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

Date: **14 April 2010**
Time: **14:00 – 17:00**

Venue: **Room 4, Friends House**
Quaker Building
Euston Road
London NW1 2BJ

MINUTES

Present:

Andrew George (Chair)
Jeremy Butler
Hugh Davies
Peter Heasman
John Saunders
Nalin Thakker
Charles Warlow
Frank Wells
Sue Wilson
Simon Woods

In attendance:

Dr Janet Wisely
Mrs Patricia Douglas
Mr Clive Collett (NREAP Secretary)

1. **Apologies:** Richard Tiner; Sarah Dyer; Art Tucker
2. **Declarations of Interest**

   There were none
3. **Minutes of meeting held on 10 March 2010**

   The minutes of the previous meeting were agreed as a true record.
4. **Matters Arising**

4.1 **Equality and Diversity Training**

Janet Wisely (JW) reiterated that online equality and diversity training currently available to REC members is also available to NRES panel members. Panel members wishing to access this training should contact Hilary Tulloch (hilary.tulloch@nres.npsa.nhs.uk)

4.2 **Disclosing Information about a Research Participant without Consent and Appropriate Action for a Researcher when Seeing Poor Practice.**

Hugh Davies (HD) told the panel that he had had discussions with GH regarding the process of dissemination of NREAP guidance and that they were in the process developing a standard template and the letter would be issued shortly

Action: CC

4.3 **Christopher Roy-Toole - email correspondence**

Clive Collett (CC) informed the panel that he had contacted Christopher Roy-Toole by e-mail regarding communication with NREAP referred to in e-mail correspondence with JW but that he had not yet received a reply.

5. **Independent Review of the Regulation and Governance of Medical Research:** Janet Wisely

JW presented her initial draft of NRES's evidence to be presented to the working group of the Academy of Medical Sciences undertaking the review of the regulation and governance of medical research.

JW informed the panel that she assumed that she would be called to give evidence to the review body in person but it was also possible that written evidence would be asked for. NRES would give evidence to the review. The NREAs may wish to submit separately; however she suggested that the panel might wish to submit evidence together with AREC who are in full support of NRES and their presentation to the Academy. John Saunders (JS) explained that whilst he was the adviser designated to liaise with AREC he had not yet had any contact with them. JW said that she would contact the chair of AREC (Mr David Anderson-Ford) in order to facilitate the attendance of JS at the next AREC Council.

JW welcomed suggestions from the panel for changes to the presentation:

JS felt that more should be made of the international dimension e.g. how the UK compares with other EU countries.

FW echoed this and explained that the UK ethical review system was well ahead of our European neighbours and that NRES should be justly proud of its achievements. In addition the introduction of IRAS (Integrated Research Application System) had given the UK a huge advantage. He felt that the review should address the lack of cohesion between NHS trusts which was the largest hurdle to performing research in this country. It was felt that the presentation to the Academy should differentiate between the R&D governance and the much transformed ethical review process.

Nalin Thakker (NT) felt that it was important to state that the main aim of ethical review was to protect patients and that any review of the process should not simply focus on the research governance process solely from the point of view of researchers.

JB acknowledged the huge improvements that had been made to the ethical review process but stated that many of these advantages would have little effect if there were not also corresponding changes in the R&D system. He suggested that NRES had a "pathfinder" role. JW agreed that many of the positive changes in NRES might not result in an overall benefit for research in the UK if developments were not made in partnership with others, particularly NHS R&D.

HD wished to emphasise that any perceived inconsistency in the ethical review system was an "urban myth". The latest shared ethical debate (SHED) project showed that the RECs taking part were all in agreement on the major ethical issues with 18 out of the 19 committees agreeing to give an 'unfavourable opinion' to the SHED application. It was though acknowledged that were inconsistencies on how decisions were presented and level of detail asked to be addressed in use of favourable, favourable with conditions and provisional opinions.

Agreed: The panel fully supported and endorsed the presentation by JW and its robust defence of the many positive improvements brought about by NRES.

6. **Localism, Expertise and Coupling:** Prof. Adam Hedgecoe, Associate Director ESRC Centre for Economic & Social Aspects of Genomics (Cesagen), Cardiff University

Prof Adam Hedgecoe presented his talk "Localism, Expertise and Coupling" which was warmly received by the panel.

The panel welcomed his assertion that RECs are good at meeting their timelines. His research data showed that comments inferring that the ethical review of research took too long were simply not justified by the facts. However, he sounded a note of caution for any push to reduce timelines beyond the current committee average of around 35 – 40 days. In doing so he echoed the comments of an MPA scientist interviewed by Abraham & Lewis in 1995:

> "Instead of competing, let's make the best evaluations instead of the quickest ones".[1]

7. **"Significant Outliers":** Mrs Patricia Douglas, NRES Interim Change Manager

Mrs Patricia Douglas briefed the panel on ongoing work looking at the consistency of decisions. The Panel welcomed such work, and Sue Wilson (SWi) agreed to help Patricia with the analysis. It was also noted that care should be taken in the use of any such analysis, though it would probably be appropriate, once the work is completed, to disseminate to Chairs.

Agreed: The panel agreed that the data need to be subject to careful statistical analysis. Sue Wilson would assist Patricia Douglas in the analysis of the data.

Action: SWi

8. **NHS Research Facilitators**

- Received and considered: DH Draft Implementation Plan "Patient and Public Awareness: Approved NHS Research Facilitators"

Due to pressure of limited time at this meeting the panel agreed to defer consideration of this item until the next meeting.

9. **Publishing a summary of applications:** Hugh Davies

- Received and considered: "Publishing a summary of applications to Research Ethics Committees in the UK: a contribution to accessible, safe research and better treatment"

SWi asked HD who the audience was for this and the 'Developing Proportionate Ethical Review of Research' paper. HD replied that these were intended for feeding back to RECs.

HD explained that initially only studies given a favourable opinion will be summarised on the NRES website, however eventually a summary of all studies will be required alongside the REC summary of opinion.

Charles Warlow (CW) felt that this would represent a huge number of studies and the published data would need to be made searchable in order to be of most use. JW explained that this was simply the first step in the process and that this information could be made available to organisations such as NHS Choice who were better placed to present the data in a more easily accessible form.

[1] Interview with MPA scientist, 2/8/95 from Abraham & Lewis (1999) Social Science & Medicine 48: 1655-1667 at 1661

Agreed: The panel agreed that the paper could be disseminated in its current form.

10. **Developing Proportionate Ethical Review of Research:** Hugh Davies

- Received and considered: "Developing Proportionate Ethical Review of Research"

JS felt that there were issues regarding 'Research Type III' presented in table 1 of the paper. This stated that "Research using "extra tissue" (e.g. further blood taken at time of routine sampling or tissue taken at "clinically directed" operation)" is suitable for proportionate review. JS stated that researchers often confidently state that such tissue is indeed clinically directed but that in reality the clinical need to take this tissue was often controversial and not always considered 'best practice' by other medical professionals. He felt that this meant that this category was not as simple as the classification suggested and not suitable for proportionate review.

JW emphasised that this table of classification of 'Research Types' was still in the pilot phase and would need to be signed off by NREAP before rollout. More information on this particular category and its incidence in the pilot would be fed back to the panel.

Andrew George (AG) commented that the issue highlighted by JS may well be the primary ethical issue related to this type of research and that this could be specifically highlighted in any guidance regarding the use of extra tissue.

JW said that the comments of the panel would be fed back to Liz Clements who was overseeing the proportionate review pilot and that further information regarding category III would be presented to the panel for their consideration before being rolled out.

Agreed: The panel agreed that the paper could be disseminated in its current form but required further information from the pilot regarding studies considered under Research Type III (research using extra tissue).

11. **NREAP Membership**

The panel agreed that extra legal expertise would be of benefit to the Panel and that Clive Collett would organise an interview panel to appoint a suitable member.

12. **Any Other Business**

There was none

13. **Date of next meeting**: The next meeting of the National Research Ethics Advisory Panel will be held on 12th May 2010. Time: 14:00 – 17:00. Venue to be arranged.