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Approved by:	Title: CEO	Name: Adrian Cosenza	Signature/date 

OUTCOME:

Medical Device companies and/or sponsors will use AOANJRR data in accordance with this policy.

BACKGROUND:

AOA owns a number of datasets. This policy pertains to one of those datasets - the AOANJRR dataset and its sub-datasets.

Individual companies/sponsors can access AOANJRR data specific to their own products in five ways:

a) **Publicly available data**: AOANJRR Annual Report, Supplementary Reports and Investigations of Prostheses with Higher Than Anticipated Rates of Revision.

b) **Web Based Industry Portal**: provides basic limited real-time information on the use and performance of individual products and product combinations.

c) **Data Request Reports**: Industry has the capacity to request detailed individualised reports on their own products through the DAU processes.

d) **The Automated Industry Report System (AIRS)**: provides industry the capacity to request and receive detailed written standardised reports online for their individual products.

e) **Data and Reports** provided during the Clinical Studies processes managed by the Clinical Studies Unit or the Data Analytics Unit.

DEFINITIONS:

- AOA - Australian Orthopaedic Association
- AOANJRR - Australian Orthopaedic Association National Joint Replacement Registry
- ACE – AOA Academy of Clinical Excellence in Orthopaedics
- CSU – ACE Clinical Studies Unit
- DAU – ACE Data Analytics Unit
- SAHMRI - South Australian Health & Medical Research Institute
- Data Requests Report - An individualised data report provided on request
- AIRS Automated Industry Report System

POLICY

This policy covers the Medical Device Industry use of any and all data produced by the AOANJRR, whether:

- publicly available (ie published);
- provided via secure electronic portal;
- provided on request to an individual, company or organisation; or
- provided during CSU/DAU processes.

STRATEGIES:

1. Publicly available data
2. Web based industry portal data
3. Data request reports
4. Automated Industry Reporting System (AIRS)
5. CSU data and reports
6. Misuse of AOANJRR Provided Data - Notification process
7. AOANJRR Data Use Matrix

1. Publicly Available Data

Data published by the AOANJRR is copyright protected. Data published by the AOANJRR provides Industry and the community with highly accurate independently analysed data.

- Annual Report data can be used to accurately promote the outcomes of products
- Annual Report data *cannot* be used to comment on, or denigrate the results of products from other companies.
- Tables and figures must be reproduced in full and unaltered from the AOANJRR publication, any deviation from this, such as use of an extract from a table, must be pre-approved by the AOANJRR
- The Annual Report must be correctly referenced as per the example provided below.
- Only data from the most recently available AOANJRR publications are to be used (unless referring to historical publication).
- Data that is reproduced must be relevant.

When the above conditions are met a company may use Annual Report data. The following applies to all AOANJRR data usage:

1.1 The AOANJRR on behalf of AOA will accept and formally review notifications where a company is reported as having misused Annual Report data

1.2 If the AOA Registry Clinical Directors determine that a company has misused Annual Report data by not adhering to the above conditions, the AOA Board will be notified. The AOA Board will consider the notification and make a determination if any action is required.

1.3 Reproducing published AOANJRR material: Tables and Figures must include the original AOANJRR description and table/figure number, and referenced to the AOANJRR source (subject to formatting requirements). For example:

1.3.1 Fig. 1: Cumulative percent revision of primary total conventional hip replacement by type of polyethylene (primary diagnosis OA). (Figure HT24, AOANJRR 2017).

1.3.2 Data from Annual and Supplementary reports must be attributed to the AOANJRR as an in-text citation with the full reference provided in the reference list (subject to formatting requirements). For example:

1.3.3 "….shows the significant reduction in revision rates when using cross-linked polyethylene when compared to non-cross-linked polyethylene (AOANJRR 2017)."

1.4 Referencing AOANJRR Annual Reports: Each annual report reference is unique, determined by its authorship list and DOI. Please refer to the inside cover of each annual report for the required citation.

2. Use of Automated Industry Report System (AIRS) Data

Standardised Automated Industry Reports provide Industry with access to up-to-date high quality independent analysis of their products and product combinations.

1.1 The use of the data in these reports can be used to accurately promote the outcomes of these products.

1.2 The data from these reports is not to be used to comment on, or denigrate the results of products from other companies.

1.3 Tables and figures used from an AIRS report must be reproduced in full and unaltered from the original report.

1.4 AIRS reports must be correctly referenced, using the AOANJRR Report ID as displayed at the top of page 1 of each report, the date the report was run, and with the inclusion of the provided AOANJRR Disclaimer as per the example provided below.

1.5 Data that is reproduced must be relevant.

1.6 When the above conditions are met a company may use AIRS reports for the purpose outlined in the Data Use Matrix (see page 5 below)

1.7 The DAU will accept and formally review notifications where a company is reported as having misused AIRS data.

1.8 If the CSU/DAU Clinical Directors and the Registry Clinical Directors determine that a company has misused AIRS data by not adhering to the above conditions, access to AIRS may be suspended for a period of time as determined by the AOA Board.

Reproducing material from the **Automated Industry Report System (AIRS):**

1.9 Tables and Figures must include the original AOANJRR description and table/figure number, and referenced to the AOANJRR AIRS source (subject to formatting requirements). For example:

1.9.1 Table 1: Revision Rates of <*Model Name*> Primary Total Conventional Hip Replacement by Acetabular Catalogue Number Range (All Diagnoses). (Table 3, AOANJRR dd/mm/yyyy).

Reference - Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR), Automated Industry Report System (AIRS), ID No.000 for < *Name of Company>,<topic of report i.e. Prosthesis Total Conventional Hip>*, (Procedures from 1 September 1999 – 8 March 2018), Accessed 9 April 2018, AOA, Adelaide: 1-65.

Disclaimer - AOANJRR is confident in the accuracy of the data included in this report, at the time it was provided. However, it was generated using an automated reporting system and has not been reviewed by the AOANJRR personnel.

3. Data Requests Reports

- Provision of a Data Request Report to a 'for profit' company or commercial enterprise will incur a fee. The fee will be based on the AOA Data Request Report Fee Schedule as approved by the AOA Board and will be reviewed annually. An invoice will be provided and must be paid prior to the release of the final report.
- The data request report data provided to companies can only be used for the purpose outlined in the Data Use Matrix (see page 5 below)

4. Web Based Portal

Web Based Industry Portal data can only be used for the purpose outlined in the Data Use Matrix (see page 5 below).

The data is available to assist companies to monitor the outcome of their own devices. It is important to understand that this data is a snapshot that usually *underestimates the number of revisions*. In addition, the data has not been verified. This data may act as a potential trigger for a company to approach the Registry for more detailed information if any issues of concern are identified.

The only exception to the "internal use only" restriction is:
In May 2016 Industry was approved to provide a copy of AOANJRR data from the Web Based Industry Portal when submitting the initial orthopaedic implant reports to the TGA in response to an adverse event.

5. Clinical Studies Data and Reports

Data and Reports using AOANJRR received by companies in the course of utilising the AOANJRR to facilitate their clinical trials and studies will be subject to all the policy conditions laid out

within this policy document or as stipulated in the trial or study agreement between the AOA and company.

CSU data can only be used for the purpose outlined in the AOANJRR Data Use Matrix (see page 5 below).

6. Misuse of AOANJRR Provided Data – Notification Process

AOA will accept and formally review notifications where a company is reported as having misused AOANJRR provided data.
If the AOANJRR determines that a company has misused AOANJRR data by not adhering to the above conditions and determines that misuse is other than minor, the AOANJRR has the option to refer the issue the AOA Board to determine if any action is required.

PERFORMANCE INDICATOR/S

Number of complaints
Number of breaches of policy

7. AOANJRR Data Use Matrix

Usage Type	AOANJRR		AOA Data Analytics Unit		AOA Clinical Studies Unit
	Annual Report	Web Based Portal	Data Reports	AIRS	Clinical Studies**
Internal use	🟢	🟢	🟢	🟢	🟢
Tendering	🟢	🔴	🟢	🟢	🟢
Benchmarking	🟢	🔴	🟢	🟢	🟢
Regulatory purposes	🟢	🔴	🟢	🟢	🟢
Industry White Papers	🟢	🔴	🟡	🟡	🟡
Industry reports to collaborating surgeons or surgeon users	🟢	🔴	🟡	🟡	🟡
Policy lobbying	🟢	🔴	🟡	🟡	🟡
Scientific Presentations*	🟢	🔴	🟡	🔴	🟡
Marketing purposes	🟢	🔴	🟡	🟡	🟡
Journal articles and scientific papers*	🟢	🔴	🟡	🔴	🟡

●	Indicates data type can be used for this purpose, provided adherence to the Medical Device Industry Use of AOANJRR Data policy is maintained.
●	Indicates data type cannot be used for this purpose without AOANJRR authorisation and review. The AOANJRR maintain the right to limit or reject the use of the data in these circumstances.
●	Indicates data type cannot be used for this purpose at any time.
*	Where permitted, the intended use of data must be declared at the outset, as data obtained for other purposes cannot be subsequently repurposed for this use.
**	Indicates data type is also subject to the data usage terms outlined in the AOA contract.