Health and Disability Ethics Committees
Ministry of Health
Freyberg Building
20 Aitken Street
PO Box 5013
Wellington
6011

0800 4 ETHICS
hdecs@moh.govt.nz

26 September 2016

Dr Riyaz Bhikoo
Palmerston North Hospital
50 Ruahine Street
Roslyn
Palmerston North 4442

Dear Dr Bhikoo

Re:	**Ethics ref:**	**16/STH/144**
	Study title:	Efficacy of subtenons bupivacaine for postoperative pain management following pterygium surgery with free conjunctiva graft and fibrin glue

This application was reviewed by the Southern Health and Disability Ethics Committee and *provisionally approved* pending receipt of further information. This decision was made through the HDEC-Full Review pathway.

Summary of Study

1. The Committee noted that overall this was a good application with quite a good Participant Information Sheet.

Summary of ethical issues (resolved)

The main ethical issues considered by the Committee and were addressed by the Researcher are as follows.

2. The Committee noted that the question regarding minimising conflict of interest was answered incorrectly, the Committee are looking for an answer relating to minimising the conflict of interest that exists from the researcher also being the participant's treating clinician. The Researcher explained that this will be minimised by the study not being mentioned until the patient has had standard surgery explained and have consented to this, then the researcher will offer the patient enrolment in the study and make sure it is clear that their participation in the study will not impact the eligibility for standard of care and study participation is a fully optional extra. The Committee agreed that this is acceptable.
3. The Committee questioned how the researcher and participant will be blinded to the participant's group allocation. The Researcher explained that the scrub nurse will prepare either the placebo solution or the study solution and the researcher will not know which one the participant is getting.

Summary of ethical issues (outstanding)

The main ethical issues considered by the Committee which require addressing by the Researcher are as follows.

4. The Committee noted that the question regarding how health information will be protected was not correctly answered, please provide a more detailed response to this question.
   r.2.1.1. Please briefly explain how you will ensure the confidentiality of this health information before the study.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

5. The Committee requested the compensation wording is updated for accuracy, they suggested the following statement: *"If you were injured in this study, which is unlikely, you would be eligible **to apply** for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover."*
6. Please revise the Participant Information Sheet to reduce technical language to make the Participant Information Sheet more suitable for lay participants. For example, participants may not understand a 'systematic complication' and this should be revised to be in lay language.
7. Please add a footer and page numbers to the Participant Information Sheet.
8. Please remove the letterhead from all pages of the Participant Information Sheet except the first page.
9. The Committee suggested revising the wording of 'blunt needle' in the Participant Information Sheet as although they understand why this is the case they feel this may make participants needlessly uncomfortable. The Committee suggested that simply calling it a 'needle' may be appropriate. The Researcher agreed to determine a different name to give the needle in the Participant Information Sheet.

Further information requested

The further information requested in order for the Southern Health and Disability Ethics Committee to make a final decision is as follows.

- Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (Ethical Guidelines for Intervention Studies para 6.22).
- Please respond to the Committee's outstanding ethical concern detailed above. The Committee noted that a response in the form of a cover letter may be appropriate as the application form cannot be modified after submission.

Timeline for providing further information, and for giving a final opinion

You have 90 days to provide this further information. Your application will be considered to have been withdrawn if this information is not received on or before 25 December 2016. A new application would be required in this case.

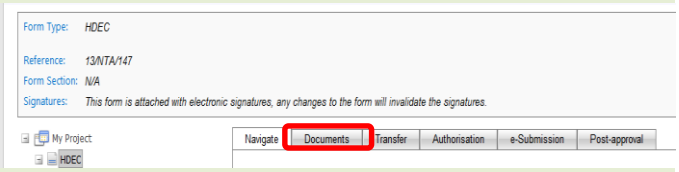
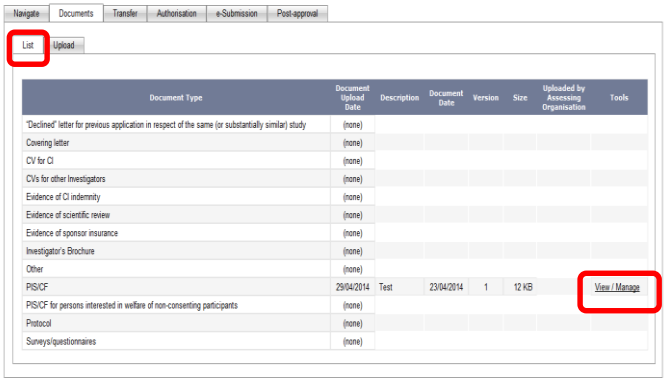
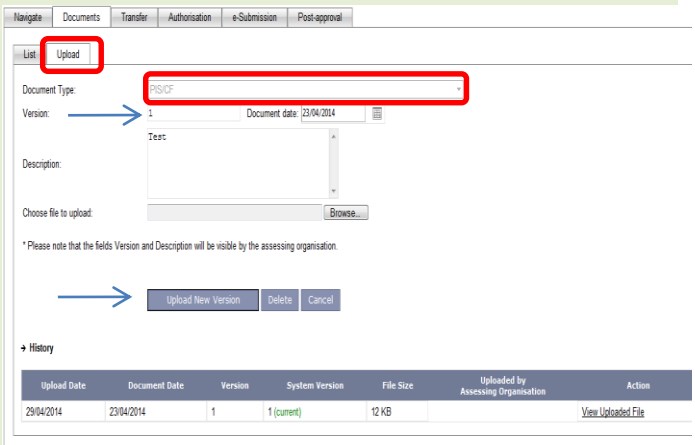
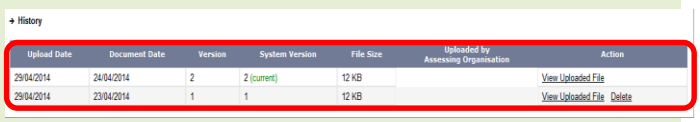
The 35-day clock within which a final decision must be made on this study is suspended as of the date of this letter. This clock, on which 17 days remain, will restart on the date on which **all** of the further information requested above is received by the Southern Health and Disability Ethics Committee.

Please remember to track changes made to new versions of documentation.

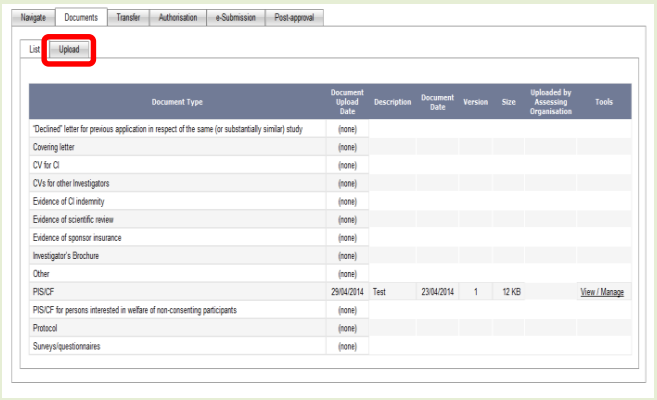
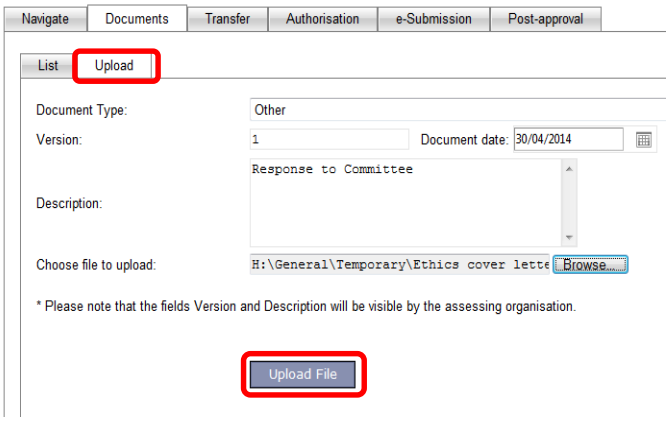
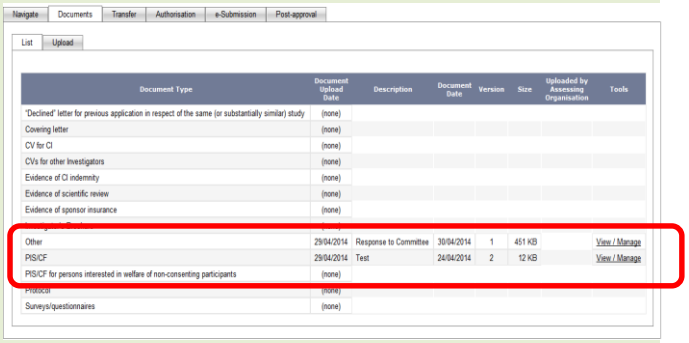
How to respond to a Provisional Approval

You will need to submit your new or amended documents through Online Forms.

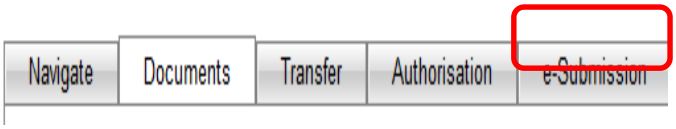
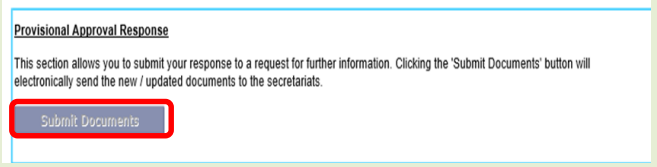
New versions of existing documents:

Steps	Screenshots
1. Go to the Documents Tab to upload the revised documentation requested by the secretariat	
2. To update versions of documents, go to the List tab. Select View/Manage to upload a newer version of the document. • For example you can upload new versions of the PIS/CF • Remember to track changes.	
3. When you click View/Manage for a particular document it will take you to the upload tab for that document. • Update the version number and document date. • Browse to find the new version of the file. • Click 'Upload New Version' • Once the upload is complete the history will populate with the new version.	 

New documents:

Steps	Screenshots
4. For New documents, go to the upload tab. • For example you can upload a word document responding to questions raised by the Committee.	
5. Select the document type. Add a version number, document date and add a description if required. Browse your computer to find the new file and select Upload File.	
6. The new document will now be uploaded and visible on the List Tab. **Before submitting check to see all your documents are on the List tab and are displaying the correct version and document date.**	

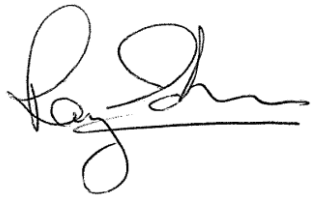
To submit:

7. Once you have uploaded all new documents or updated all existing documents click the E-Submissions tab.	
8. Scroll down until you see 'Provisional Approval Response'. This button will only be able to be used when you have received a 'Provisional Approval' letter.	

Please note: only click submit once.

Please don't hesitate to contact the HDEC secretariat if you have any queries. We look forward to receiving your response.

Yours sincerely,



Ms 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*
CV for CI	1	27 August 2016
Protocol	1	05 September 2016
Evidence of scientific review	1	05 September 2016
Survey/questionnaire	1	05 September 2016
PIS/CF	1	05 September 2016
Application		
Covering Letter		

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*	*Present on 20/09/2016?*	*Declaration of interest?*
Ms Raewyn Idoine	Lay (consumer/community perspectives)	27/10/2015	27/10/2018	Yes	No
Dr Devonie Eglinton	Non-lay (intervention studies)	13/05/2016	13/05/2019	Yes	No
Mrs Angelika Frank-Alexander	Lay (consumer/community perspectives)	27/10/2015	27/10/2018	No	No
Dr Sarah Gunningham	Non-lay (intervention studies)	27/10/2015	27/10/2018	Yes	No
Assc Prof Mira Harrison-Woolrych	Non-lay (intervention studies)	27/10/2015	27/10/2018	Yes	No
Dr Fiona McCrimmon	Lay (the law)	27/10/2015	27/10/2018	Yes	No
Dr Nicola Swain	Non-lay (observational studies)	27/10/2015	27/10/2018	Yes	No
Dr Mathew Zacharias	Non-lay (health/disability service provision)	27/10/2015	27/10/2018	Yes	No

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