Health Research Authority
National Research Ethics Service

National Research Ethics Advisors' Panel

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

Date: 09 May 2012
Time: 14:00 – 17:00

Venue: Room 128A
Health Research Authority
National Research Ethics Service (NRES)
Skipton House,
80 London Road,
London SE1 6LH

MINUTES

Present:

Hugh Davies (Chair)
Sarah Dyer
Caroline Harrison
Peter Heasman
John Saunders
Nalin Thakker
Richard Tiner
Frank Wells
Simon Woods
Jeremy Butler

In attendance:
Mr Clive Collett
Janet Wisely

1. Apologies: Andrew George; Art Tucker; Sue Wilson

2. Declarations of Interest

   There were none

3. Minutes of meeting held on 14 March 2012

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

4. Matters Arising

4.1 National Research Ethics Advisors' Panel (NREAP) New Terms of Reference

Received and noted for information:

- National Research Ethics Advisors' Panel (NREAP) New Terms of Reference

The revised NREAP terms of reference were approved by UKECA on the 15th March 2012. These emphasise the panel's role in helping research ethics committees deliver robust, consistent and fair decisions. The primary focus of the panel will be on engagement and consultation with all stakeholders, including RECs, with an interest in health research to inform and deliver appropriate guidance and training to the REC community.

The panel will meet less frequently, every 3 months rather than monthly, with current NREA appointments running until September 2012 when appointments to new NREA posts will be made following open advertisement.

The NREAP Manager, Clive Collett, now provides secretariat support for the panel on a full-time basis.

5. **HRA Update – Janet Wisely**

JW informed the panel that interviews for the Chair of the HRA would take place later this month and that the interviews for the HRA Chief Executive would take place on 11 June. JW has applied for the Chief Executive position.

Shaping an effective national role for the HRA:

JW explained that it has been agreed with DH that whilst the HRA would not be directly responsible for R&D governance it would have a role in describing, communicating and facilitating R&D governance. The HRA has been tasked with coordinating and leading work on the harmonisation of R&D processes.

As part of this harmonisation work it has been agreed that from June Q.23 ("Authorisations") in the IRAS Site-specific information form, which required a number of signatures, should be replaced with a question that asks applicants to indicate whether they had contacted their local R&D departments with regards setting up the study locally. Signatures would no longer be required for this section. JW also commented that R&D departments do not differentiate between "minor" and "substantial" amendments in terms of their procedures. It is proposed that the HRA lead on work to redefine amendments as either "notifiable" or "non-notifiable" changes.

JW also explained that the introduction of the "favourable opinion with conditions" category had caused some problems for R&D offices as the version number of documents submitted to them would often be at variance with the version numbers that were indicated on the REC favourable opinion letter. In order to deal with this it is proposed that a new category of provisional opinion is introduced which may be delegated to the coordinator to sign off and issue the approval letter where the changes requested are simply administrative and would result in a change to the document version number.

JW also stated that from June NRES would use the IRAS Project number as well as the NRES REC number to identify studies as it become apparent that different numbers were being used by different R&D offices and other stakeholders. She explained that she and HD had recently met with Prof. Doug Altman (Director of CSM and Cancer Research UK Medical Statistics Group and co-convenor of the statistical Methods Group of the Cochrane Collaboration) and had had useful discussions regarding the possibility of a universal study title to support robust systematic review.

JW noted that there were often discrepancies between what applicants had written in the IRAS form and what was written in the information sheet and other documents. As part of the initiative to explore whether research may be reviewed ethically by reviewing the documents actually used to carry out the research e.g. protocol etc, it was explained that NRES would look at whether REC members could be trained to review the research protocol directly. This would be complemented by guidance to researchers on how to write appropriate protocols.

JW explained that there was some work to be done in terms of the provision of a platform for the unified approval process from IRAS as not all NHS research currently goes through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP).

A letter would be sent out shortly to all chairs giving them a "heads up" on the themes emerging from the “shaping an effective national role for the HRA” group.

HD asked JW how the panel could assist in shaping this vision of an effective national role for the HRA. JW said that the panel could assist in helping RECs focus on the ethical issues involved in research and not get bogged down in trivial issues that were often outside of their remit. The panel can help by facilitating discussion amongst committee members on differing ethical positions and then issuing definitive guidance on these issues which all RECs would be expected to follow. I.e. there was a need for a more corporate approach from RECs.

HD summarised this approach as being based on two principles:

1) Engagement with RECs followed by
2) Issuing prescriptive guidance.

The panel broadly agreed with this approach. SiWo commenting that prescription is fine provided one is confident that what is being prescribed is good. JB noted that there was significant variation in ethical opinions and that there was a real need to address this in order to promote greater consistency. CH felt that the panel should be as prescriptive as possible but felt that such prescriptive advice should not be given in contentious areas where there was a lack of clear ethical consensus.

HD felt that there were three main channels by which NRES and the panel might address consistency:

- NREA-hosted chairs network meetings;
- Appraisal of RECs and
- the Shared Ethical Debate (ShED) exercises.

AGREED: the panel supported the initiatives described by JW in seeking to achieve an effective national role for the HRA. The panel recognised a role for the NREAs in promoting consistency of ethical opinions through fair and reasonable prescription.

6. **Shared Ethical Debate (ShED) Cycle 8 “Phase 1”– Hugh Davies**

Received for Information/Discussion:

- Report: An analysis of 21 Research Ethics Committees’ review of a study investigating multiple ascending doses of “AZD7687”
- Shared Ethical Debate QA Audit Report
- Collated Minutes for Exercise 8 (phase 1)
- PowerPoint Presentation

The panel welcomed the report and its conclusions which it felt were valuable. However, the panel wondered whether the ShED exercises were continuing to unearth new lessons or whether the same issues were cropping up each time and that the issue now was to decide how to translate these lessons into effective training.

HD explained that he proposed to produce a powerpoint presentation summarising the findings from the ShED (viewing the powerpoint and taking part in the following discussion would count towards the member’s training requirement). This would point out where there was agreement and disagreement and where RECs had appeared to step outside of their remit. It was hoped that the use of video presentations, which could be shown to REC members at REC meetings, would help to spread the lessons learned to all members. The panel welcomed the idea of video presentations and ask HD to provide a video presentation for comment at the next meeting.

PH commented that the outcome of this particular debate would be well suited for inclusion in phase I training days organised by NRES.

JB considered that he felt that the majority of the issues identified by RECs taking part in this ShED fell into two categories: i) safety and ii) issues with the participant information sheet. He noted the significant variation in comments and felt that it was important to engage with chairs, who were key to the promotion of consistency, to understand where this variance was coming from. He felt that attendance by chairs at the NREA-hosted chairs network meetings was paramount. Such meetings were important to facilitate a common understanding and approach to ethical issues.

JS asked whether Chairs in England were afforded appropriate time by their employers to carry out their duties. HD explained that the support given to chairs, in terms of time to carry out their duties, by the NHS and other employers was variable. RT explained that he had raised the issue of release of NHS staff to take part in RECs with Sally Davies and she referred him to a letter that had been published addressing this issue. He indicated that Sally Davies confirmed that the letter also applied to taking part in research ethics committee work. He would forward this letter to CC.

JS asked whether chairs accept responsibility for the education of their members. PH explained that the educational role is one of the better parts of being a chair and that he found it an inspiring, positive and enjoyable role. SiWo agreed but stated that the involvement of chairs in ensuring that members were appropriately trained was variable.

AGREED:

- Consideration should be given to reducing the frequency of ShED exercises whilst promoting greater follow up and feedback from RECs.
- Consideration should be given to how the learning points may be better communicated to all REC members.
- The outcomes and learning points from the ShED reports should be included in relevant NRES training days.
- The NREA hosted chairs network meetings were an important forum for promoting consistency by ensuring that the learning points coming out of ShED were communicated to and debated by chairs.
- The panel welcomed the idea of using video presentations to distribute the learning outcomes arising from the shared ethical debates. HD would provide the video presentation for comment at the next meeting.

ACTION: HD

7. **Confidentiality, Privacy and Secrecy – Hugh Davies**

The panel were invited to comment on this draft guidance addressing the issue of 'Confidentiality, Privacy and Secrecy'

Received for Discussion:

- Confidentiality, Privacy and Secrecy

SiWo felt that important foundations regarding data protection were missing i.e.

1) The Data Protection Act
2) Common law
3) EU legislation

He also felt that there were issues that might need to be addressed regarding the increasing use of cloud-based data storage. He felt that the use of a flow diagram might be useful in guiding the questions that RECs might need to ask although he recognised that this might be somewhat complicated.

RT noted that there was an existing ABP I document on secondary use of data which included an algorithm that might be useful to incorporate into this guidance. RT would e-mail this to CC. He also noted that the NHS Future Forum's report on "information" was also a useful document which may be helpful to refer to in the drafting of this guidance (http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_132086.pdf)

JS said that the redrafted guidance should focus on what REC members actually need to know. RT stated that he had met the previous Information Commissioner who had suggested that anyone processing data should always ask themselves the question "do I need to know who the person is?". If the answer to this question was "no" then the data should be anonymised or pseudo-anonymised. He noted that RECs should always ask this of researchers proposing to use identifiable data.

AGREED: the draft document should be rewritten by in the standard NREAP guidance format CC taking into account the panel's comments with a view to future publication.

ACTION: CC

8. Chair - Coordinator Relationship/Remote Working

At a recent panel meeting, the issue was raised of how the chair/coordinator relationship was affected by some coordinators being based at regional centres remote from the REC and the Chair.

Received for information only:

- Comments from Prof Wellman (Chair); Dr Lorraine Lighton (Chair) and Miss Shehnaz Ishaq (coordinator)

The panel noted that the comments were generally positive regarding the remote working relationship of chairs and coordinators and were pleased to note that remote working appeared to raise few practical difficulties.

9. NREA-Hosted Chairs network Meetings - Minutes

Received for information only:

- Minutes of the East Midlands NREA-Hosted Chairs Network Meeting held on 16 April 2012

The panel noted the minutes and raised the general question of whether attendance at the NREA-Hosted Chairs Network Meetings should be deemed to count towards chairs and vice chairs training record. CC agreed to raise this with the HRA training Department.

10. NRES Appeals Register

Received for information only:

- NRES Appeals Register April 2011 – March 2012

11. Action Register

Received for information:

- NREAP Action Register – Live and Closed items

It was noted that the item "The Ethics of Transplantation Research: current guidance and a framework

for review" could now be closed.

12. **Research Integrity Concordat - Universities UK**

Received for information/discussion:

- Draft "Research Integrity Concordat"

"Universities UK has been working with the Higher Education Funding Council for England (HEFCE), Research Councils UK (RCUK), the Wellcome Trust and government departments to develop a concordat to support research integrity.

The concordat outlines five important commitments that those engaged in research can make to help ensure that the highest standards of rigour and integrity are maintained. It also makes a clear statement about the responsibilities of researchers, employers and funders of research in maintaining high standards in research.

Invitation to comment

To inform the development of the concordat we would like to invite your organisation to provide feedback on the current draft. We are interested in any feedback you are able to provide, but particularly your views on the four specific areas (see "invitation to comment). The consultation phase will be open for a period of six weeks, from Friday 30 March 2012 until Friday 11 May 2012."

The panel welcomed and fully supported the commitments put forward in this document but felt that it was not necessary for the panel to comment on the current draft. The panel recognised the importance of research integrity in promoting trust in healthcare research and acknowledged that further work is needed to define proportionate regulatory systems to monitor misconduct and fraud in research and investigate possible breaches of research integrity.

13. **International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) announced an expansion of its Code of Practice**

Received and noted for information:

- IFPMA News Release
  http://www.ifpma.org/fileadmin/content/News/2012/FINAL_IFPMA_Press_Release_-Code_of_Practice_1_March_2012.pdf

- International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Code of Practice
  http://www.ifpma.org/fileadmin/content/Publication/IFPMA_Code_of_Practice_2012.pdf

14. **Any Other Business**

14.1 RCP Guidelines on the practice of ethics committees in medical research with human participants

JS asked the panel whether the panel would wish to be involved in a possible revision of the Royal College of Physicians "Guidelines on the practice of ethics committees in medical research with human participants" last revised in 2007. The panel agreed that JS should bring a discussion paper highlighting the key questions he would wish to be addressed by the panel to the next meeting in June where it would be discussed as a major agenda item.

ACTION: JS

14.2 Insurance for Participants in Clinical Trials

FW wish to raise this issue as a marker for possible future discussion.

It was noted that the DH were about to publish "Guidance Developed by ABPI, BIA, and CCRA in Consultation with the Department of Health and The National Research Ethics Service (Phase 1 Clinical Trials)" and it was felt impractical to discuss this issue further until this had been issued. HD asked CC to ascertain whether the document had been published.

ACTION: CC

14.3 Meeting announcements

HD informed the panel of the following meetings:

"Quantitative clinical trials" HRA meeting

- 3 October 2012.

"Revising guidance on Participant Information Sheets and consent":

- Tuesday, 22 May 2012 – Edinburgh – Victoria Quay
- Wednesday, 20 June 2012 – London – Skipton House
- Tuesday, 26 June 2012 – Manchester – North West REC Centre

14.4 July Meeting

It was noted that the panel meeting scheduled for 11th July 2012 might need to be cancelled as the HRA were not normally holding meetings in London during July because of the Olympics. The panel asked CC to find out whether this meeting would still be taking place.

ACTION: CC

Post meeting: CC confirmed that this meeting would still take place as it was taking place some time before the Olympics opening ceremony and did not involve overnight accommodation for the attendees.

15. Date of Next Meeting:

The next meeting of the National Research Ethics Advisory Panel will be held on 13 June 2012.

Time: 14:00 – 17:00
Venue: Room 133B Skipton House
Health Research Authority
National Research Ethics Service (NRES)
Skipton House,
80 London Road,
London SE1 6LH