National Research Ethics Advisors' Panel

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

Date: **08 June 2011**
Time: **14:00 – 17:00**

Venue: NRES
Ground Floor, 4-8 Maple Street,
London W1T 5HD

MINUTES

Present:

Andrew George (Chair)
Jeremy Butler
Hugh Davies
Caroline Harrison
Peter Heasman
Nalin Thakker
Art Tucker
Charles Warlow
Frank Wells
Simon Woods

In attendance:

Dr Janet Wisely
Mr Clive Collett

1. Apologies: John Saunders; Sarah Dyer; Richard Tiner; Sue Wilson
2. Declarations of Interest

   There were none
3. Minutes of meeting held on 11 May 2011

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

4. MATTERS ARISING

4.1. Annual Review of NREAP Guidance: Disclosure of information about the research participant without consent and appropriate action for researcher when seeing poor practice' (NREAP/01, publication date 22 April 2010)

Following discussion between AG, HD, CC it was decided that the existing guidance would not be updated at this time. The panel were asked to consider:

- The provision of further guidance in the future regarding forewarning of limits to confidentiality

- Increasing the default period for review of NREAP guidance from yearly to every 3 years

AG explained that following discussion with HD and CC that the existing letter to REC Chairs dealt with the issue of whether there was a duty to disclose rather than the wider issue of whether participants should be forewarned that sensitive information gained during research may be disclosed to third parties/authorities and as such did not require updating. However it was acknowledged that this wider issue of the 'forewarning' of participants of the limits to confidentiality was important and might by the subject of subsequent guidance.

SiWo pointed out that the existing letter to REC Chairs was not itself "guidance" but merely pointed towards guidance that was already in existence. He felt that there was a need for more detailed guidance in this area regarding the forewarning of participants. In addition he felt that the panel should be clearer about what any future guidance or communications issued on behalf of the panel are meant to achieve.

PH felt that there might be a compromise position whereby such communications from the panel might include an introductory paragraph on the background to the issue which could explain the position taken by various professional bodies pointing out where there is agreement. This could also explain which aspects of existing guidance the panel explicitly endorse or conversely indicate those areas that the panel do not agree with or feel may be out of date.

Agreed:

It was agreed that the existing letter (NREAP/01) would not be updated at this time and that any future guidance/communications should follow the format suggested by PH. The panel also agreed that advice concerning forewarning of research participants regarding the limits of confidentiality might well be useful.

It was agreed that all guidance issued by the panel would initially be reviewed after one year and then subject to further review every three years.

4.2. **PACE Trial – Text of joint letter calling for more information, 24 May 2011**

Received for information only:

- PACE Trial – Text of joint letter from the ME Association together with the Young ME Sufferers Trust and the West Midlands ME Groups Consortium to Professor Peter D White (investigator, PACE Trial) calling for more information, 24 May 2011 (http://www.meassociation.org.uk/?p=6171)

5. **NRES update – Janet Wisely**

JW informed the panel that the GTAC Secretariat and had now been moved to the Charing Cross site.

The NPSA would now remain the NRES host until transfer to HRA and as such assist with recruitment to business critical posts, continuation of IRAS and IT support functions etc. until 2012 when these functions and NRES staff would transfer to the Special Health Authority prior to the formal establishment of the HRA. NRES were now starting to think more strategically about the future and would present their plans at the joint NRES NMG/NREAP meeting in July. The July meeting would concentrate on the following areas:

- "Nature of REC membership" and
- "Efficiency and proportionality".

6. **HRA Update – Janet Wisely & Stephen Tebbutt**

Mr Stephen Tebbutt (joint NRES/DH secretariat for the Department of Health (DH) Establishment Group) attended this part of the meeting.

JW introduced Stephen Tebbutt and gave a short presentation updating the panel on the establishment of HRA.

JW was asked whom the special health authority would report to. JW replied that she expected the Special Health Authority would report through DH R&D to Professor Dame Sally Davis (Chief Medical Officer for England, Director General of Research and Development and Chief Scientific Adviser for the Department of Health and NHS).

7. **PRS Update – Joan Kirkbride/Stephen Tebbutt**

Received: a presentation and update on the Proportionate Review Service

During the presentation the panel noted that PRS sub committees were able to give an unfavourable opinion where applications were considered to be of "poor quality". The panel wondered whether this might be somewhat misleading as the REC had not considered that the application was unethical but rather that the application was not of sufficient quality to be considered at all. It was suggested that an additional category for such applications might be introduced. JW / JK explained that an unfavourable opinion through full committee may also be based on quality of application and accepted that could be made clearer.

CW questioned whether there should be a minimum level of experience required to be a member of the PRS Sub-Committee. Joan Kirkbride (JK) acknowledged that currently there was no requirement for a PRS member to have attended a specific number of full REC meetings but that generally only experienced members had volunteered to be part of the PRS Sub-Committee. However, she acknowledged that it may be helpful to specify a specific level of experience required in order to be part of a PRS Sub-Committee.

JK explained that she wished to carry out a survey of members involved in the PRS scheme as well as those who were not in order to inform future expansion of the scheme and the categories of research that would be eligible for PRS review. She asked the panel whether it would be useful to ask current PRS members whether they could have made a decision with less documentation than currently provided. The panel were happy for the survey to be carried out and felt that it would be useful to seek the views of PRS members regarding the amount of documentation they would require to reach a decision.

JB asked whether it would be possible to ask RECs to comment on how much of their workload they believed might be suitable for PRS review. JK explained that this information had been gathered some time ago but that this would be useful information to have up to date and might be collected by use of a checklist completed by the co-ordinator.

Agreed:

The panel agreed that it would be sensible for the operations team to explore options for expansion of the PRS review and to undertake a survey to support this.

8. **Framework for Considering Consent in Emergency Research – Hugh Davies**

Received for discussion with a view to issuing NREAP guidance:

- A Framework for Considering Consent in Emergency Research

- Effect of consent rituals on mortality in emergency care research – Roberts et al.[1]
- Background document: Framework for Consideration of Consent Provisions in Emergency Research: Legal Provisions

The National Research Ethics Service stands by the principles evinced in the Declaration of Helsinki and other international guidelines that we should seek consent before participation in research but there are valid ethical exceptions that meet legal stipulations. Emergency research may be one example and a recent report raises important issues in this area. This discussion paper puts forward a framework of questions researcher and reviewer should consider when assessing consent in emergencies.

HD explained that the impetus for the discussion of this item arose from a recent paper by Roberts et al. along with discussions that David Neal and Simon Woods had been having with ICU consultants at St Thomas' Hospital. Whilst legal provisions existed to allow the waiving of consent in specific circumstances it appeared that sponsors, researchers, RECs and NHS Trusts were often not keen to implement these provisions or allow their use in emergency research.

SiWo stated that he was not convinced by the argument put forward by Roberts et al. as he felt that the authors had used evidence that delay in administering the study drug in one trial being deleterious to patients as a basis for arguing that delay introduced by "consent rituals" in a separate trial was itself harmful and to conclude that a delay in administering trial drugs was harmful in all cases. He pointed out that in the case of a 'research' trial any delay introduced by seeking consent was not a delay to 'treatment' as such as at the time of the study it would not be clear whether the study drug was in fact useful as a 'treatment' at all. HD disagreed and felt persuaded by the argument put forward.

Regardless of the merits of the arguments put forward to support the reduction of delays to the recruitment of patients to emergency research HD felt that what was important was the fact that the law allowed for flexibility in such research regarding consent procedures and that the various stakeholders in research needed to be "brave" in allowing consent to be waived in accordance with existing law.

Agreed:

The panel agreed that this issue should be taken forward and that NRES should proceed with this. It was agreed that NRES would consult more widely, host an event and bring a paper back later in the year to the panel

Action: David Neal / HD

9. **Action Register**

Received for information/discussion:

- NREAP Action Register

JW informed the panel that the issue of conflict of interest was often raised by RECs and applicants and asked whether the panel might consider issuing guidance on this matter as a high priority.

The panel agreed that the issue of conflict of interest would be discussed at the August meeting.

10. **Any Other Business**

There was none

11. **Date of Next Meeting:**

[1] The Lancet, Volume 377, Issue 9771, Pages 1071 - 1072, 26 March 2011 (doi:10.1016/S0140-6736(11)60317-6)

The next meeting of the National Research Ethics Advisory Panel will be a Joint NRES NMG/NREAP strategic meeting held on 13 July 2011.

Time: 11:00-12:00 NREAP Meeting
12:15 – 17:00 Joint NRES NMG/NREAP strategic meeting
(Lunch 13:00 – 14:00)

Venue: The Seminar and Learning Centre (SALC 6)
5th floor Sherfield Building
Exhibition Road
South Kensington
London SW7 2AZ