Australasian Cardiac Outcomes Registry Ltd

Australasian Cardiac Outcomes Registry Limited
ACN 152 969 518

CLIENT .....

ACN .....

ACOR Limited
Suite 4, Level 12, 189 Kent St
SYDNEY NSW 2000

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KEY DETAILS

1	**Date**	See Execution on page 11

2 Parties entering into this agreement are:

ACOR	**Australasian Cardiac Outcomes Registry Limited**
Name	ACN 152 969 518
Address	Suite 4, Level 12, 189 Kent Street, Sydney NSW 2000
Client	
Name	.....
	ACN .....
Address	.....
	.....
	.....

BACKGROUND

A ACOR has been established by CSANZ to oversee development of National Cardiac Registries for Australia and New Zealand in order to improve standards of patient cardiac care.

B ACOR will collect and report on standardised information from all patients undergoing specific cardiac procedures and therapies within hospitals in Australia and New Zealand through the Registries it oversees.

C The aim of ACOR is to improve patient care and outcomes by supporting hospitals and medical practitioners in continuous quality improvement. ACOR will provide data that will support risk management processes.

D ACOR has engaged a Registry Operator to administer and maintain the Registries it establishes on its behalf.

1 Registries

1.1 ACOR obligations

(a) ACOR agrees to:

(i) provide to the Client access to the Registry for the submission of Data;

(ii) receive and review Data from the Client in respect of cardiac outcomes in Australia and New Zealand;

(iii) collate reports based on Data collected for the Registry and distribute reports to the Client from time to time;

(iv) provide information and annual reports of performance and outcomes and comparator data on a national and regional basis;

(v) provide risk-adjusted assessments of performance and outcomes;

(vi) provide information and help desk support to the Client's staff who access a Registry; and

(vii) review Data submitted by the Client to maintain data quality,

(b) ACOR may undertake these obligations either itself or through the Registry Operator as its agent.

2 Registry Design

2.1 Purpose of ACOR

(a) The purpose of the Registries is to collect a standard set of information from all patients undergoing specific cardiac procedures, devices and therapies within hospitals in Australia and New Zealand.

(b) ACOR will collect data from contributing sites including identifying information, clinical details and outcome measures as determined by ACOR.

(c) ACOR will provide reports to Clients at scheduled periods and upon specific request when approved by ACOR.

(d) ACOR will contribute to the continued professional development of clinicians performing cardiac procedures to support quality assurance.

2.2 Features of the ACOR Registries

The features of the ACOR Registries include:

(a) data collected from patients undergoing cardiac procedures, devices and therapies and the identification of the clinician, including primary and secondary clinician where appropriate, and the institution where the operation was performed;

(b) identification of patients, clinicians and institutions which will be deidentified in any publicly available reports;

(c) collection restricted to a minimum data set of essential epidemiologically sound data elements;

(d) co-morbidity data collected to allow risk adjustment;

(e) follow-up data sought routinely including in-hospital as required;

(f) Registry operation, management and reporting by an experienced research group;

(g) rigorous quality control procedures to ensure high levels of data accuracy; and

(h) governance and performance measures according to established terms of reference.

2.3 **Collection and reporting of data**

The receiving and reporting of data by ACOR will provide opportunities to:

(a) benchmark outcomes both retrospectively and prospectively to stimulate improvement of patient care by an educational feedback loop to clinicians and institutions of both positive and negative performance;

(b) identify areas of excellence and opportunities for improvement across systems of care to institutions to encourage and support enhancement of individual and institutional performance;

(c) provide an advisory role to institutional and regulatory bodies in the delivery of clinical governance;

(d) apply relevant emerging best practice principles and share knowledge for both established and new cardiac procedures, devices and therapies;

(e) facilitate development of standard operating procedures and guidelines where they do not exist or are deficient;

(f) account for individual, cohort and system related risk factors including recognition of risk in models of care;

(g) provide accurate and transparent assessment of the safety of cardiac procedures, devices and therapies;

(h) document trends in use of established and new cardiac procedures, devices and therapies; and

2.4 **Aims of ACOR Registry research**

The research aims of the ACOR Registries include:

(a) ongoing research into improvement of the reliability of information acquisition and outputs of cardiac procedures, devices and therapies;

(b) improvements in the science and research of clinical cardiac registries; and

(c) development of research methodologies to enquire and answer clinical management questions with publication where appropriate, including in peer reviewed literature.

3 ACOR

3.1 Role of ACOR

ACOR will, either itself or through its Registry Operator:

(a) provide materials and training programs to the Client to assist the Client in using and contributing to the ACOR Registries;

(b) generate certain reports which may include aggregated, de-identified, demographic information, general procedural information and patient outcomes;

(c) review data for accuracy and completeness;

(d) ensure that there are adequate security measures in place to protect the integrity and confidentiality of data that has been submitted.

4 Client

4.1 Role of the Client

(a) The Client will:

(i) Provide the ACOR patient information sheet to patients who may be included in the ACOR Registries;

(ii) manage the submission of Data to the Registry;

(iii) liaise with ACOR, or its agent, to resolve any data queries which may arise;

(iv) co-operate and assist ACOR in respect to audits carried out by or on behalf of ACOR of data submitted by the Client.

5 Fees – where relevant (see Schedule 1)

5.1 Payment

The Client will pay to ACOR the Registry Use Fees for the Services by no later than 30 days of the date of any invoice from ACOR.

If the client fails to pay the Registry Use Fee the relevant consequence (stipulated in Schedule 1) will be imposed.

6 Intellectual Property Rights

6.1 Data

(a) Subject to clause 6.2(a), the Client retains all Intellectual Property Rights in the Data submitted by the Client to the Registry.

(b) The Client grants to ACOR an irrevocable, non exclusive, worldwide, perpetual, royalty free licence to use, reproduce, publish, communicate and adapt the Data submitted to the Registry in accordance with this agreement for its purposes including to incorporate the Data in ACOR's reports and to aggregate that Data with other data.

(c) ACOR has the right to grant a sub-licence to its agents and others, at its discretion, to use, reproduce, publish, communicate and adapt the Data for the purpose of:

(i) maintaining and administering the Registry (including aggregating that Data with other data); and

(ii) subject to such requirements as may be imposed by ACOR on its agents and others, all related activities including research.

(d) ACOR will obtain the prior written consent of the Client prior to publishing, or distributing to third parties, any Data that identifies the Client or individual clinicians.

(e) ACOR will, where practicable and to the extent it considers reasonably appropriate, consult and work responsibly with the Client and individual clinicians in respect of the interpretation of Data that identifies the Client and individual clinicians.

6.2 **ACOR's Intellectual Property Rights**

(a) The Client acknowledges and agrees that ACOR retains all Intellectual Property Rights in all software, the Website, the Registry, databases, aggregated Data and all derivative works based on the Data including reports, calculations and models (collectively, the **ACOR Intellectual Property**).

(b) The Client must not reproduce, publish or distribute the ACOR Intellectual Property to any third party without the prior written consent of ACOR, subject to the Client's right to use such materials for its own internal purposes in accordance with the terms of this agreement.

(c) The Client may not use any of ACOR's registered or unregistered trademarks without the prior written consent of ACOR.

6.3 **Patients' rights in respect of Data**

(a) The parties acknowledge and agree that each patient has certain rights in respect of Data relating to him or her, both under Privacy Laws and otherwise.

(b) The parties acknowledge and agree that any patient may request:

(i) access to his or her Data;

(ii) that his or her Data be corrected; or

(iii) that his or her Data be removed from the Registry.

(c) The parties agree to use reasonable endeavours to comply with any written request by a patient in the exercise of rights available under the Privacy Laws in respect of the Data of any such patient.

6.4 Access to Data

(a) ACOR may from time to time publish or make available rules regarding access to or use of Data within the Registry. The Client must comply, and must ensure that its employees, agents and contractors comply, with all such rules.

(b) Without limiting clause 6.4(a):

(i) the Client may only access aggregated de-identified Data; and

(ii) individual clinicians may only access aggregated de-identified Data and Data relating to themselves.

7 Termination

7.1 Termination for convenience

Either party may terminate this agreement at any time for any reason by providing 30 days' notice in writing to the other party.

8 Confidentiality

8.1 Confidential Information

In this clause, **Confidential Information** means information:

(a) disclosed by or on behalf of one party (**Discloser**) to the other party (**Recipient**); or

(b) relating to one party (**Discloser**) of which the other party (**Recipient**) becomes aware,

during the Term or in prior discussions between the parties in anticipation of this agreement, including:

(c) information designated as confidential by the Discloser; and

(d) any other information which by its nature should reasonably be considered to be confidential information of the Discloser or of a person to whom the Discloser owes a duty of confidence.

Confidential Information may be provided in writing, electronically, verbally or otherwise. Confidential Information does not include any information which the Recipient can prove either is in the public domain or was known by the Recipient at the time of disclosure, other than through a breach of this agreement.

8.2 **Confidentiality**

ACOR and the Registry Operator must:

(a) not use or permit the use of any Confidential Information for any purpose other than Registry operations; and

(b) establish and maintain comprehensive security measures to ensure that all Confidential Information in its possession, custody or control is secure at all times. Without limiting this obligation, the Recipient must keep all Confidential Information no less secure than its own confidential information.

8.3 **Permitted disclosure**

ACOR and the Registry Operator may disclose Confidential Information:

(a) as expressly required or permitted by this agreement (if applicable);

(b) with the written consent of the Client;

(c) to the extent required by law, by an order of a court or of a regulatory body; and

(d) in the case of ACOR, to the Registry Operator.

9 Collection of information and privacy

9.1 **Privacy law**

The parties must, and must procure that their employees, agents and contractors, act in accordance with the Privacy Laws in dealing with any Personal Information which is collected under or in connection with this agreement or the Registry.

9.2 **Personal Information**

The parties must not, and must procure that their employees, agents and contractors do not, use any Personal Information which is collected under or in connection with this agreement or the Registry for any purpose other than the purposes of the Registry.

9.3 **Further requirements**

The Client must do anything reasonably required by ACOR for compliance with the Privacy Laws including to:

(a) resolve any complaint made under any Privacy Laws;

(b) respond to any request by any person for access to the Personal Information held concerning that person; and

(c) comply with any reasonable directions issued by ACOR with respect to the collection, use, storage and distribution of Personal Information as necessary to ensure that ACOR complies, and continues to comply, with its statutory obligations with respect to Personal Information.

10 Further assurance

Each party must do everything necessary, or reasonably required, by another party to give effect to this agreement and the transactions contemplated by this agreement.

11 Entire agreement

This agreement:

(a) records the entire agreement between the parties; and

(b) supersedes all previous negotiations, understandings, representations and agreements,

in relation to the subject matter of this agreement.

12 Governing law and jurisdiction

This agreement is governed by the law in force in New South Wales and the parties submit to the jurisdiction of the courts of New South Wales.

Schedule 1 - Registry Use Fees

The Registry Use Fees are as set out below.

ACOR TAVI Registry

Fee (ex GST)

Initial Enrolment fee	$5,000
Annual fee (invoiced yearly)	$5,000

- Failure to pay the TAVI Registry use fees will result in immediate suspension from the Registry until the matter is resolved

EXECUTION

Signed as an agreement on _____20__

Signed on behalf of **Australasian Cardiac Outcomes Registry Limited** ACN 152 969 518:

Signature of authorised representative

Print name

Signed on behalf of

Signature of authorised representative

Client name and ABN

Print name