

# HDEC Update

12/1/2013

Ministry of Health

[Edition 1, Volume 1]

## 2013 Overview

One year into the new system and changes ahead

Seasons Greetings from the HDEC team. 2013 has seen a few changes to the HDEC team, so we thought we would provide you with a quick end

survey of your experiences with the HDEC system. We will keep you posted about future changes and



Helen Colebrook, Kirsten Forrest, Kelly Traynor, Awhina Rangiwai, Nic Aagaard. Tania Siwatibau

of year update.

We have a number of improvements in the pipeline for HDECs in the New Year. In particular, we will be improving the online system so that you will be able to submit responses to provisionally approved applications via Online Forms.

To help us improve the service we offer we will be inviting you to participate in a

improvements.

This newsletter provides a quick update on peer review and annual safety reports and a handy list of meeting dates for 2014.

I have made some changes to the way we work. The Advisors are responsible for reviewing incoming applications and checking that they are in

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**Contact Us:**

**Post:**

Ethics Committees

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scope or outside of the scope of review, checking applications for completeness and providing advice and support to committees. They are your point of contact for issues relating to new applications and meetings. You are welcome to ring the advisors for advice on whether your application requires review, or about any other queries relating to the ethical approval requirements for your study.

Administrators handle all post approval items and can advise

on progress of your application or post approval item.

The HDEC secretariat comprises:

Helen Colebrook (Acting Manager)

Nic Aagaard (Advisor)

Kirsten Forrest (Advisor)

Kelly Traynor (Advisor)

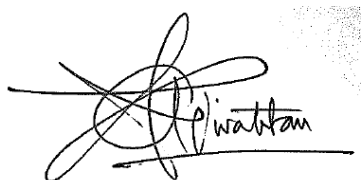
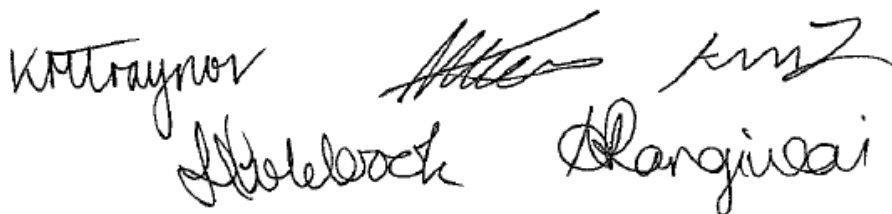
Awhina Rangiwai (Administrator)

Tania Siwatibau (Administrator)

Please do call us or email us; we are here to help.

Thank you for your goodwill and support over the past year. We look forward to working with you in 2014 and hope you have a relaxing break.

The HDEC Team

The HDEC office will be closed from 5pm Tuesday 24 December until Monday 6 January. Applications will not be validated between 24 December and 15 January 2014. The first meeting in 2014 will be the Central Ethics Committee meeting on Thursday 30 January. Please see the Meeting Dates section for more information.



## Peer Review

What constitutes peer review

Researchers are responsible for ensuring the scientific validity of their studies. Ethics Committees do not conduct a comprehensive review of the scientific merits of studies; their role is to check that this has already been carried out.

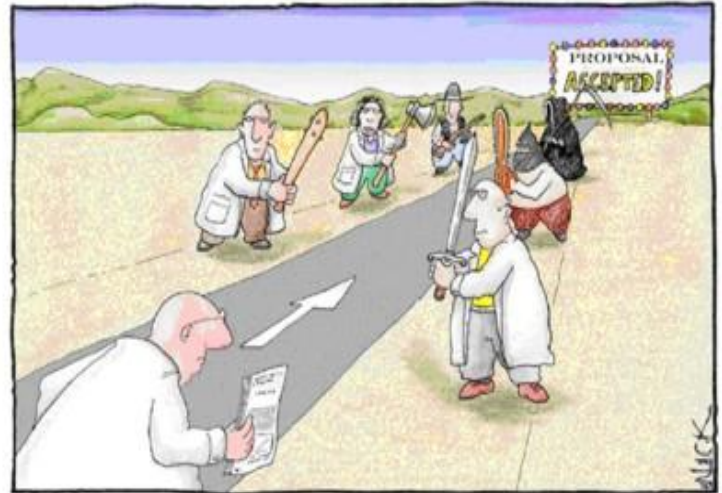
Only complete applications will be accepted onto a meeting agenda. This means that before submitting your application to an HDEC for review you should ensure that evidence of the scientific validity of your study is attached as a supporting document.

The HDEC team has developed a peer review template that researchers can use to document peer review for new applications. You can find the template on the HDEC website. This template outlines the evidence HDEC needs to see before it can approve a study. This includes information about:

- Relative merit of the research
- Design and methods
- Feasibility
- Independence of Peer Review. Peer review should deliver an objective opinion and be perceived to be free from bias.

Please note any peer review noted in question B.2.2.2 in the application should be submitted as a supporting document to provide evidence to HDEC.

## Peer-Review



A non-exhaustive list of examples of established robust peer review of scientific validity processes includes:

- Health Research South peer review process
- HRC grants funding process
- University of Otago at Wellington Research Grants funding process
- SCOTT review of new medicines is regarded as sufficient evidence of peer review for scientific validity.

If your study has been peer reviewed in order to receive a funding grant please provide evidence of the review undertaken or evidence that the funding grant process incorporated features of peer review.

For more information on peer review please read Appendix 1 of:

- Ethical Guidelines for Intervention Studies
- Ethical Guidelines for Observational Studies





## Minimal Dataset Forms – A Reminder

It has been over a year since the system change has occurred. All on-going studies must submit a progress report annually.

If you have not completed a Minimal Dataset Form (MDF) it is likely that your study's progress report is overdue.

Note that any Post Approval Form (PAF) submitted at the same time as an MDF is not able to be reviewed until the MDF has been approved.

To create an account visit:

<https://www.ethicsform.org/Nz>

Please Login

If you are a first time user of the Online Forms website please read the information on the help page before selecting the 'Create Account' option from the menu at the top of the page.

Login:

(Your full e-mail address)

Password:

Forgotten Password? [Click here](#)

## Progress Reports and Safety Reports for New Medicines

An annual safety report must be attached to each annual progress report for an intervention study involving a new medicine. While there is no prescribed format for annual safety reports, they must be no longer than two pages in length, written in lay language, and include:

- a brief description and analysis of new and relevant findings that may have a significant impact on the safety of participants
- a brief analysis of the safety profile of the new medicine and its implications for participants, taking into account all safety data as well as the results of any relevant non-clinical studies
- a brief discussion of the implications of safety data to the risk-benefit ratio for the intervention study, and whether study documentation has been or will be updated
- a description of any measures taken or proposed to minimise risks. Where such a proposed measure would be a substantial amendment, it must be submitted to the HDEC for review in the normal way.

Summaries of safety information such as [Development Safety Update Reports](#) may serve as annual safety reports to HDECs provided that they contain the information outlined above. These summaries should usually be accompanied by comment from the CI of the study in New Zealand.





## Tracked Changes

Please remember to track any changes for new versions of documents submitted either as Post Approval Items or Provisional Approval Responses.

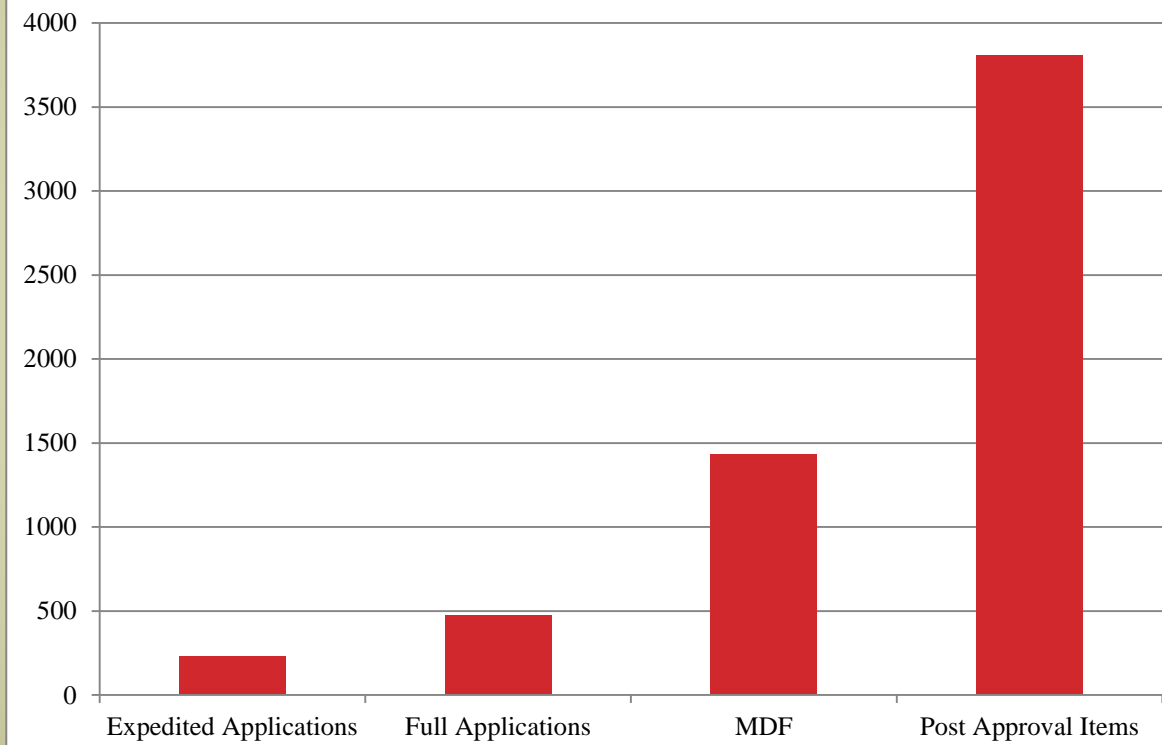
Tracked changes make it easier for the Committee to review amendments which results in faster review and better document history.

## HDEC Documents

1. [Ethical Guidelines for Observational Studies](#)
2. [Ethical Guidelines for Intervention Studies.](#)
3. [SOP's for HDEC's \(docx, 390 KB\)](#)
4. [Online forms user manual](#)

## *A Snapshot of HDEC*

### Received Items: June 2012 to October 2013





## Meeting Dates for 2014

HDEC	Meeting date and start time	Venue	Agenda closes 12 noon
Central	Thursday, 30 January 2014 12 noon	Deloitte House 10 Brandon St, Wellington	Thursday, 16 January 2014
Northern B	Tuesday, 4 February 2014 12 noon	CEO Meeting Room, Level 3, Hockin Building, Waikato Hospital Campus	Thursday, 23 January 2014
Northern A	Tuesday, 11 February 2014 1 pm	Novotel Ellerslie 72-112 Greenlane Rd East, Auckland	Thursday, 30 January 2014
Southern	Tuesday, 18 February 2014 12 noon	NZ Blood Service, 87 Riccarton Road, Riccarton, Christchurch	Thursday, 6 February 2014
Central	Tuesday, 25 February 2014 12 noon	Terrace Conference Centre 114 The Terrace, Wellington	Thursday, 13 February 2014
Northern B	Tuesday, 4 March 2014 12 noon	CEO Meeting Room, Level 3, Hockin Building, Waikato Hospital Campus	Thursday, 20 February 2014
Northern A	Tuesday, 11 March 2014 1 pm	Novotel Ellerslie 72-112 Greenlane Rd East, Auckland	Thursday, 27 February 2014
Southern	Tuesday, 18 March 2014 12 noon	NZ Blood Service, 87 Riccarton Road, Riccarton, Christchurch	Thursday, 6 March 2014
Central	Tuesday, 25 March 2014 12 noon	Deloitte House 10 Brandon St, Wellington	Thursday, 13 March 2014
Northern B	Tuesday, 1 April 2014 12 noon	Novotel Ellerslie 72-112 Greenlane Rd East, Auckland	Thursday, 20 March 2014
Northern A	Tuesday, 8 April 2014 1 pm	Novotel Ellerslie 72-112 Greenlane Rd East, Auckland	Thursday, 27 March 2014
Southern	Tuesday, 15 April 2014 12 noon	NZ Blood Service, 87 Riccarton Road, Riccarton, Christchurch	Thursday, 3 April 2014
Central	Tuesday, 22 April 2014 12 noon	Terrace Conference Centre 114 The Terrace, Wellington	Thursday, 10 April 2014
Northern B	Tuesday, 6 May 2014 12 noon	Novotel Tainui, 7 Alma Street, Hamilton	Thursday, 24 April 2014
Northern A	Tuesday, 13 May 2014 1 pm	Novotel Ellerslie 72-112 Greenlane Rd East, Auckland	Thursday, 1 May 2014
Southern	Tuesday, 20 May 2014 12 noon	NZ Blood Service, 87 Riccarton Road, Riccarton, Christchurch	Thursday, 8 May 2014
Central	Tuesday, 27 May 2014 12 noon	Deloitte House 10 Brandon St, Wellington	Thursday, 15 May 2014
Northern B	Tuesday, 3 June 2014 12 noon	Novotel Ellerslie 72-112 Greenlane Rd East, Auckland	Thursday, 22 May 2014
Northern A	Tuesday, 10 June 2014 1 pm	Novotel Ellerslie 72-112 Greenlane Rd East, Auckland	Thursday, 29 May 2014
Southern	Tuesday, 17 June 2014 12 noon	NZ Blood Service, 87 Riccarton Road, Riccarton, Christchurch	Thursday, 5 June 2014
Central	Tuesday, 24 June 2014 12 noon	Terrace Conference Centre 114 The Terrace, Wellington	Thursday, 12 June 2014
Northern B	Tuesday, 1 July 2014 12 noon	Novotel Tainui, 7 Alma Street, Hamilton	Thursday, 19 June 2014





<b>Northern A</b>	Tuesday, 8 July 2014 1 pm	Novotel Ellerslie 72-112 Greenlane Rd East, Auckland	Thursday, 26 June 2014
<b>Southern</b>	Tuesday, 15 July 2014 12noon	NZ Blood Service, 87 Riccarton Road, Riccarton, Christchurch	Thursday, 3 July 2014
<b>Central</b>	Tuesday, 22 July 2014 12 noon	Deloitte House 10 Brandon St, Wellington	Thursday, 10 July 2014
<b>Northern B</b>	Tuesday, 5 August 2014 12 noon	Novotel Ellerslie 72-112 Greenlane Rd East, Auckland	Thursday, 24 July 2014
<b>Northern A</b>	Tuesday, 12 August 2014 1 pm	Novotel Ellerslie 72-112 Greenlane Rd East, Auckland	Thursday, 31 July 2014
<b>Southern</b>	Tuesday, 19 August 2014 12 noon	NZ Blood Service, 87 Riccarton Road, Riccarton, Christchurch	Thursday, 7 August 2014
<b>Central</b>	Tuesday, 26 August 2014 12 noon	Terrace Conference Centre 114 The Terrace, Wellington	Thursday, 14 August 2014
<b>Northern B</b>	Tuesday, 2 September 2014 12 noon	CEO Meeting Room, Level 3, Hockin Building, Waikato Hospital Campus	Thursday, 21 August 2014
<b>Northern A</b>	Tuesday, 09 September 2014 1 pm	Novotel Ellerslie 72-112 Greenlane Rd East, Auckland	Thursday, 28 August 2014
<b>Southern</b>	Tuesday, 16 September 2014 12 noon	Sudima Hotel, Christchurch Airport, 550 Memorial Ave, Christchurch	Thursday, 4 September 2014
<b>Central</b>	Tuesday, 23 September 2014 12 noon	Deloitte House 10 Brandon St, Wellington	Thursday, 11 September 2014
<b>Northern B</b>	Tuesday, 30 September 2014 12 noon	Novotel Ellerslie 72-112 Greenlane Rd East, Auckland	Thursday, 18 September 2014
<b>Northern A</b>	Tuesday, 7 October 2014 1 pm	Novotel Ellerslie 72-112 Greenlane Rd East, Auckland	Thursday, 25 September 2014
<b>Southern</b>	Tuesday, 14 October 2014 12noon	Sudima Hotel, Christchurch Airport, 550 Memorial Ave, Christchurch	Thursday, 2 October 2014
<b>Central</b>	Tuesday, 23 October 2014 12 noon	Terrace Conference Centre 114 The Terrace, Wellington	Thursday, 11 October 2014
<b>Northern B</b>	Tuesday, 4 November 2014 12 noon	CEO Meeting Room, Level 3, Hockin Building, Waikato Hospital Campus	Thursday, 23 October 2014
<b>Northern A</b>	Tuesday, 11 November 2014 1 pm	Novotel Ellerslie 72-112 Greenlane Rd East, Auckland	Thursday, 30 October 2014
<b>Southern</b>	Tuesday, 18 November 2014 12 noon	Sudima Hotel, Christchurch Airport, 550 Memorial Ave, Christchurch	Thursday, 6 November 2014
<b>Central</b>	Tuesday, 25 November 2014 12 noon	Deloitte House 10 Brandon St, Wellington	Thursday, 13 November 2014
<b>Northern B</b>	Tuesday, 2 December 2014 12 noon	Novotel Ellerslie 72-112 Greenlane Rd East, Auckland	Thursday, 20 November 2014
<b>Northern A</b>	Tuesday, 09 December 2014 1 pm	Novotel Ellerslie 72-112 Greenlane Rd East, Auckland	Thursday, 27 November 2014
<b>Southern</b>	Tuesday, 16 December 2014 12 noon	Sudima Hotel, Christchurch Airport, 550 Memorial Ave, Christchurch	Thursday, 4 December 2014

