

## National Research Ethics Advisors' Panel

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

**Date:** 10 November 2010

**Time:** 14:00 – 17:00

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

## MINUTES

### Present:

Andrew George (Chair)  
Jeremy Butler  
Sarah Dyer  
Nalin Thakker  
Richard Tiner  
Art Tucker  
Charles Warlow  
Frank Wells  
Simon Woods

### In attendance:

Dr Janet Wisely  
Mr Clive Collett (NREAP Manager)

1. Apologies: Hugh Davies; Caroline Harrison; Peter Heasman; John Saunders; Sue Wilson
2. Declarations of Interest  
There were none
3. Minutes of meeting held on 13 October 2010  
The minutes of the previous meeting were agreed as a true record.

## 4. Matters Arising

### 4.1 NRES Update – NRES Risk Register

Following the panel's request to have sight of the NRES risk register, Andrew George (AG) reported that he had now seen the register and had sent e-mails to both Professor Dame Sally Davies and Professor Sir Michael Rawlins informing them of the panel's concerns regarding the identified risks to the continued provision of the service provided by NRES during this current period of uncertainty.

### 4.2 2nd World Conference on Research Integrity 2010 Leadership Challenges and Responses – Singapore Statement

Frank Wells (FW) thanked the panel for its welcome of the Singapore statement on research integrity. He asked that the panel consider how best to promulgate this statement to the wider

research community. JW agreed a link could be provided from the NREAP minutes.

#### **4.3 Call to Include Pregnant Women in Clinical Trials (Clinical Research and Clinical Quality Assurance Advisor, 20 September 2010)**

AG informed the panel that he had written to the charity 'Action Medical Research' raising the issue of the inclusion of pregnant women in clinical trials and that they would take this forward for discussion.

#### **5. NRES Update - Janet Wisely**

JW informed the committee that she continued to receive assurances from the DH that the future of NRES was assured; however, the service continues to face considerable practical difficulties whilst announcements regarding future arrangements for NRES and other bodies are awaited. She explained that, in the absence of a formal date for closure, it was possible that the NPSA may effectively close down by the end of this financial year, although formally it may exist for longer. Head office staff have been assured that their employment contracts will be transferred to another organisation but the detail has not been agreed. The continued provision of key resources through the NPSA is still at risk due to the need to transfer them and potentially renegotiate them. These include:

- NRES-wide IT (currently provided through NPSA)
- NRES Website (currently provided through NPSA)
- Research Ethics Database (contract NPSA and Infonetica)
- IRAS (contract NPSA and Infonetica)

JW indicated that it was hoped that the headline recommendations from the AMS review will be made available at the end of November.

#### **6. Future Role of NREAP - Janet Wisely**

JW explained that during this current period of uncertainty regarding future hosting arrangements for NRES she wished to discuss future options for the role of the panel in the event that NRES was hosted by the DH. In such a circumstance she explained that NRES might be perceived to have a potential conflict of interest as it would be hosted by a body that funds medical research and takes the role of research sponsor whilst at the same time having operational control over RECs who would be ethically reviewing such research. The NREA Panel already fulfil some of the functions of a "non-executive board" and JW suggested that if NRES were to be hosted by DH the panel might be formally constituted as a non-executive board in order to provide an independent body between NRES and DH. NRES would thus be accountable to this board and in turn the board would ensure that the service continued to provide an independent ethics review service to all stakeholders. Such a "board" would continue to provide the current advisory services offered by the panel but in addition it would also take on governance responsibilities and would sign-off NRES business plans.

JW expects the NRES to be moved closer to DH, but also wanted to consider the future role for the NREAP if a different interim solution was put in place by DH, for example transfer as an interim to another ALB. In this scenario JW would also see a role for the panel as a non-executive Board which could provide governance assurance on most aspects of NRES business to another host. Finance would be the likely exception.

JW also informed the panel that The Government's Advisory Non-Departmental Public Bodies Review had concluded that the Gene Therapy Advisory Committee (GTAC) no longer needed to provide advice directly to Ministers and that responsibility for supporting its Research Ethics Committee (REC) statutory functions should be transferred to NRES. In light of this, the services of the panel would need to be offered to GTAC in future. It was also possible that NRES may be asked to provide support to other RECs after the AMS review. JW suggested that whilst the position was that NRES was asked to provide support to other RECs, the panel could offer to also provide

support and that this offer should be made by AG. If NRES were in the future given responsibility for other RECs then there would be an expectation that the NREAP would assume this wider remit.

**Agreed:**

- The panel agreed in principle that it would be acceptable to formally constitute the current NREA Panel as an 'NRES Non-Executive Board'.
- The panel were content to offer to extend the provision of its services to GTAC, and, if required in the future, to other ethics committees. It was not considered that the membership of the panel would need to be modified in order to extend provision of its services to GTAC. It was agreed that AG would write to GTAC during this interim period to offer the services of the NREA panel to them.

**Action: AG**

## 7. Submissions from the ME Association and others to NRES concerning the 'SMILE' study

Received for discussion:

- The ME Association and the Young ME Sufferers Trust joint statement
- NRES response letter
- Notes written by Hugh Davies in early response
- IRAS application for the 'SMILE' study

The ME Association has raised concerns over a study of ME in young people that was recently approved by a REC. The panel were asked for comments/advice on the broader ethical issues and the actions proposed by NRES:

*"...we feel that a fair way forward is to seek the responses of the researchers, sponsor and the ME charities involved in the development of the study before asking the REC to review its favourable opinion. We also note that in this project, subjects will not be deprived of what is current care in this clinic. Research participants will receive this intervention in addition to their standard treatment.*

*We will also be seeking the views of our National Research Ethics Panel."*

The panel were supportive of the proposed NRES action put forward to deal with the concerns raised by the ME Association and others. It agreed that the main REC should be asked to review its favourable opinion in the light of new information (as per current NRES SOPs). The panel were in broad agreement with the preliminary notes written by Hugh Davies in response to complaints made about the SMILE study. However, the panel felt that in reviewing its decision the REC involved should limit itself to considering only the relevant new information regarding the study itself and not to consider allegations which were outside of its remit or competence to comment upon.

The panel stated that it was important to conduct impartial research into ME and that, where appropriate, it was equally important to ensure the benefits of research are extended to children in line with existing guidelines. It was noted that in the SMILE study participants were not being deprived of current care and the research question was the effectiveness of the additional tool which the study was designed to evaluate.

**Agreed: The panel agreed and endorsed the proposed NRES action**

## 8. Interim NREAP Deputy Chair - Andrew George

Discussed: appointment of an interim NREAP Deputy Chair pending outcome of AMS review

AG proposed that once future arrangements for NRES, and therefore the panel, were clearer the panel should nominate a Deputy Chair as currently there was no one to chair the panel in his absence. AG further proposed that as an interim measure pending the outcome of the AMS review the panel should ask Hugh Davies (NRES Ethics Advisor) to chair the meetings in his absence.

**Agreed: The panel agreed that a Deputy Chair should be appointed following the announcement of the outcome of the AMS review when the future of NRES and the role of the panel would be clearer.**

**The panel supported the proposal that Hugh Davies be asked to Chair the meetings in Andrew's absence.**

JW and AG would review the process for the appointment of a deputy chair following the outcome of the AMS review.

#### **9. Research project to investigate the 'efficacy' of the currently piloted proportionate review system – Andrew George**

Discussed following verbal update from Andrew George

AG explained that NRES proposed to conduct a trial of its proportionate review service (currently being piloted). The trial would compare proportionate review with full committee review and explore whether the proportionate review service might be expanded beyond its current remit. In addition, the study might also explore the level of information required by REC members to reach a robust ethical decision.

It was hoped that the final study design would be presented to the panel in early 2011

#### **10. National Level Clinical Excellence Awards – Andrew George**

Received for discussion:

- Email sent on behalf of Andrew George.

AG explained that there was a mechanism for NREAs who wish to be nominated for a merit award to gain citation in support subject to the consideration of the Chair of the NPSA. NREAs wishing to put themselves forward for such an award and seeking a citation in recognition of their contribution to NRES should ask JW to put the proposal through to NPSA.

The panel also discussed the issue of whether members of RECs might be supported for such awards or other honours and it was recognised that there was no clear mechanism for such nominations. In the light of this the panel felt that there should be a means of recognising particularly good service provided by members of RECs. Such individuals might be recognised and proposed through the NREA hosted Chairs network meetings.

#### **11. BBC News item: NMT libel case intensifies for cardiologist**

Received for information only:

- BBC news item "NMT libel case intensifies for cardiologist"  
(<http://www.bbc.co.uk/news/science-environment-11678725>)

## 12. Any Other Business

### 12.1 NREA Hosted Chairs Network Meetings – Proposed NREA Hosts

A provisional list of NREA hosts for the proposed NREA Hosted Chairs Network Meetings suggested by Joan Kirkbride (NRES Head of Operations) was tabled for discussion.

The members of panel present at the meeting were happy with the proposed allocation.

Frank Wells was happy to host both the East of England and East Midlands network meetings and Richard Tiner would host the South West Chairs network meetings. Jeremy Butler offered to assist Hugh for the South Central (Reading) meetings. Peter Heasman had previously indicated in e-mail correspondence that he would prefer that Yorkshire and the Humber were combined with the North East network for the purposes of these meetings.

### 12.2 Time Limits for Storage of Research Data

Charles Warlow asked the panel whether they knew of any maximum time limit for the retention of research data. Simon Woods explained that there was no time limit for the retention of such data under the Data Protection Act. The panel were aware of a *minimum* time limit of 15 years required by ICHGCP for clinical trials and that research active institutions might impose their own minimum time limits but no panel member was aware of any *maximum* limit.

## 13. Date of Next Meeting:

The next meeting of the National Research Ethics Advisory Panel will be held on 08 December 2010.

Time: 14:00 – 17:00.  
Venue: Room 7  
NRES/National Patient Safety Agency  
4-8 Maple Street  
London W1T 5HD