Health and Disability Ethics Committees
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24 April 2014

Dr Ian Crozier
Cardiology Department
Christchurch Hospital
PO Box 4710
Christchurch 8011

Dear Dr Crozier

Re:	**Ethics ref:**	**14/STH/37**
	Study title:	Vado™ Steerable Sheath System; A Safety and Performance Study to evaluate access to the Pulmonary Veins in the Treatment of Paroxysmal and Persistent Atrial Fibrillation

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

The main issues considered by the HDEC in giving approval were as follows.

- The researcher explained that this sheath is advancing on the equipment already used for percutaneous ablation in a variety of arrhythmia problems. What is new about this sheath is that it is able to bend to allow for better contact with tissue inside the heart and this is a key aspect to delivering better therapy. The researchers in this study have experience using other steerable sheaths – the difference between this sheath and others they have used is the way in which it bends.
- The researcher explained that drawing on his experience he estimated that the procedure duration would be shorter as they would be able to accomplish what is needed faster with this steerable sheath.
- The Committee queried what the disadvantages and risks of this new device might be. The researcher said that it may be that the device may not hold shape as well or better than older versions. No danger will be posed if it doesn't work and the researchers will always be able to remove and replace the sheath with an older sheath during a procedure if this is the case. The Committee asked that this be clearly stated in the participant information sheet and consent form.
- The Committee noted with interest, the answer given at question p.4.2 on the application form that it is a common perception that Māori are over researched and asked where the researchers had drawn this information from. The researcher advised that he would query this with the study's lead investigator and noted that statistically Māori have been under represented in research. The Committee commended the researchers of a well-answered consultation with Māori section.

- The Committee queried the data safety monitoring committee arrangements and sought clarification on who would have an oversight of safety data and review cumulative data. The assessing of the device will be done by the surgeon - it was noted that there are only 10 patients in this study and this is the only site.
- The Committee asked whether the researchers would discuss any incidental findings with participants if anything significant was found during the testing. The researcher explained that they will do a number of standard screening procedures but not a lot of true diagnostics and any follow up with patients would be as usual.
- The Committee requested the following changes to the participant information sheet:
  - Please revise the study title and introduction and rewrite in lay language.
  - Please remove the pregnancy clause as it is not needed.
  - Please review the document for consistency of font size and type.
- The Committee commended the researchers for clearly identifying complications raised for each procedure in the information sheet.

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 Southern 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 WHO-approved clinical trials registry (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au).

3. Before the study commences at *a 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 amend the information sheets and consent form, taking into account the suggestions made by the committee (*Ethical Guidelines for Intervention Studies para 6.22*)

Non-Standard conditions must be completed before commencing your study. Non-standard conditions do not need to be submitted to HDEC before commencing your study.

If you would like to submit your Non-standard conditions please email Non-standard conditions to HDECS@moh.govt.nz. Do not submit Non-standard conditions as a Post Approval form.

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.

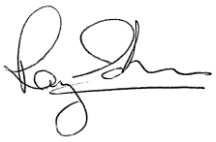
Your next progress report is due by 24 April 2015.

Participant access to ACC

This clinical trial is to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled. Section 32 of the Accident Compensation Act 2001 provides that participants injured as a result of treatment received as part of this trial will **not** 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,



Ms Raewyn Idoine
Chairperson
Southern 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*
PIS/CF: Participant infomration sheet and consent form.	1	19 March 2014
Investigator's Brochure	version A	24 March 2014
Protocol: Protocol CP1_001	0	27 March 2014
CV for CI: Dr Ian Crozier's CV	2014	28 March 2014
Evidence of CI indemnity	2014	01 February 2014
Evidence of scientific review: Peer review	20/3/14	20 March 2014
Evidence of sponsor insurance	2014	31 March 2014
Application		

Appendix B
Statement of compliance and list of members

Statement of compliance

The Southern 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 00008713) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

Name	*Category*	*Appointed*	*Term Expires*	*Present on 15/04/2014?*	*Declaration of interest?*
Ms Raewyn Idoine	Lay (consumer/community perspectives)	01/07/2012	01/07/2015	Yes	No
Mrs Angelika Frank-Alexander	Lay (consumer/community perspectives)	01/07/2012	01/07/2014	Yes	No
Dr Sarah Gunningham	Non-lay (intervention studies)	01/07/2012	01/07/2015	No	No
Ms Gwen Neave	Lay (consumer/community perspectives)	01/07/2012	01/07/2014	Yes	No
Dr Nicola Swain	Non-lay (observational studies)	01/07/2012	01/07/2014	Yes	No
Dr MARTIN THAN	Non-lay (intervention studies)	01/07/2012	01/07/2014	No	No
Dr Devonie Waaka	Non-lay (intervention studies)	01/07/2013	01/07/2016	No	No
Dr Mathew Zacharias	Non-lay (health/disability service provision)	01/07/2012	01/07/2015	Yes	No

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