

19 July 2017

Ms Emma Reeves
Cardio-Respiratory Integrated Specialist Services (CRISS)
5th Floor, Riverside Block, Christchurch Hospital
Private Bag 4710
Christchurch 8140

Dear Ms Reeves

Re: Ethics ref:	17/STH/114
Study title:	Transitioning from hospital to reality: Do newly diagnosed heart failure patients benefit from a heart failure clinical nurse specialist providing focused education at discharge?

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-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.

- G is incorrect: Health information will be accessed in order to identify potential patients for the study.
- b.4.6. This study must be registered on a clinical trial registry prior to the study commencing.
- r.5.6 To remove assessor bias the CI should not be involved in the follow-up assessments of EITHER group (not just of the intervention group). Assessments of the control group are open to negative bias to the same extent that assessments of the intervention group are open to positive bias. Bias would be limited further if the nurse specialists making the telephone call were blinded to the group allocation of the participants they contact. At the least, the group allocation should not be listed on the checklist/questionnaire (the box headed "randomisation" should be removed from the checklist).
- p.2.9 The intended means of making results available is not suitable for a lay audience. Please give participants the option of being provided with a plain english, lay summary of the results.
- p.4.6 It is preferable for ethnicity to be collected as part of the study; ethnicity may be a variable in terms of the impact of the intervention on the outcome measures.

Participant Information Sheet The section 'What will my participation involve?' needs editing.

- Please explain what 'randomisation' is - please add what the chances will be of a patient being randomised to the intervention group or the usual care group (e.g. you will have a 50% chance of being in the intervention group, and a 50% chance of being in the usual care group. You cannot choose which group you will be placed in.)

- What happens for each group is not well explained. Suggest changing to: **1.** You will receive pre-discharge education from the ward nurses (both groups) **2.** If you are in the Intervention group, you will also receive an extra 10 - 25 minute education session before you leave hospital (intervention group only) **3.** You will be contacted by one of the heart failure nurse specialists 48 hours after leaving hospital (both groups). The nurse will ask you a series of questions.....
- Consent form: - please replace the phrase "the testing" with "taking part" or "participation".

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 17 October 2017. A new application 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 1 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

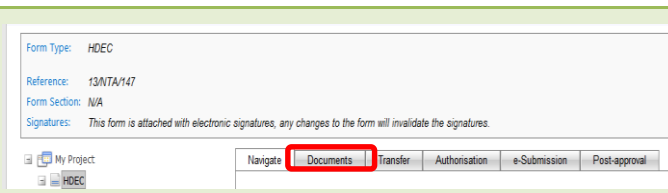
You will need to submit your new or amended documents through Online Forms.

New versions of existing documents:

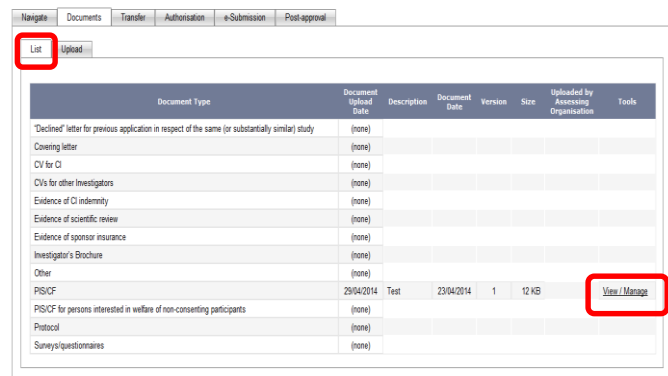
Steps

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.

Document Type: PIS/CF

Version: 1 Document date: 23/04/2014

Description: Test

Choose file to upload:

* Please note that the fields Version and Description will be visible by the assessing organisation.

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

Upload Date	Document Date	Version	System Version	File Size	Uploaded by Assessing Organisation	Action
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 <input type="button" value="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

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)	(none)					
Covering letter	(none)	(none)					
CV for CI	(none)	(none)					
CVs for other Investigators	(none)	(none)					
Evidence of CI indemnity	(none)	(none)					
Evidence of scientific review	(none)	(none)					
Evidence of sponsor insurance	(none)	(none)					
Investigator's Brochure	(none)	(none)					
Other	(none)	(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)	(none)					
Protocol	(none)	(none)					
Surveys/questionnaires	(none)	(none)					

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.

Document Type: Other

Version: 1 Document date: 30/04/2014

Description: Response to Committee

Choose file to upload: H:\General\Temporary\Ethics cover letter

* Please note that the fields Version and Description will be visible by the assessing organisation.

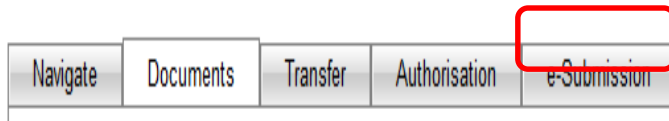
6. The new document will now be uploaded and visible on the List Tab.

Before submitting check to see all your documents are on the List tab and are displaying the correct version and document date.

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)						
CI for CI	(none)						
CI's for other investigators	(none)						
Evidence of CI indemnity	(none)						
Evidence of scientific review	(none)						
Evidence of sponsor insurance	(none)						
Other	29/04/2014	Response to Committee	30/04/2014	1	451 KB		View / Manage
PRISCF	29/04/2014	Test	24/04/2014	2	12 KB		View / Manage
PRISCF for persons interested in welfare of non-consenting participants	(none)						
Protocol	(none)						
Surveys/questionnaires	(none)						

To submit:

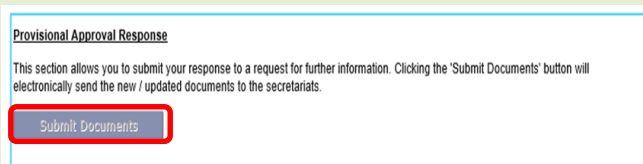
7. Once you have uploaded all new documents or updated all existing documents click the E-Submissions tab.



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

<i>Document</i>	<i>Version</i>	<i>Date</i>
Protocol: Protocol shows flow chart of how participants will be recruited.	1	28 June 2017
Survey/questionnaire: Checklist and questionnaire the researcher will use to obtain information from recruited participants.	1	28 June 2017
PIS/CF: Consent form for participants	1	28 June 2017
PIS/CF: Participant information sheet to be used by the researcher in the recruitment process.	1	28 June 2017
CV for CI: Curriculum vitae for researcher	1	28 June 2017
Covering Letter: Covering letter for researcher	1	28 June 2017
Weight diary used by the researcher for the brief educational intervention at the bedside	1	28 June 2017
Evidence of scientific review: Scientific Peer review by Senior Nursing Colleague	1	05 July 2017
Evidence of scientific review: Scientific Peer Review by researchers nurse manager	1	05 July 2017
Application		

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)	13/05/2016	13/05/2019
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>