Health and Disability Ethics Committees

Minutes

Committee:	Northern A Health and Disability Ethics Committee
Meeting date:	06 November 2012
Meeting venue:	Novotel Ellerslie

Time	**Item of business**
13:00	Welcome
	Confirmation of minutes of meeting of 09 October 2012
	New applications (see over for details)
13:30 – 14:00	i 12/NTA/63
14:00 – 14:30	ii 12/NTA/64 – Closed meeting
14:30 – 15:00	iii 12/NTA/66
15:00 – 15:30	iv 12/NTA/67
15:30 – 16:00	v 12/NTA/68
14:00 – 14:30	vi 12/NTA/69 – Closed meeting
16:30 – 17:15	General business: Noting section of agenda
17:15	Meeting ends

Member Name	Member Category	Appointed	Term Expires	Apologies?
Dr Brian Fergus	Lay (consumer/community perspectives)	01/07/2012	01/07/2015	Absent
Ms Susan Buckland	Lay (consumer/community perspectives)	01/07/2012	01/07/2015	Present
Ms Shamim Chagani	Non-lay (health/disability service provision)	01/07/2012	01/07/2014	Present
Mr Kerry Hiini	Lay (consumer/community perspectives)	01/07/2012	01/07/2014	Present
Assoc Prof Wayne Miles	Non-lay (intervention studies), Non-lay (health/disability service provision)	01/07/2012	01/07/2013	Present
Dr Etuate Saafi	Non-lay (intervention studies)	01/07/2012	01/07/2014	Present
Ms Michele Stanton	Lay (the law)	01/07/2012	01/07/2014	Present

Welcome

The Chair opened the meeting at 13:00 and welcomed Committee members.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

Confirmation of previous minutes

The minutes of the meeting of 09 October 2012 were confirmed.

New applications

1	**Ethics ref:**	**12/NTA/63**
	Title:	Safety and efficacy of empagliflozin in two different daily doses as a
	Principal Investigator:	Dr Andrew Veale
	Sponsor:	Boehringer Ingelheim Pty Limited
	Clock Start Date:	25 October 2012

Research Nurse, Carol Veale, was present in person for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

No potential conflicts of interest related to this application were declared by any member.

Summary of ethical issues

The main ethical issues considered by the Committee were as follows.

- Please clarify the New Zealand commencement date for the study.
- Please clarify if b.1.2 should read “hyperglycemia” and not “hypoglycaemia”.
- Please ensure that participants who are referred to the trial by their own practitioner have independent consent.
- The Committee thanks the researchers for supplying hard copies of the SCOTT and Maori approval for the study.
- Please clarify if the answer to r.4.1 should be yes.
- Please clarify if the answer to f.3.1 should be yes.
- The Committee notes that participants will not be able to continue with the study treatment even if the treatment given was effective as the proposed dosing regime does not have full approval. The Committee’s concern is that patients with this difficult to treat illness (Type 2 diabetes) might experience a good response and then not be able to continue with the treatment. Therefore, please explore the possibility of having some kind of extended access to this treatment with the sponsor.

- The Committee requested the following changes be made to the Participant Information Sheet:
  - on letterhead
  - please reword the “*purpose*” (page 2) to reflect what is in the protocol
  - please replace the word “regiment” with a more appropriate word

- only include all necessary information. The Committee feels the information sheet reads like an instruction manual at times (e.g. page 4)
- please refer to the correct HDEC committee (Northern A Health and Disabilities Ethics Committee) for all instances
- page 10, first paragraph, please revise the sentence "*This means that you will be likely to receive compensation from Boehringer Ingelheim Pty Limited, unless your injury is serious and not just temporary*"
- item 15 in the pharmaco-genomic patient information sheet, "*additional scientific study may be done*" is too open. Please be more specific and include limits to the use. For example, "in relationship with diabetes and this medicine"
- please include Maori contact information

- The Committee requested the following changes be made to the Consent Form:
    - on letterhead

<u>Decision</u>

This application was *provisionally approved* by consensus, subject to the above amendments being addressed, and a resubmission of the revised versions of the PIS and CF.

This following information will be reviewed, and a final decision made on the application, by Mr Kerry Hiini.

3	**Ethics ref:**	**12/NTA/66**
	Title:	Phase 2 study for Safety, Efficacy, PK, PD of ASKP1240 vs Placebo in P
	Principal Investigator:	Dr Chris Wynne
	Sponsor:	Astellas Pharma Global Development, Inc (APGD)
	Clock Start Date:	25 October 2012

Dr Chris Wynne was present by teleconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

No potential conflicts of interest related to this application were declared by any member.

Summary of ethical issues

The main ethical issues considered by the Committee were as follows.

- Dr Wynne clarified that he will check with his research manager regarding the progress of Maori consultation/review of the study.

- The Committee noted that results may be restricted and questioned whether "negative" data will be included in the publication of results. Dr Wynne clarified that the restrictions regarding the publication of results are solely for commercial/proprietary reasons.

- The Committee was concerned that there might be risk to participants, particularly those in the placebo arm, that psoriasis may worsen as participants are required to stop all other forms of treatment. Dr Wynne clarified that:

    - most of the participants who enrol in the study would have given up on other treatment options due to the hard-to-treat nature of psoriasis
    - the study is short (duration)
    - study clinicians can and will withdraw participants if it is no longer in their best interest to be involved with the study
    - participants can withdraw from the study at any time to pursue other treatment options

- Please clarify if you will be screening for health information. R.2.1 states 'no' but p.3.1 states that the "CCST database" will be used for recruitment, which suggests health information will be reviewed/screened.

- Please consider de-identifying any data held beyond the end of this study and outside the legal requirements for retention of data. Please document this in the PIS/CF

- The Committee requested the following changes be made to the Participant Information Sheet:
    - please reword the "purpose" (page 2) to reflect what is in the protocol
    - it is not acceptable that there is no expiration date regarding the release of protected health information (PIS, page 19 – states a minimum of 15 years). Page 14 of the

application (b.4.4 and b.4.4.1 states that data may be made available to other researchers that is potentially identifiable (r.2.4.1).

  - Please clarify what is intended here.
  - There needs to be a definitive time framework, for example, a *maximum* of 15 years.
  - There needs to be a limit on the consent of future research in the PIS/CF to, for example, studies related to psoriasis and at the very least make it clear to participants (consent) that health information is stored in a way that is potentially identifiable.

- please clarify if the answer to f.3.1 should be a yes.

- The Committee requested the following changes be made to the Consent Form:
  - the genetic consent form states that samples will be stored for 15 years. Please also state that sample will not be returned and will be destroyed at the end of this period.

<u>Decision</u>

This application was *provisionally approved* by consensus, subject to the above amendments being addressed, and a resubmission of the revised versions of the PIS and CF.

This following information will be reviewed, and a final decision made on the application, by Ms Michèle Stanton.

4	**Ethics ref:**	**12/NTA/67**
	Title:	How do older adults cope with a diagnosis of mild cognitive impairment
	Principal Investigator:	Ms Alison Mckinlay
	Sponsor:	Massey University
	Clock Start Date:	25 October 2012

Ms Alison Mckinlay was not available for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

No potential conflicts of interest related to this application were declared by any member.

Summary of ethical issues

The main ethical issues considered by the Committee were as follows.

- Please clarify what is meant by a "*mild and often tenuous diagnosis*" (a.1.6.). What exactly does that mean? And is that true? The protocol seems to suggest that patients will not be interviewed unless they have definitive cognitive impairments.

- Information obtained, during the interview, from an individual, an individual and a support person and a support person alone, could be quite different. How does the study design take these potential differences into account?

- Consent should be obtained from the participant for a named support person(s). And since the support person will be providing information, consent should be obtained from them as well. Therefore an additional PISCF for the support person(s) is required.

- Please clarify who will be transcribing the interviews and the confidentiality arrangements.

- Consider including an option for participants to review the interview transcripts.

- The participants described in clause 9 of the study protocol (page 9) should be excluded from the study as not being able to give true informed consent.

- Please specify the actual source of patient referral. Please also provide assurance regarding appropriate consultation and approval processes for these referrals.

- Please clarify transport arrangements - the Committee notes that interviews will be carried out in Wellington. Will the CI be going to Wellington, or will interviews in Wellington be conducted by someone else?

- The Committee requested the following changes be made to the Participant Information Sheet:
    - interview times should be consistent between the study protocol and the PISCF i.e. 60 minutes or 60-90 minutes
    - please state that the interview is going to be recorded and transcribed

- please simplify and soften the tone/language of the PIS (e.g. ACC compensation, page 2 – rights of the participants "*Though not expected, if any ill effects or threats to your health…*"), especially given the targeted participants
- please state that the interview tapes are going to be destroyed. Please also consider destroying the tapes shortly after they have been transcribed
- please include information on the counselling and psychological services

- The Committee requested the following changes be made to the Consent Form:
    - will interpreters be made available if required? If so, please include a request for interpreter at the beginning of the consent form
    - please change all instances of "experience memory difficulties" to Mild Cognitive Impairment.
    - please itemise/include individual consent clause "e.g. I consent to having the interview recorded etc)

Decision

This application was *provisionally approved* by consensus, subject to the above amendments being addressed, and a resubmission of the revised versions of the PIS and CF.

This following information will be reviewed, and a final decision made on the application, by Ms Susan Buckland, Ms Shamim Chagani and Associate Professor Wayne Miles.

5	**Ethics ref:**	**12/NTA/68**
	Title:	Avian Flu Vaccine Study in Healthy Elderly Subjects
	Principal Investigator:	Dr Simon Carson
	Sponsor:	
	Clock Start Date:	25 October 2012

Dr Kerr was present by teleconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

No potential conflicts of interest related to this application were declared by any member.

Summary of ethical issues

The main ethical issues considered by the Committee were as follows.

- The Committee notes that SCOTT approval and Maori review/consultation is pending.
- Please clarify why there are no formal data safety arrangements? The Committee feels that it is unusual for a study such as this one not to have an independent DSM. Please justify.
- Please clarify why "other" is chosen for question r.3.11. Tissue samples will not be returned and will most probably be disposed of (incinerated) at the lab site. Dr Kerr will check with the sponsor and update the Committee accordingly.
- Please clarify how independence will be ensured when recruiting participants via the method described in r.5.6 (page 20) of the application.

- The Committee requested the following changes be made to the Participant Information Sheet:
  - please provide information on the tissue samples (e.g sent overseas, storage and disposal arrangements)
  - the Committee looks forward to receiving your own version of the study PISCF (for the New Zealand participant), on letterhead, and not just a copy of the Novartis consent form.

- The Committee requested the following changes be made to the Consent Form:
  - please include the Health and Disability Commissioner and Maori contact details
  - please add (under compensation) that there will be no ACC cover for participants
  - please itemise/include individual consent clause "e.g. I consent to having the my tissue samples sent overseas etc)
  - please state that data will only be stored for 15 years.

- please include the above four points/information in the amended PIS as well
- please itemise/include individual consent clause “e.g. I understand the compensation provisions for this study”
- please include a request for interpreter at the beginning of the consent form

Decision

This application was *provisionally approved* by consensus, subject to the above amendments being addressed, and a resubmission of the revised versions of the PIS and CF.

This following information will be reviewed, and a final decision made on the application, by Ms Michèle Stanton, Ms Shamim Chagani and Associate Professor Wayne Miles.

General business

1. The Committee noted the content of the "noting section" of the agenda.

2. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

Meeting date:	04 December 2012
Meeting venue:	Novotel Ellerslie

3. **Problem with Last Minutes**

   The minutes of the previous meeting were agreed and signed by the Chair and Co-ordinator as a true record.

4. **Matters Arising**

   Ms Michèle Stanton would like to notify the Committee that she will also be a member of the UNITEC ethics committee from 21 November 2012 and would like this declaration of interest known for all subsequent HDEC meetings.

5. **Other business**

6. **Other business for information**

7. **Any other business**

The meeting closed at 17:15.