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HUMAN RESEARCH ETHICS COMMITTEE (TASMANIA) NETWORK

UTAS

17 February 2015

Dr Nitin Verma
School Of Medicine
University of Tasmania

Sent via email

Dear Dr Verma

REF NO: H0014556
TITLE: Prospective Study to assess the efficacy and safety of a treat and extend regimen of aflibercept for the treatment of diabetic macular oedema.

Document	***Version***	***Date***
Consent Form	V2	12 December 2014
Information Sheet for clinical trial	V2	12 December 2014
NEAF Application		
Privacy Form		March 2014
Protocol	V3	17 October 2014
Protocol	V4	12 December 2014

The Tasmanian Health and Medical Human Research Ethics Committee considered and approved the above documentation on **13 January 2015** to be conducted at the following site(s):

Hobart Eye Surgeons, Argyle Street, Hobart
Royal Hobart Hospital, Ophthalmic Outpatients, Wellington Clinics, Hobart
Burnie Ophthalmology, North West Private Hospital, Cooee TAS

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.

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 2014).

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

(1) The individual researcher's protocol complies with the HREC approved protocol.

(2) Modifications to the protocol do not proceed until **approval** is obtained in writing from the HREC. 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) Section 5.5.3 of the National Statement states:

Researchers have a significant responsibility in monitoring approved research as they are in the best position to observe any adverse events or unexpected outcomes. They should report such events or outcomes promptly to the relevant institution/s and ethical review body/ies and take prompt steps to deal with any unexpected risks.

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.research.utas.edu.au/human_ethics/medical_forms.htm

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

(5) The Committee is notified if any investigators are added to, or cease involvement with, the project.

(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 **13 January 2016.** You will be sent a courtesy reminder closer to this due date.

(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.

Should you have any queries please do not hesitate to contact me on (03) 6226 2764.

Yours sincerely

Digitally signed by Lynda Hobman
DN: cn=Lynda Hobman, o=University of Tasmania, ou=Office of Research Services, Research Integrity & Ethics, email=lynda.hobman@utas.edu.au, c=AU
Date: 2015.02.19 11:52:55 +11'00'

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