National Research Ethics Advisors' Panel

A meeting of the National Research Ethics Advisors' Panel was held on:

Date: **13 October 2010**
Time: **14:00 – 17:00**

Venue: Conference Room
Indian YMCA
41 Fitzroy Square
London W1T 6AQ

MINUTES

Present:

Andrew George (Chair)
Jeremy Butler
Hugh Davies
Caroline Harrison
Peter Heasman
John Saunders
Richard Tiner
Art Tucker
Charles Warlow
Simon Woods

In attendance:

Dr Janet Wisely
Mr Clive Collett (NREAP Manager)

1. Apologies: Sarah Dyer; Nalin Thakker; Frank Wells; Sue Wilson
2. Declarations of Interest

   There were none
3. Minutes of meeting held on 08 September 2010

   The minutes of the previous meeting were agreed as a true record.

4. Matters Arising

4.1 NREAP/AREC Response to the AMS second call for evidence – Final Version

- Received for information only: NREAP/AREC Response to the AMS second call for evidence

4.2 Ethical review of student research: guidance for students, supervisors and Research Ethics Committees.

- Received for information only: Final NRES paper "Ethical review of student research: guidance for students, supervisors and Research Ethics Committees"

4.3 Single Issue SHED - Issue 1 "Time to consent: do we need to delay decisions about participation in research or should the patient have the right to choose to make an immediate or a deferred decision?"

Received for discussion:

- Letter from NREAP Chair/NREAP: "NRES Shared Ethical Debate: Single Issue Debate.
- Original NRES document "NRES Shared Single Issue Ethical Debate"

At the September meeting: The panel endorsed the original paper and agreed that an NREAP paper based on this should be drafted for discussion with a view to issuing NREAP guidance without further consultation.

CC redrafted the original paper ('Letter from NREAP Chair/NREAP: "NRES Shared Ethical Debate: Single Issue Debate') but upon reflection wished to present several further options to the panel.

The panel were asked to consider the following options for further action:

1) Following discussion by the panel; issue the redrafted paper as NREAP "guidance".

2) Do not issue as formal NREAP "guidance" but issue as a "letter from NREAP Chair/NREAP" attaching either the original NRES SHED document or amended document making clear that this was an NRES document being circulated by the Panel.

3) Do not issue as formal NREAP "guidance" or "letter". NRES to issue either the original document or an amended document based on the revised document including the following NREAP statement:

> "The NREA Panel note the outcome of the shared ethical debate detailed in the attached document and agree that there are no easy answers regarding the time that should be allowed for potential participants to consider taking part in research. Each study should be considered on its own merits."

The panel discussed the circulated documents and agreed that there was a need for the conclusions of the NRES document to be circulated as there appeared to be a widespread belief amongst RECs that allowing participants a minimum of 24 hours to consider their participation in a study was the default time and was supported by existing guidance. This was not the case and the panel agreed that each study should be considered on its own merits.

Agreed:

1. The panel agreed to issue a 'Letter from NREAP Chair/NREAP' endorsing the 'NRES Shared Single Issue Ethical Debate' document. This document would highlight and endorse the conclusions reached but instead of including the document with the letter would simply reference the NRES document.

Action: CC

5. **NRES Update – Janet Wisely**

- JW informed the panel that the WHO has agreed to use the research summaries produced by NRES. In addition, the NHS Choices website has a link to the WHO site. This will promote greater awareness and wider access to the published research summaries.

- JW would meet with Dr Rustam Al-Shahi Salman next week to discuss his proposal for a research project which would investigate the 'efficacy' of the currently piloted proportionate review system by treating NRES ethical review as a 'public health intervention' amenable to investigation by a randomised controlled trial.

- JW had recently returned from China where she had positive discussions involving the setting up of an international "Shared Ethical Debate" exercise involving China, Norway, the UK and possibly Belgium. She would update the panel on the details of this initiative at a future meeting.

- JW reported that the service provided by NRES was currently "under strain" because of delays to decisions affecting its future operation. The panel expressed its concern and asked for the current NRES risk register to be forwarded to AG. JW agreed that this would be provided to the Chair. The panel expressed their support for NRES staff during these current uncertainties.

6. Post-Trial Access to Treatments: Issues, Current Guidance and a Draft Framework For RECs – Prof Penney Lewis/Dr Neema Sofaer/HD

Prof Penney Lewis and Dr Neema Sofaer from King's College, London gave a presentation to the panel on the issue of post-trial access to treatments.

Received for discussion/advice without further consultation:

- Draft Post-Trial Access to Treatments: Issues, Current Guidance and a Draft Framework For RECs
- Questions to consider when reading "Post-trial access to treatments: Issues, Current Guidance and a Draft Framework for RECs
- For information: Letter from Janet Wisely to REC Chairs on continued treatment for research participants at the end of a clinical trial dated 13 March 2008
- For information: ADPH & FPH Statement on the responsibility for ongoing funding of experimental treatments for patients who have participated in commercially funded research dated 11 December 2007

Dr Neema Sofaer explained that the draft document was intended to help NHS RECs address the issue of post-trial access (PTA) to trial treatments and that its development was funded both by the Wellcome Trust and NRES. Previous drafts had been reviewed by different groups of REC members and chairs at three NRES meetings. It was envisaged that a further consultation meeting would be held with REC chairs and members (on 24 November 2010), and that this would be followed by an independent workshop bringing together various stake-holders in research, to be held at KCL's Centre of Medical Law and Ethics in January 2011.

The panel discussed the draft document with Professor Lewis and Dr Sofaer and made a number of comments. It was generally felt that the current document could be seen to imply that post-trial access to investigational treatments was always to be desired, however the panel felt that both pragmatic and ethical concerns meant that the issue of PTA for each study would need to be examined on a case-by-case basis. RT emphasised that the stage of development of the drug in question would be of prime importance. He explained that only around 50% of investigational medicinal products (IMP) investigated in phase 2 studies eventually reach the market and therefore it would be inappropriate to provide post-trial access to a drug at a stage where its efficacy was still unknown and indeed may never be licensed (or possibly even withdrawn for safety reasons). The panel agreed that as the development of an IMP progressed towards being licensed then the issue of PTA becomes less controversial as the efficacy of the product and risks associated with its use become known.

Professor Lewis and Dr Sofaer welcomed the committee's comments and would be happy to receive further feedback from the NREAs.

7. NREAP Strategic Themes

- Discussed: The panel were invited to suggest new strategic themes/issues to take forward with a view to issuing NREAP guidance.

It was agreed that any suggestions for new strategic themes/issues should be e-mailed to either AG or CC

8. NREA-Hosted Chairs Network Meetings

The panel has previously agreed that NREAs would facilitate and host 'chairs network meetings' in their local patches. It is envisaged that these meeting will take place in the near future.

- Discussed: The panel were invited to suggest and discuss possible agenda items for these meetings

The following suggestions were made:

- Translation of information sheets (JS)
- Post-trial access to treatments (RT)
- Time to consent (CH)
- Public involvement in the design of trials (IRAS Q14.1) (JB)
- How is "research" defined? (JS)

PH felt that the network meetings needed to be well structured and have clear objectives for each meeting. He also suggested that a register should be set up so that items could be "opened", discussed and "closed" following a pre-agreed outcome. AG agreed and suggested that there should be a maximum of two items per meeting (unless there were good reasons to increase this). A number of items could be presented to local chairs who would then choose, in discussion with the host NREA, which items should be taken forward for discussion at the meetings.

9. 2nd World Conference on Research Integrity 2010 Leadership Challenges and Responses – Singapore Statement

Received for information only:

- 2nd World Conference on Research Integrity 2010 Leadership Challenges and Responses – Singapore Statement

The panel noted and welcomed the Singapore statement on research integrity.

10. Call to Include Pregnant Women in Clinical Trials (Clinical Research and Clinical Quality Assurance Advisor, 20 September 2010)

- Received for discussion: An article from the 'Clinical Research and Clinical Quality Assurance Advisor' on the issue of involving pregnant women in clinical trials*

The Advisor article cited two separate articles in the NEJM and Nature which can be accessed at:

http://www.nejm.org/doi/full/10.1056/NEJMp1003462 and

http://www.nature.com/nature/journal/v465/n7299/full/465689a.html

The panel noted the article and expressed the view that there was a large amount of data produced regarding medicines used in pregnancy outside of clinical trials but that this data was not adequately harvested to provide useful evidence to inform future treatment decisions. It was acknowledged that trials involving pregnant women were fraught with difficulties and therefore there was a need to "think outside the box" in order to use the existing clinical data to inform treatment options for pregnant women.

11. **Proportionate Review Service: an assurance framework - HD**

- Received for endorsement: Proportionate Review Service: an assurance framework (Final Version)

The panel endorsed the final version of the "Proportionate Review Service: an assurance framework"

12. **Any Other Business**

13. **Date of Next Meeting:**

The next meeting of the National Research Ethics Advisory Panel will be held on 10 November 2010.

Time: 14:00 – 17:00.
Venue: Jubilee Room
Indian YMCA
41 Fitzroy Square
London W1T 6AQ