HDEC BI-ANNUAL NEWSLETTER

Winter Edition 2018

Welcome to the Winter 2018 Edition of the HDEC Bi-annual Newsletter.
This Newsletter will give you an update on changes to HDECs standards and expectations, as well as pointing you in the direction of new guidance that has been created to help you through the application process.

HDEC WEBSITE

We have recently updated our website to include user-focused guidance on practical and ethical issues.

You should review the website and templates before completing your next application.

New ethics guidance includes	New practical guidance includes
• use of health information, • vulnerable participants, and • research with Māori.	• check if your study requires HDEC review, • submit an application for HDEC review, and • the HDEC review and post-approval process.

SCOPE OF REVIEW FORM

Version 9 of the HDEC Scope of Review form is now live.
This version contains much clearer questions and is easier to use.

Scope of review form Version 9

ACC STANDARD WORDING

We have recently updated the suggested compensation wording for "commercially sponsored" intervention studies. Please use the updated wording in future Participant Information Sheets.

Please see the Participant Information Sheet template for the updated wording

IDENTIFIABILITY OF SAMPLES

We have received requests for clarification on the HDEC position on this issue acceptable level of identifiability of tissue samples being sent overseas.

Samples sent overseas should retain the least identifiers possible.

- This should usually be restricted to a unique study number, year of birth, and gender.
- Sham day and month of birth can be used if necessary for formatting.
- Samples for optional analysis, or Future Unspecified Use of Tissue, should only retain the unique study code.

You must justify any deviation from this to the HDEC.

OPTIONAL USE OF TISSUE & SEPARATE INFORMATON AND CONSENT

We have recently updated the requirements for optional use of tissue and separate Participant Information Sheets and Consent Forms.

A summary is included below, see our website for more information.

Mandatory Tests

To ensure participants are able to access the benefits of study participation without unnecessary burden, uses of tissue (as with all aspects of study participation) should be optional whenever possible.

Use of tissue can be a mandatory when it is required for the primary purpose of the study. If the study can achieve its primary objectives without the proposed use of tissue then this must be optional.

Consent for use of tissue can be specific or broad, meaning not all tests that will be conducted need to be known at the time of consent.

Distinct Information and Consent

Information and consent for optional aspects of a study must be distinct, to ensure it is clear what is required for study participation and what is optional.

Information on optional parts of the study participation can be contained in the main Participant Information Sheet and Consent Form document, but must be fully distinct.

In practice this means that the information and consent for optional parts of a study should follow the main Participant Information Sheet and Consent Form, in either the same or separate documents.

Further information is available on our website

RESULT LETTER TO PARTICIPANTS

Applicants have recently queried whether result letters to participants are substantial or minor, and whether they need to be reviewed by HDECs.

A result letter to participants does not necessarily require review, as the proposal to have one is usually part of the original study application and protocol.
However, if the results letter poses new risks or discloses significant new information to participants (e.g. unblinding information) then this should be submitted as a substantial amendment.

SECRETARIAT UPDATE

In the last 12 months the HDEC Secretariat, who also support the Ethics Committee on Assisted Reproductive Technology (ECART), have merged with the Secretariat for the Advisory Committee on Assisted Reproductive Technology (ACART) and the National Ethics Advisory Committee (NEAC).

This merger will help ensure the Secretariat are able to continue to provide high quality advisory and administrative support to all seven Committees.

This year the Secretariat have said goodbye to Fox Swindells, Carla Denneny, and Vicki Maaka who have all moved on to exciting new roles. This has opened the opportunity for new people to come on board and develop in this interesting area.

COMMITTEE UPDATE

A number of valued committee member's terms are running out this year, opening up vacancies for enthusiastic new members to be appointed.

If you, or someone you know, are interested in serving as a member of one of the four HDECs please see: careers.health.govt.nz

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ETHICS GUIDELINES UPDATE

The National Ethics Advisory Committee has finalised the draft National Ethical Standards for Health and Disability Research, developed by a working party appointed by the Ministry of Health. These new standards update and expand on the guidelines issued by NEAC in 2012 and bring together the Ethical Guidelines for Observational Studies and Intervention Studies into one document.

The new National Ethical Guidelines are being processed for targeted consultation. To receive further information on this consultation please contact neac@moh.govt.nz

We will be updating our Standard Operating Procedures and approval process to align with the National Ethical Guidelines when they are published.

APPLICATION VOLUME

Application volume is steadily increasing, with 2017 seeing 118 more submissions than 2016. To date this year, application volume is up again on 2017.

This puts pressure on the full HDEC meeting agendas, with a maximum of 12 applications able to be assigned to any one meeting. Agendas for full meets will close at noon on the agenda close date, or when 12 valid applications are received, whichever comes first.

To ensure your application can be assigned to your preferred meeting, applications should be submitted in advance of the agenda close date.

HDEC Meeting Dates and Venue Jan-Dec 2018 (Word, 102 KB)