UNIVERSITY of TASMANIA

29 April 2019

Dr Feng Pan
C/- Menzies Institute for Medical Research

Sent via email

Dear Dr Pan

REF NO: H0017601
TITLE: PROVOKE - A randomised controlled trial of Venlafaxine to treat patients with knee osteoarthritis pain

Document	***Version***	***Date***
HREA		25 Mar 2019
Protocol	v1.6	
Patient Information Sheet	v1.5	
Consent Form	v1.2	
Medicare Privacy Form		
Ad Menzies		
Ad Newspaper		
GP Letter		
Memo ad	v1.2	
Questionnaire Ipaq - PROVOKE		
Questionnaire Short Form FFQ PROVOKE		
Study wallet card		
SW01973 1 BDI-II		
SW01973 1 Evidence of Outcome		
SW01973 1 Fibromyalgia-ness score		
SW01973 1 Gen Quest		
SW01973 1 HADS-anxiety depression		
SW01973 1 Interview form		
SW01973 1 Knee Pain Vas (2)		
SW01973 1 Pain Disability Index (2)		
SW01973 1 painDETECT-Questionaire		
SW01973 1 Pain Catastrophizing Scale		
SW01973 1 phq-9		
SW01973 1 ScreeningPi Randomised		
SW01973 1 SF-36		
SW01973 1 WOMAC Osteoarthritis		

Human Research Ethics Committee (Tasmania) Network
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The Tasmania Health and Medical Human Research Ethics Committee (HREC) considered and approved the above documentation on **15 April 2019** to be conducted at the following site(s):

Menzies Institute for Medical Research

Please ensure that all investigators involved with this project have cited the approved versions of the documents listed within this letter and use only these versions in conducting this research project.

This approval constitutes ethical clearance by the Health and Medical HREC. The decision and authority to commence the associated research may be dependent on factors beyond the remit of the ethics review process. For example, your research may need ethics clearance from other organisations or review by your research governance coordinator or Head of Department. It is your responsibility to find out if the approvals of other bodies or authorities are required. It is recommended that the proposed research should not commence until you have satisfied these requirements.

In accordance with the National Statement on Ethical Conduct in Human Research, it is the responsibility of institutions and researchers to be aware of both general and specific legal requirements, wherever relevant. If researchers are uncertain they should seek legal advice to confirm that their proposed research is in compliant with the relevant laws. University of Tasmania researchers may seek legal advice from Legal Services at the University.

All committees operating under the Human Research Ethics Committee (Tasmania) Network are registered and required to comply with the *National Statement on the Ethical Conduct in Human Research* (NHMRC 2007 updated 2018).

Therefore, the Chief Investigator's responsibility is to ensure that:

(1) All investigators are aware of the terms of approval, and that the research is conducted in compliance with the HREC approved protocol or project description.

(2) Modifications to the protocol do not proceed until **approval** is obtained in writing from the HREC. This includes, but is not limited to, amendments that:

(i) are proposed or undertaken in order to eliminate immediate risks to participants;
(ii) may increase the risks to participants;
(iii) significantly affect the conduct of the research; or
(iv) involve changes to investigator involvement with the project.

Please note that all requests for changes to approved documents must include a version number and date when submitted for review by the HREC.

(3) Reports are provided to the HREC on the progress of the research and any safety reports or monitoring requirements as indicated in NHMRC guidance.
The appropriate forms for reporting such events in relation to clinical and non-clinical trials and innovations can be located at the website below. All adverse events must be reported regardless of whether or not the event, in your opinion, is a direct effect of the therapeutic

goods being tested. http://www.utas.edu.au/research-admin/research-integrity-and-ethics-unit-rieu/human-ethics/human-research-ethics-review-process/health-and-medical-hrec/managing-your-approved-project

(4) The HREC is informed as soon as possible of any new safety information, from other published or unpublished research, that may have an impact on the continued ethical acceptability of the research or that may indicate the need for modification of the project.

(5) All research participants must be provided with the current Participant Information Sheet and Consent Form, unless otherwise approved by the Committee.

(6) This study has approval for four years contingent upon annual review. A *Progress Report* is to be provided on the anniversary date of your approval. Your first report is due **15 April 2020,** and you will be sent a courtesy reminder closer to this due date. Ethical approval for this project will lapse if a Progress Report is not submitted in the time frame provided

(7) A *Final Report* and a copy of the published material, either in full or abstract, must be provided at the end of the project.

(8) The HREC is advised of any complaints received or ethical issues that arise during the course of the project.

(9) The HREC is advised promptly of the emergence of circumstances where a court, law enforcement agency or regulator seeks to compel the release of findings or results. Researchers must develop a strategy for addressing this and seek advice from the HREC.

Should you have any queries please do not hesitate to contact me on (03) 6226 6254 or via email Human.ethics@utas.edu.au.

Yours sincerely

Ailin Ding
Administration Officer