Health and Disability Ethics Committees
Ministry of Health
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25 January 2018

Dr Prathima Chowdary
173c Mokoia road
Birkenhead
Auckland 0626

Dear Dr Chowdary

Re:	**Ethics ref:**	**17/STH/196**
	Study title:	An early (phase II), unblinded, single-arm, proof-of-concept clinical trial to assess the safety, toxicity and tolerability profiles of oral vinorelbine as a treatment for women with ectopic pregnancies

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.

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 clinical trials registry. This should be a WHO-approved (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au). However https://clinicaltrials.gov/ is acceptable provided registration occurs prior to the study commencing at *any* locality in New Zealand.

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:

— Please replace/rewrite the paragraph on the purpose of the research from the previous PIS, as it is currently unclear why Vinorelbine is being trialled.

- Please include the Maori tissue statement as per the provisional approval letter (12).
- Please include the table of risks of Vinorelbine as per protocol (15).
- The protocol needs amending to state that the retrospective review of patients will be performed as a later amendment to this protocol.
- Top of page 2 please change the sentence on conditional approval, as the study cannot be started until approval has been granted.

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

If you would like an acknowledgement of completion of your non-standard conditions letter you may submit a post approval form amendment. Please clearly identify in the amendment 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 at http://ethics.health.govt.nz/home.

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 January 2019.

As your study is an intervention study involving a new medicine then all progress reports must be accompanied by an annual safety report. While there is no prescribed format for annual safety reports, they must be no longer than two pages in length, written in lay language, and include:

- a brief description and analysis of new and relevant findings that may have a significant impact on the safety of participants
- a brief analysis of the safety profile of the new medicine and its implications for participants, taking into account all safety data as well as the results of any relevant non-clinical studies
- a brief discussion of the implications of safety data to the risk-benefit ratio for the intervention study, and whether study documentation has been or will be updated
- a description of any measures taken or proposed to minimise risks. (Where such a proposed measure would be a substantial amendment, it must be submitted to the HDEC for review in the normal way.)

For the avoidance of doubt Development Safety Update Reports (DSURs) may serve as annual safety reports to HDECs provided that they contain the information outlined above. These summaries should usually be accompanied by comment from the CI of the study in New Zealand. Please refer to the *Standard Operating Procedures for Health and Disability Ethics Committees* paras 206 - 208 for further information.

Participant access to ACC

The Southern 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,

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*	
CVs for other Investigators	1	21 September 2017	
CV for CI	1	21 September 2017	
Protocol	1	21 September 2017	
Covering Letter	1	21 September 2017	
PIS/CF	2	21 September 2017	
Evidence of scientific review	1	21 September 2017	
PIS/CF	2	21 September 2017	
Letter explaining the changes made following previous submission	1	27 September 2017	
Declined letter for previous application in respect of the same (or substantially similar) study	1	27 September 2017	
PIS/CF: Revised version after provisional approval	Version 3	25 November 2017	

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*
Ms Raewyn Idoine	Lay (consumer/community perspectives)	27/10/2015	27/10/2018
Dr Sarah Gunningham	Non-lay (intervention studies)	27/10/2015	27/10/2018
Assc Prof Mira Harrison-Woolrych	Non-lay (intervention studies)	27/10/2015	27/10/2018
Dr Fiona McCrimmon	Lay (the law)	27/10/2015	27/10/2018
Dr Anna Paris	Lay (other)	24/08/2017	24/08/2020
Dr Nicola Swain	Non-lay (observational studies)	27/10/2015	27/10/2018
Dr Devonie Waaka	Non-lay (intervention studies)	13/05/2016	13/05/2019

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