**
 | Name: | St John of God Health Care IncARBN 051 960 911ABN: 21 930 207 958 |
|  | Contact:  | ***[insert]***Telephone: ***[insert]***Email: ***[ insert]*** Address: ***[insert]*** |
| 1. **Coordinator**
 | Name: | ***[insert]***ABN: ***[insert]*** |
|  | Contact:  | ***[insert]***Telephone: ***[insert]***Email: ***[ insert]*** Address: ***[insert]*** |
| 1. **Commencement Date**
 | ***[insert]*** |
| 1. **Term**
 | ***[insert]*** |
| 1. **Study Site**
 | ***[insert]*** |
| 1. **Principal Investigator**
 | ***[insert]***Telephone: ***[insert]***Email: ***[ insert]*** Address: ***[insert]*** |
| 1. **Responsible HREC**
 | ***[insert]*** |
| 1. **Study Protocol Identification**
 | Full Title:  | ***[insert]*** |
|  | Version Number: | ***[insert]*** |
|  | Date: | ***[insert]*** |
| 1. **Fees**
 | ***[insert]*** |

ANNEXURE – PROTOCOL DOCUMENTATION

**Executed as an agreement**

|  |  |  |  |
| --- | --- | --- | --- |
| **Executed** for and on behalf of **St John of God Health Care Inc** by its authorised officer in the presence of: |  |  |  |
| Signature of authorised officer |
| Signature of witness |  |  |  |
| Name of witness | Name of authorised officer |
| Address of witness |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Executed** by [***insert***] in the presence of: |  |  |  |
| Signature |
| Signature of witness |  |  |  |
| Name of witness |  |
| Address of witness |  |  |  |