Health and Disability Ethics Committees
Ministry of Health
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0800 4 ETHICS
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17 October 2018

Dr Ryan Gao
26A Highland Road
Mount Albert
Auckland 1025

Dear Dr Gao

Re:	**Ethics ref:**	**18/NTA/161**
	Study title:	Should Ankle Should Ankle Syndesmosis Screws Be Removed? - Medium Term Outcomes With A Minimum of Five Years Follow-up

I am pleased to advise that this application has been *approved* by the Northern A Health and Disability Ethics Committee. This decision was made through the HDEC-Expedited Review pathway.

Conditions of HDEC approval

HDEC approval for this study is subject to the following conditions being met prior to the commencement of the study in New Zealand. It is your responsibility, and that of the study's sponsor, to ensure that these conditions are met. No further review by the Northern A Health and Disability Ethics Committee is required.

Standard conditions:

1. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.

2. Before the study commences at *any* locality in New Zealand, it must be registered in a clinical trials registry. This should be a WHO-approved registry (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au) or https://clinicaltrials.gov/.

3. Before the study commences at *each given* locality in New Zealand, it must be authorised by that locality in Online Forms. Locality authorisation confirms that the locality is suitable for the safe and effective conduct of the study, and that local research governance issues have been addressed.

Non-standard conditions:

4. Please look into the protocol and adjust. It has no detail on the original study, or the number of patients, original mode of randomisation etc. It simply references the publication of the original study. It also lacks any description of patient recruitment other than they will be contacted by phone and invited for a follow-up visit. There are disparities in patient sample size stated in the follow-up study and that of the original study.

5. The Participant Information Sheet/Consent Form (PIS/CF) needs amending as it lacks detail on length of time involved for patients study visit.
   There is a disparity between the number of pts in the original study (published as n=51), that required for the power calculation (n=61) and that in the application (n=80).
6. Please make the following changes to the PIS:
   a) Please add a lay title (ASSET Study)
   b) Please simplify the term radiological for example, add X-ray in brackets in the first use of this term.
   c) In the information to the participants as to why they have been contacted, please name the original study by its short lay title.
   d) In the details of what the study visits involve, please indicate how long the total visit will take that is, to complete the PISCF, the various questionnaires and X-rays. If more than one visit is required to have X-rays please indicate this to patients.
   e) Please consider giving a petrol voucher and/or reimbursing parking for the study visit(s). This should be stated in the PIS.

If you would like an acknowledgement of completion of your non-standard conditions you may submit a post approval form amendment through Online Forms. Please clearly identify in the amendment form that the changes relate to non-standard conditions and ensure that supporting documents (if requested) are tracked/highlighted with changes.

For information on non-standard conditions please see section 128 and 129 of the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz)

After HDEC review

Please refer to the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz) for HDEC requirements relating to amendments and other post-approval processes.

Your next progress report is due by 16 October 2019.

Participant access to ACC

The Northern A Health and Disability Ethics Committee is satisfied that your study is not a clinical trial that is to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled. Participants injured as a result of treatment received as part of your study may therefore be eligible for publicly-funded compensation through the Accident Compensation Corporation (ACC).

Please don't hesitate to contact the HDEC secretariat for further information. We wish you all the best for your study.

Yours sincerely,

Dr Brian Fergus
Chairperson
Northern A Health and Disability Ethics Committee

Encl: appendix A: documents submitted
appendix B: statement of compliance and list of members

Appendix A
Documents submitted

Document	*Version*	*Date*
Evidence of scientific review: Prof Pitto Scientific Review	1	07 September 2018
PIS/CF: asset PIS and CF	1	07 September 2018
Protocol: ASSET - Protocol	1	07 September 2018
Survey/questionnaire: aaos	1	07 September 2018
Survey/questionnaire: aaos hindfoot	1	07 September 2018
Survey/questionnaire: OM score	1	07 September 2018
asset study follow-up sheet	1	07 September 2018
CV for CI: CV RYAN GAO	1	04 August 2018
CVs for other Investigators: CV MATTHEW BOYLE	1	04 August 2018
CVs for other Investigators: CV BRENDAN COLEMAN	1	04 August 2018
Evidence of CI indemnity	1	04 August 2018
Application		

Appendix B
Statement of compliance and list of members

Statement of compliance

The Northern A Health and Disability Ethics Committee:

- is constituted in accordance with its Terms of Reference
- operates in accordance with the *Standard Operating Procedures for Health and Disability Ethics Committees*, and with the principles of international good clinical practice (GCP)
- is approved by the Health Research Council of New Zealand's Ethics Committee for the purposes of section 25(1)(c) of the Health Research Council Act 1990
- is registered (number 00008714) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

Name	*Category*	*Appointed*	*Term Expires*
Dr Brian Fergus	Lay (consumer/community perspectives)	11/11/2015	11/11/2018
Dr Karen Bartholomew	Non-lay (intervention studies)	13/05/2016	13/05/2019
Dr Christine Crooks	Non-lay (intervention studies)	11/11/2015	11/11/2018
Dr Catherine Jackson	Non-lay (health/disability service provision)	11/11/2016	11/11/2019
Ms Toni Millar	Lay (consumer/community perspectives)	11/11/2016	11/11/2019
Dr Kate Parker	Non-lay (observational studies)	11/11/2015	11/11/2018
Ms Rochelle Style	Lay (ethical/moral reasoning)	14/06/2017	14/06/2020

Unless members resign, vacate or are removed from their office, every member of HDEC shall continue in office until their successor comes into office (HDEC Terms of Reference)

http://www.ethics.health.govt.nz