

## National Research Ethics Advisors' Panel

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

**Date:** 12 January 2011

**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  
Sarah Dyer  
John Saunders  
Nalin Thakker  
Richard Tiner  
Art Tucker  
Frank Wells  
Sue Wilson  
Simon Woods

### In attendance:

Dr Janet Wisely (NRES Director)  
David Neal (NRES Deputy Director (Policy))  
Clive Collett (NREAP Manager)

1. Apologies: Peter Heasman; Caroline Harrison; Charles Warlow

2. Declarations of Interest

There were none

3. Minutes of meeting held on 08 December 2010

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

### 4. Matters Arising

#### 4.1 Time-critical research in intensive care – compliance with the Mental Capacity Act

Received for information only:

- Email update from David Neal

#### 4.2 The 'SMILE' study

Received for information only:

- Letter from Joan Kirkbride

## 5. NRES Update : Janet Wisely

### 5.1 NRES Governance report

Received for information only:

- 2010-11 Business Plan Progress Report - NRES

### 5.2 NRES transition update

Received for information only:

- NRES Transformation Plan
- Leeds Transfer Gantt Chart

### 5.3 The Academy of Medical Sciences review, 'A new pathway for the regulation and governance of health research'

Janet Wisely gave a presentation summarising the main recommendations of The Academy of Medical Sciences review, 'A new pathway for the regulation and governance of health research' published on 11 January 2011.

The report recommends the establishment of a new independent Health Research Agency (HRA) to bring together existing approval processes. The Agency would work with regulatory and governance bodies in the devolved nations to develop an integrated approvals system for the UK. The report recommends that the Department of Health should establish a new National Research Governance Service (NRGS) for England, to be housed within the HRA. The NRGS would facilitate rapid approval of research studies conducted in single or multiple NHS sites by assuming responsibility for all study-wide checks that are currently duplicated by each participating NHS Trust.

With regards to NRES the review recommends that:

“Recommendation 12: NRES should lead on improving support and advice for researchers by providing centralised, coordinated guidance and training on ethical issues for health researchers. Institutions engaged in health research should also improve the local availability of ethics advice and the training of local support staff.”

The panel welcomed the review and the positive comments made concerning the progress that the National Research Ethics Service had made in recent years. The panel noted the call for a more “proportionate approach” and it was acknowledged that NRES were already committed to the provision of a proportionate service including the piloting of a system of proportionate review that would eventually be rolled out across the entire service. In addition JW explained that NRES were in the process of assessing all of the questions currently asked in the IRAS application form to ensure that they were proportionate and appropriate.

The panel noted the specific recommendation regarding the improvement of support and advice for researchers with regard to ethical issues and agreed that this was an important aim and that NRES was well placed to coordinate the provision of such support.

The panel wished to formally congratulate Janet Wisely and all NRES staff on both the progress made and the acknowledgement of this progress in the Academy's review. In addition it was noted how well both NRES and the Department of Health, particularly Sally Davies and Marc Taylor, had worked together to ensure that the Academy were presented with an accurate account of the efficient and

coordinated service provided by NRES with the support of the DH.

The panel agreed that Andrew George should write to Sally Davies on behalf of the panel to thank her for the support given to NRES by her and her office

**Action: AG**

## 6. NIHR Research Support Services – Communication between JW and Marc Taylor – Janet Wisely

Janet Wisely gave a short presentation

Received for information only:

- Letter from Janet Wisely to Marc Taylor
- Letter from Marc Taylor to Janet Wisely

The panel welcomed the approach set out in the NIHR Research Support Services Framework and endorsed the stated principles and objectives particularly the aim of streamlining and standardising R&D practices which is a key element of the AMS recommendations.

It was agreed that AG would draft a letter to Marc Taylor for review by the panel.

**Action: AG**

## 7. Incidental findings in imaging research - Hugh Davies

Received for discussion:

- Incidental Findings in Imaging Research: a framework for considering the ethical issues

The panel considered the document to be an excellent starting point for the consideration of incidental findings in research and particularly liked the table of questions and considerations to be raised by RECs.

The panel discussed whether the framework should confine itself to imaging research alone or be made more general so that it applied to all research. Whilst many of the questions and considerations were of relevance to all research it was considered that some research, such as genetic research, had unique considerations such as the potential impact of incidental findings upon other family members and not just the participants themselves. The panel felt that, whilst it did not wish to issue a plethora of guidance on this issue, it might be useful to think further about how best to tailor the guidance to specific research. It was suggested that Simon Woods and Nalin Thakker might utilise this current framework as a starting point to think about guidance relating specifically to genetic research.

**Agreed:** It was agreed that the document provided an excellent template for the production of guidance which could be tailored to different types of research e.g. genetic research. Hugh Davies would update the document and bring back to the panel for further discussion once the full report of the symposium on 'Ethical Management of Research Imaging' organised by The Royal College of Radiologists (RCR), and Scottish Imaging Network: A Platform for Scientific Excellence (SINAPSE) was available.

The panel also agreed that there should be a general question in IRAS regarding the possibility of producing an incidental finding and that this should apply to all research as incidental findings were not confined to clinical or quantitative research alone but could also be an issue for qualitative studies.

**Action: HD**

## 8. Shared Ethical Debate (SED5: Phase 1 studies) – Hugh Davies

Received for discussion:

- National Research Ethics Service Shared Ethical Debate Report - Autumn 2010

HD introduced the report and stated that the main learning point to emerge from the study was the need for relevant training and expertise concerning phase 1 research amongst flagged RECs. The debate also highlighted that some RECs were inappropriately using condemnatory phrasing in their comments. Whilst it was recognised that these phrases were made in the context of an internal exercise and that such comments might be suitably toned down were they to be used in real outcome letters, it raised legitimate concerns regarding the tone adopted by some RECs.

HD concluded that this debate had been extremely valuable and was grateful to the researcher who allowed their application to be used for this exercise.

The panel had some concern regarding the variation in the number of phase I studies seen by flagged RECs and endorsed a review of phase I flagging amongst RECs by NRES to ensure that such RECs were reviewing an appropriate number of studies to ensure maintenance of their expertise in this area.

The panel considered that the shared ethical debate exercises continue to be an extremely useful initiative which is able to identify areas requiring further training and help promote consistency of ethical review amongst RECs.

## 9. NREAP guidance regarding 'Conflict of Interest' - Hugh Davies

Following discussion of the SED phase I report the panel are asked to further consider whether they wish to issue NREAP guidance on 'conflict of Interest'.

David Neal expressed the opinion that the NRES paper "Medical Device Review and CI Conflict of Interest" previously considered by the panel, whilst specific to medical devices, was an extremely useful document and hoped that it would eventually be disseminated amongst the REC community. The panel manager referred DN to the panel's previously agreed statement concerning this paper which supported the publication by NRES of this guidance:

"The panel ... supported the proposed guidance drafted by NRES regarding medical device review and CI conflict of interest." (NREAP Minutes, 8 September 2010)

**Agreed:** The panel agreed that it might be useful for the panel to consider issuing guidance which might simply identify existing guidelines that may be of use to RECs in considering this issue. Both John Saunders and Hugh Davies would collate relevant guidance for consideration at a future meeting with a view to issuing NREAP guidance.

**Action: HD & JS**

## 10. Follow-up contact of potential participants who have not responded to an initial invitation to take part in research

Received for discussion:

- Email correspondence regarding possible revision of NREAP published Guidance
- Published guidance on the follow-up contact of potential participants who have not responded to an initial invitation to take part in research (NREAP/02)

The panel considered whether they would wish to update their previously issued guidance regarding follow-up contact of potential participants in the light of e-mail correspondence concerning initial telephone contact of potential research participants.

**Agreed:** The panel agreed that there was no reason why potential participants should not be contacted initially by telephone (as long as this was in line with the principles set out in the previously published NREAP guidance (NREAP/02)).

They did not feel it was necessary to revise their existing guidance which related to the specific issue of *follow-up* contact.

## 11. Any Other Business

## 12. Date of Next Meeting:

The next meeting of the National Research Ethics Advisory Panel will be held on 09 February 2011.

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