

07 April 2016

Prof Sally D Poppitt  
University of Auckland Human Nutrition Unit  
18 Carrick Place  
Mt Eden  
Auckland 1024

Dear Prof Poppitt

Re:	<b>Ethics ref:</b>	<b>16/STH/23</b>
	Study title:	Characterising the Prediabetic Asian and Caucasian Phenotype: The TOFI Profile

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-Expedited 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 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.

After HDEC review

Please refer to the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on [www.ethics.health.govt.nz](http://www.ethics.health.govt.nz)) for HDEC requirements relating to amendments and other post-approval processes.

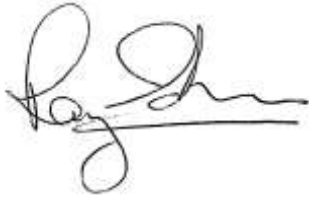
**Your next progress report is due by 06 April 2017.**

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,

A handwritten signature in black ink, appearing to read 'Raewyn Idoine', written over a horizontal line.

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**

<i>Document</i>	<i>Version</i>	<i>Date</i>
CV for CI: Professor Sally Poppitt CV	1	27 February 2016
Protocol	1	16 February 2016
PIS/CF	2	03 April 2016
Evidence of sponsor insurance	1	27 February 2016
Evidence of scientific review	1	27 February 2016
Evidence of CI indemnity	1	27 February 2016
Survey/questionnaire: Screening form	1	24 February 2016
Advertisement	1	24 February 2016
CVs for other Investigators: Karl Fraser CV	1	27 February 2016
CVs for other Investigators: Rinki Murphy CV	1	27 February 2016
Application		
Evidence of scientific review		
Demographics	2	04 April 2016
CVs for other Investigators: Louise CV	1	16 March 2016
Other (No Description Entered)	1	04 April 2016

## 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

<i>Name</i>	<i>Category</i>	<i>Appointed</i>	<i>Term Expires</i>
Ms Raewyn Idoine	Lay (consumer/community perspectives)	27/10/2015	27/10/2018
Dr Devonie Eglinton	Non-lay (intervention studies)	01/07/2013	01/07/2016
Mrs Angelika Frank-Alexander	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 Nicola Swain	Non-lay (observational studies)	27/10/2015	27/10/2018
Dr Mathew Zacharias	Non-lay (health/disability service provision)	27/10/2015	27/10/2018

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>

24 June 2016

Prof Sally D Poppitt  
University of Auckland Human Nutrition Unit  
18 Carrick Place  
Mt Eden  
Auckland 1024

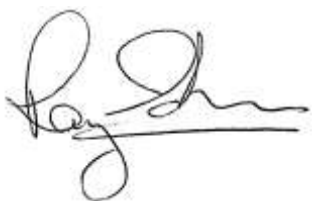
Dear Prof Poppitt

Re: <b>Ethics ref:</b>	<b>16/STH/23/AM01</b>
Study title:	Characterising the Prediabetic Asian and Caucasian Phenotype: The TOFI Profile

I am pleased to advise that this amendment has been approved by the Southern 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,



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 and approved**

Document	Version	Date
PIS/CF: Translated Chinese version of V2 English PIS/CF.	2	03 April 2016
Covering letter: Letter to HDEC	1	30 May 2016
CVs for other Investigators: CV for backtranslator	1	07 April 2016
Post Approval Form	AM01	08 June 2016

## Appendix B Statement of compliance and list of members

### Statement of compliance

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Ms Raewyn Idoine	Lay (consumer/community perspectives)	27/10/2015	27/10/2018
Dr Devonie Eglinton	Non-lay (intervention studies)	13/05/2016	13/05/2019
Mrs Angelika Frank-Alexander	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 Nicola Swain	Non-lay (observational studies)	27/10/2015	27/10/2018
Dr Mathew Zacharias	Non-lay (health/disability service provision)	27/10/2015	27/10/2018

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18 July 2016

Prof Sally D Poppitt  
University of Auckland Human Nutrition Unit  
18 Carrick Place, Mt Eden  
Auckland 1024

Dear Prof Poppitt

Re:	<b>Ethics ref:</b>	<b>16/STH/23/AM02</b>
	Study title:	Characterising the Prediabetic Asian and Caucasian Phenotype: The TOFI Profile

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

Non-standard conditions:

1. In the PISCF there is a statement regarding stopping the test. Please change 'would' to 'could' (p3, 2<sup>nd</sup> para, second to last sentence).
2. Please submit an amended, re-versioned protocol (tracked changes) incorporating the requested change for our records, prior to instituting the new test.


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>.

Please don't hesitate to contact the HDEC secretariat for further information. We wish you all the best for your study.

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 and approved**

Document	Version	Date
Covering letter	1	27 June 2016
PIS/CF: Changes from version 2 highlighted.	3	24 June 2016
PIS/CF: Chinese translation of V3 english PIS.	3	24 June 2016
Post Approval Form	AM02	29 June 2016

## Appendix B Statement of compliance and list of members

### Statement of compliance

The Southern Health and Disability Ethics Committee:

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### List of members

<i>Name</i>	<i>Category</i>	<i>Appointed</i>	<i>Term Expires</i>
Ms Raewyn Idoine	Lay (consumer/community perspectives)	27/10/2015	27/10/2018
Dr Devonie Eglinton	Non-lay (intervention studies)	13/05/2016	13/05/2019
Mrs Angelika Frank-Alexander	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 Nicola Swain	Non-lay (observational studies)	27/10/2015	27/10/2018
Dr Mathew Zacharias	Non-lay (health/disability service provision)	27/10/2015	27/10/2018

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>

19 September 2016

Prof Sally D Poppitt  
University of Auckland Human Nutrition Unit  
18 Carrick Place, Mt Eden  
Auckland 1024

Dear Prof Poppitt

Re: <b>Ethics ref:</b>	<b>16/STH/23/AM03</b>
Study title:	Characterising the Prediabetic Asian and Caucasian Phenotype: The TOFI Profile

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

Non-standard conditions:

1. Please submit an amended, re-versioned protocol with tracked changes incorporating the requested amendment which needs to be submitted to HDEC for our records prior to the changes being implemented..

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>.

Please don't hesitate to contact the HDEC secretariat for further information. We wish you all the best for your study.

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 and approved**

Document	Version	Date
Covering letter: HDEC letter	1	04 August 2016
PIS/CF: Changes highlighted in yellow.	5	30 August 2016
Post Approval Form	AM03	09 August 2016
PIS/CF: PIS_ICF_TOFI profile Asian vs Caucasian_V4_Ivana_9Aug16_SDP.docx	4	09 August 2016

## Appendix B Statement of compliance and list of members

### Statement of compliance

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- is registered (number 00008713) 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>
Ms Raewyn Idoine	Lay (consumer/community perspectives)	27/10/2015	27/10/2018
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Mrs Angelika Frank-Alexander	Lay (consumer/community perspectives)	27/10/2015	27/10/2018
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Dr Nicola Swain	Non-lay (observational studies)	27/10/2015	27/10/2018
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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>

27 October 2016

Prof Sally D Poppitt  
University of Auckland Human Nutrition Unit  
18 Carrick Place  
Mt Eden  
Auckland 1024

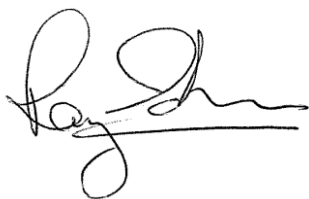
Dear Prof Poppitt

Re: <b>Ethics ref:</b>	<b>16/STH/23/AM04</b>
Study title:	Characterising the Prediabetic Asian and Caucasian Phenotype: The TOFI Profile

I am pleased to advise that this amendment has been approved by the Southern 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,



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 and approved**

Document	Version	Date
Protocol: changes on page 15. highlighted.	3	07 October 2016
PIS/CF: changes highlighted on page 3.	6	07 October 2016
Post Approval Form	AM04	11 October 2016

## 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
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### List of members

<i>Name</i>	<i>Category</i>	<i>Appointed</i>	<i>Term Expires</i>
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Dr Devonie Eglinton	Non-lay (intervention studies)	13/05/2016	13/05/2019
Mrs Angelika Frank-Alexander	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 Nicola Swain	Non-lay (observational studies)	27/10/2015	27/10/2018
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<http://www.ethics.health.govt.nz>



06 July 2017

Prof Sally D Poppitt  
University of Auckland Human Nutrition Unit  
18 Carrick Place  
Mt Eden  
Auckland 1024

Dear Prof Poppitt

Re: <b>Ethics ref:</b>	<b>16/STH/23/AM05</b>
Study title:	Characterising the Prediabetic Asian and Caucasian Phenotype: The TOFI Profile

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

Non-standard conditions:

1. Please only re-contact those participants who have given consent for this. Please provide HDEC with a tracked changes copy of the amended protocol, incorporating the requested change.

Non-standard conditions must be completed before commencing any changes as a result of this amendment. Non-standard conditions do not need to be submitted to or reviewed by HDEC before commencing any changes as a result of this amendment.

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>.

Please don't hesitate to contact the HDEC secretariat for further information. We wish you all the best for your study.

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 and approved**

Document	Version	Date
food frequency questionnaire	1	15 June 2017
Post Approval Form	AM05	16 June 2017

## Appendix B Statement of compliance and list of members

### Statement of compliance

The Southern Health and Disability Ethics Committee:

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### List of members

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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
Assoc 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 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
Dr Mathew Zacharias	Non-lay (health/disability service provision)	27/10/2015	27/10/2018

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<http://www.ethics.health.govt.nz>

24 July 2017

Prof Sally D Poppitt  
University of Auckland Human Nutrition Unit  
18 Carrick Place  
Mt Eden  
Auckland 1024

Dear Prof Poppitt

Re: <b>Ethics ref:</b>	<b>16/STH/23/AM06</b>
Study title:	Characterising the Prediabetic Asian and Caucasian Phenotype: The TOFI Profile

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

#### 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 supply an amended protocol with track changes, incorporating the requested change(s).
- Please supply an updated ICF that specifies that you wish to perform genetic analysis. It is recognised that the SNPs intended for analysis have been not associated with any known hereditary diseases or health outcomes. It is standard, however, for participants to be informed (and have the right to decline the use of their samples) when any analysis of this sort is intended.
- The amended information should include: - a lay description of SNPs/ miRNAs and their potential role in influencing disease
- That the genetic markers you will be testing for are not known to be involved with any known disorders or health outcomes
- That participants will not be informed of the results of the analyses.
- That participants can decide not to give consent for their samples to be used in these analyses, and that a decision not to give consent will not affect their participation in the remainder of the study.

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

You have 90 days to provide this further information. Your amendment will be considered to have been withdrawn if this information is not received on or before 22 October 2017. A new amendment would be required in this case.

The 15-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 2 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 - Amendment

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

### New versions of existing documents:

#### Steps

#### Screenshots

Step 1: Locate the post approval form

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.

Document Type	Document Upload Date	Description	Document Date	Version	Size	Uploaded by Assessing Organisation	Tools
'Declined' letter for previous application in respect of the same (or substantially similar) study	(none)						
Covering letter	(none)						
CV for CI	(none)						
CVs for other Investigators	(none)						
Evidence of CI indemnity	(none)						
Evidence of scientific review	(none)						
Evidence of sponsor insurance	(none)						
Investigator's Brochure	(none)						
Other	(none)						
PIS/CF	29/04/2014	Test	23/04/2014	1	12 KB		View / Manage
PIS/CF for persons interested in welfare of non-consenting participants	(none)						
Protocol	(none)						
Surveys/questionnaires	(none)						

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.

Upload Date	Document Date	Version	System Version	File Size	Uploaded by Assessing Organisation	Action
29/04/2014	23/04/2014	1	1 (current)	12 KB		View Uploaded File
29/04/2014	24/04/2014	2	2 (current)	12 KB		View Uploaded File
29/04/2014	23/04/2014	1	1	12 KB		View Uploaded File Delete

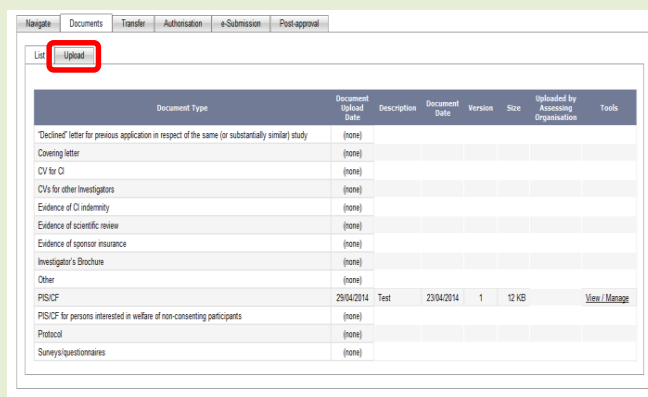
## New documents:

### Steps

4. For New documents, go to the upload tab.

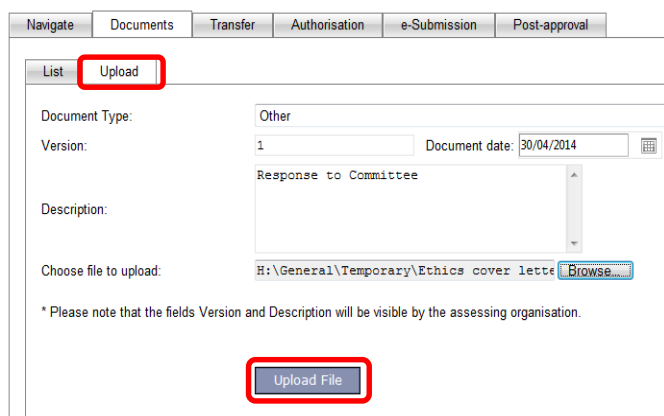
- For example you can upload a word document responding to questions raised by the Committee.

### Screenshots



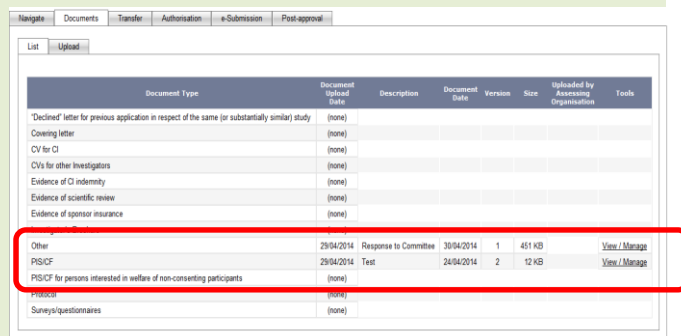
5. Select the document type. Add a version number, document date and add a description if required.

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.**



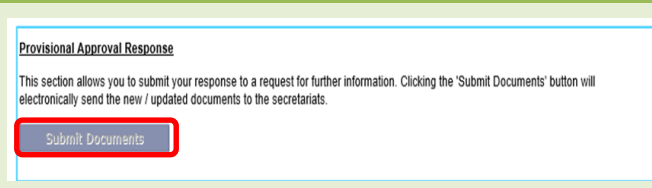
## To submit:

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

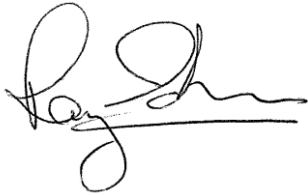


received a 'Provisional Approval'  
letter.

**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,

A handwritten signature in black ink, appearing to read 'Raewyn Idoine', with a horizontal line underneath.

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
Post Approval Form	AM06	11 July 2017
Extra information re AM06 via email.pdf		11 July 2017



## Appendix B Statement of compliance and list of members

### Statement of compliance

The Southern Health and Disability Ethics Committee:

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Dr Devonie Waaka	Non-lay (intervention studies)	13/05/2016	13/05/2019
Dr Mathew Zacharias	Non-lay (health/disability service provision)	27/10/2015	27/10/2018

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>