Health and Disability Ethics Committees
Ministry of Health
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20 August 2020

Associate Professor Andrew Holden
Radiology-Level 5
Auckland City Hospital
Building 32
Auckland 1142

Dear Associate Professor Holden

Re:	**Ethics ref:**	**20/NTA/75**
	Study title:	A Feasibility Study of the GPX Embolic Device

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-Full 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 amend the reference to HDEC, to refer to the Northern A HDEC.

5. Please amend the advocacy email address to advocacy@advocacy.org.nz.

Non-standard conditions must be completed before commencing your study, however, they do not need to be submitted to or reviewed by HDEC.

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 19 August 2021.

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,

Mrs Kate O'Connor
Acting 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*
CV for CI: CV for PI	1	14 February 2020
Investigator's Brochure: Fluidx IB	RF-0031 Rev 1	08 April 2020
Evidence of sponsor insurance	1	03 February 2020
CVs for other Investigators: CV for Sub-I	1	24 January 2020
Evidence of scientific review: Peer Review- Completed by Dr Daniel Sze	1	07 December 2019
Evidence of CI indemnity	1	31 January 2021
PIS/CF: Fluidx PICF 15Apr2020	1	15 April 2020
Protocol: Fluid X Protocol	1	05 May 2020
Covering Letter: Fluidx Cover letter	1	07 May 2020
Application		07 May 2020
Covering Letter: Cover letter response to provisional approval 08JUL2020	1	08 July 2020
PIS/CF: Updated PICF for provisional approval-15APR2020	1	15 April 2020
Response to Request for Further Information		
FLUIDX FINAL PICF REDLINED.docx		

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*
Mrs Kate O'Connor	Lay (consumer/community perspectives)	29/01/2020	29/01/2021
Dr Karen Bartholomew	Non-lay (intervention studies)	18/07/2016	18/07/2022
Dr Sotera Catapang	Non-lay (observational studies)	11/02/2020	11/02/2023
Ms Catherine Garvey	Lay (the law)	19/03/2019	19/03/2022
Dr Michael Meyer	Non-lay (health/disability service provision)	11/02/2020	11/02/2023
Dr Kate Parker	Non-lay (observational studies)	11/02/2020	11/02/2026
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