

13 October 2020

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

Dear Associate Professor Holden

Re: <b>Ethics ref:</b>	<b>20/NTA/75/AM01</b>
Study title:	A Feasibility Study of the GPX Embolic Device

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

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 and approved**

Document	Version	Date
Summary of changes to the protocol. RF-0032 Rev A --> RF-0032 Rev B	1	11 September 2020
Protocol: Protocol Rev0032-B Redlined	Rev 0032-B	17 September 2020
Protocol: Protocol Rev0032-B clean	Rev 0032-B	17 September 2020
Post Approval Form	AM01	17 September 2020

## 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

<i>Name</i>	<i>Category</i>	<i>Appointed</i>	<i>Term Expires</i>
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>