DATA MANAGEMENT PLAN

Version: 1

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Protocol: Intraosseous Regional Administration of Diclofenac (IRAD) in Primary Total Knee Arthroplasty Study: A prospective, double-blinded, randomised controlled trial of Intraosseous Regional Diclofenac vs Intravenous Diclofenac for Postoperative Pain Management in Primary Total Knee Arthroplasty

Sponsor: Mr Simon Young

Site: Southern Cross North Harbour

Co-ordinating Investigator: Mr Simon Young

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1 Introduction

This Data Management Guide outlines how data will be handled during the study (Intraosseous Regional Administration of Diclofenac (IRAD) in Primary Total Knee Arthroplasty Study: A prospective, double-blinded, randomised controlled trial of Intraosseous Regional Diclofenac vs Intravenous Diclofenac for Postoperative Pain Management in Primary Total Knee Arthroplasty) and after its completion.

2 Study Structure

TABLE 1. STUDY STRUCTURE

Lead Site (New Zealand)	Private Surgical Service, Orthopaedics Southern Cross North Harbour 232 Wairau Road Glenfield 0627 Auckland
Co-ordinating Investigator	Mr Simon W Young Axis Sports Medicine Northern Clinic Southern Cross Hospital 212 Wairau Road Wairau Valley Auckland 0627

3 Organisational Data Governance Oversight

The following institutional data policies apply for the Study:

- *Southern Cross Healthcare Privacy Statement*

4 Consent for Data Collection and Use

Consenting: All participants will be informed of, and provide consent for, the collection and use of their data for the purposes of this study, and for any mandatory secondary uses.

5 Data Collection

Data will be collected from the following sources:

- Direct communication with the participant
- Study assessments, including questionnaires/surveys

- Participant medical records (indicated in PISCF)

Data will be collected primarily by the Investigator or designated study staff. All study personnel involved in data collection will be trained in GCP, study protocol, and collection requirements.

Collection of data will be limited to that necessary for the specified purposes of the study, or for additional purposes that the participant has explicitly consented to.

6 Privacy and confidentiality

Participants' privacy and confidentiality will be respected through the protection of their data as outlined in this plan. The Investigator will comply with legal and regulatory requirements regarding the privacy and confidentiality of participants' data.

Participants have the right to access and correct personal data held by the site. Other results may be available on request, and will not result in the participant being withdrawn from the study.

6.1 Breach of Privacy / Confidentiality

A breach of privacy means unauthorised or accidental access to, or disclosure, alteration, loss, or destruction of a participant's information.

In the event participant privacy and confidentiality is breached during the study, the following steps will be taken:

- Action will be taken to reduce the risk of harm following the breach. Where possible, the recipient will be contacted and asked to destroy or return any disclosed material.
- The participant will be informed of the breach as soon as practicable (unless the participant is under the age of 16 and notification would be contrary to his/her interests; or notification would be likely to prejudice the health of the participant (after consultation with the participant's health practitioner, where practicable), and provided with support as required.
- A site and/or CRO and/or Sponsor (as appropriate) quality review will be conducted to ascertain factors contributing to the breach, and any corrective action required to prevent future breaches.
- The approving HDEC will be informed.
- For notifiable privacy breaches of privacy under the Privacy Act 2020, the New Zealand Privacy Commissioner will be notified in accordance with that Act.

7 Forms of Data

7.1 Identifiable Data

Some Study data will be collected in identifiable form.

Source documents refer to identifiable data collected for the purposes of this study. For the purposes of this data management plan, identifiable data includes the participant's existing medical / clinical records.

Source documents will be held at the site in identifiable form.

7.2 De-identified Data

De-identified data in this study includes but is not limited to:

- Case Report Forms.
- Safety and screening results entered into the analysis data set.

De-identified data will carry the participant's unique study code. The Investigator will retain a log linking participant code with identifiers. Only the co-ordinating investigator, co-investigators and research assistants, who are bound by standard Southern Cross Healthcare confidentiality and privacy agreements, will have access to this log.

All data sent to other researchers will be de-identified. All data generated by these parties will be in de-identified form. No attempt will be made to re-identify participants.

7.3 Anonymous / Anonymised Data

Not applicable.

8 Access to and Use of Data

Collected data will be used to answer the research questions and fulfil the study requirements described in the study protocol, and for the secondary purposes outlined in Sections 7.4 and 7.5.

8.1 Identifiable Data

Identifiable data may be accessed by the following groups:

- The Investigator and designated study staff, to fulfil protocol requirements.
- Study monitor(s), for eligibility confirmation and source data verification purposes.
- The Health and Disability Ethics Committee, for legal and regulatory purposes.
- Health, regulatory, or government agencies, for legal and regulatory purposes.
- The participant's GP or appropriate specialist, to inform them of study participation, and in the event of an incidental finding of potential clinical significance.

Rarely, it may be necessary for the Investigator to share identifiable data with people or groups not listed above – for example, in the event of a serious threat to public health or safety, or to the life or health of the participant or another person; or if the data is required for certain legal situations.

8.2 De-identified Data

De-identified data may be accessed and used by the following groups:

- The Investigator and suitably trained and experienced study staff, to conduct the study.
- The Health and Disability Ethics Committee, to comply with legal and regulatory duties.
- Health, regulatory, or government authorities, to comply with legal and regulatory duties.

De-identified data may be included in published study results including, but not limited to, peer-reviewed publications, clinical trial registry websites, scientific meetings, and regulatory / marketing submissions.

8.3 [Anonymous/Anonymised] Data

Not Applicable

8.4 Sending of Data Overseas

Not Applicable

8.5 Future Use of Data

De-identified [and/or anonymised] data will be used by the Sponsor for future medical or scientific research as specified below:

- unspecified purposes which are directly related to the study question(s)
- unspecified purposes which are related to the item and/or condition under study
- unspecified medical or scientific purposes which are not related to the study questions
- other unspecified research

*I*f participants provide optional additional consent, de-identified data will be made available to other researchers on request for future research as specified above

In all cases, the Sponsor must be satisfied that appropriate Data and Tissue Management Plans are in place and that ethical approval for use has been obtained in accordance with local laws and regulations.

8.6 Commercial Use of Data

Not Applicable

8.7 Data Linking

The study will link data obtained from participant medical records. This data linking is mandatory for participants.

Details of planned data linking:

- Participant medical records will only be used to obtain demographic data (e.g. age, gender, ethnicity, BMI) and previous medical history (e.g. comorbidities, previous surgical history in the knee joint) that is relevant to the study question.
- Data linkage will be undertaken by the research assistants bound by standard Southern Cross Healthcare confidentiality and privacy agreements.
- A list of identifiable NHIs will be stored in a password-protected file on a secure computer.
- Only members of the study team bound by standard Southern Cross Healthcare confidentiality and privacy agreements (i.e. the Coordinating Investigator and the research assistants) will have access to this list of identifiable NHIs.
- For the purpose of this study, all participants who meet the inclusion/exclusion criteria, and who have provided written consent, will be included. There will be no risk of bias for participants.

8.8 Databank / Registry

Not Applicable

9 Storage and Destruction of Data

9.1 Identifiable Data and Source Documents

During the study, study-specific source documents will be maintained in a locked file cabinet in a locked room or on a password-protected file on a secure Southern Cross North Harbour computer.

Post-study, study-specific source documents will be archived in a locked file cabinet in a locked room or on a password-protected file on a secure Southern Cross North Harbour computer.

Source documents will be retained for at least 10 years, then destroyed by appropriate contracted secure document disposal services.

9.2 De-identified Data

Identifiable data will be converted to a de-identified form at the study site, at which point it is entered into an electronic spreadsheet stored on a secure data platform with limited access. The data platform complies with international and national regulatory requirements for electronic data capture systems in the countries where it is used. Data entry will be limited to designated study staff trained and experienced in transcribing data for this purpose.

De-identified data will carry the study ID for each participant. The Investigator will retain a log linking participant code with identifiers.

De-identified data will be retained for at least 10 years

10 Consultation

Consultation regarding data management will be undertaken with the following relevant communities/stakeholders: Southern Cross Healthcare.

10.1 Māori Data Sovereignty

During the study, data may be collected from participants identifying as Maori.

Personal and health information is a tāonga (treasure) and will be treated accordingly.

Formal Māori consultation for this study will be completed as part of the Locality Approval Process for New Zealand study site(s). Any recommendations for additional measures to improve Māori rights and interests in relation to data will be acted upon.

11 Return of Results

Screening and safety results will be provided to participants on request.

Participants have the right to request a lay summary of study results.

11.1 Incidental Findings

In the event that a study assessment returns a result of potential clinical significance, the participant will be informed. The participant's usual doctor and / or an appropriate specialist will be notified, and follow-up will be arranged.

11.2 Results Arising from Future Research

11.2.1 Data

Results will be made available to participants of any future research conducted using data collected in this study. Participants are informed of this in the PISCF.

11.2.2 Databank / Registry

Not Applicable

12 Withdrawal of Data

Participants may withdraw consent for the collection of data at any time, without providing a reason.

Should a participant withdraw consent, no further data will be collected by study staff.

Data collected prior to the participant's withdrawal will continue to be used and analysed.