National Research Ethics Advisory Panel

Minutes of the fifth meeting of the National Research Ethics Advisory Panel held on Wednesday the 10th of February at the Royal College of Physicians, 11 St Andrew's Place, Regent's Park, London NW1 4LE

MINUTES

Present:

Andrew George (Chair)
Jeremy Butler
Hugh Davies
Sarah Dyer
Peter Heasman
John Saunders
Nalin Thakker
Richard Tiner
Art Tucker
Charles Warlow
Frank Wells
Sue Wilson
Simon Woods

In attendance:

Dr Janet Wisely
Mr David Neal
Mr Clive Collett (NREAP Secretary)

1. **Apologies**

There were none

2. **Declarations of Interest**

There were none

3. **Minutes of meeting held on 13 January 2010**

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

4. **Matters Arising**

Following the panel's discussion, at the last meeting, of the recent publication by Christopher Roy-Toole ("Research ethics committees and the legality of the protocol: a rejoinder and a challenge to the Department of Health" Christopher Roy-Toole, *Research Ethics Review* (2009) Vol 5, No 1, 35-36) it was noted that this issue was likely to remain live. David Neal (DN) clarified that the view put forward by Roy-Toole was not the view of the UK government nor the MHRA. Hugh Davies (HD) stated that whilst he did not agree with Roy-Toole's interpretation of the legal issues he did make some sensible points regarding the distinction between ethics and science and how they should be dealt with by RECs in their review.

NRES Briefings and Updates

5. **Update of NRES – Janet Wisely (JW)**

JW further explained that the move to REC centres is well underway and this will go some way to reduce administrative costs and provide closer and more effective management of RECs.

The NRES management team held a meeting in January to agree timing for initiatives already in the planning stage:

- Proportionate review - expansion of a pilot
- Publication of summary of opinion - progression to phase 2 of pilot
- Publication of research summaries – to continue roll out
- Publication of research findings – to be adopted within SOPs next year

However, the timing of the pilot of the provision of electronic information to REC members is to be agreed pending budget confirmation.

The proportionate review pilot was discussed by the panel. Art Tucker (AT) noted that the provision of proportionate review was not well known by researchers. JW acknowledged that this was the case and the current intention was to test the process with relatively small numbers. The second phase of the pilot will have increased capacity with the East Midlands centre coming on stream soon and the pilot will be publicised more widely once NRES was confident that the process was deliverable and that there was sufficient capacity to meet demand.

The panel discussed how the definition of the term "no material ethical issues" had affected the "bounce rate" experienced during the pilot (around 20% of applications for proportionate review had been "bounced" back for full committee review). HD explained that once they had spent some considerable time on producing the guidance regarding what constituted an application with no material ethical issues and this guidance would continue to be reviewed and revised. Once the scheme moved to routine service the sign off of the guidance would sit with the NREAP. HD offered to circulate a brief paper regarding the criteria for no "material ethical issues" for future discussion by the panel.

Action: HD

NRES Strategic Meeting

The recent NRES strategic meeting noted that chairs network meetings had not taken place as often as had been wished. JW suggested that NREAs might host these meetings in their local patches. It was emphasised that such meetings should concentrate on issues such as consistency and guidelines rather than operational issues which would be dealt with via coordinator network meetings.

It was also suggested that the management team were in support of the issue of "guidelines" which RECs would be asked to follow. Where these guidelines were not followed the RECs would be required to justify their reasons for not doing so. JW suggested that the panel should play a central role in the production of these guidelines and that this should be taken up as an agenda item for a future panel meeting.

Agreed in principle:

1. **The panel agreed in principle that NREAs would facilitate and host chairs network meetings in their local patches. HD indicated that he would be happy to attend any local chairs network meetings to assist where needed.**
2. **The panel agreed in principle to facilitate the production of guidelines for RECs. This would be discussed at a future NREA meeting.**

6. Policy Items – David Neal (DN)

6.1 Clinical Trials Directive

DN presented the “UK response to the commission's consultation on review of the clinical trials directive to the committee”.

The panel agreed that this was a strong and robust response which defined clearly the important issues present in the consultation. It noted that as this had now been submitted to the commission the panel were not required to comment on the response at present.

DN would keep the panel up-to-date with further developments regarding the outcome of the consultation and also the result of meetings of the ad hoc working group responsible for the review of guidance documents (first meeting in February 2010)

DN was asked for an update on the revision of the Governance Arrangements for Research Ethics Committees (GAfREC). It was explained that UKECA will review the "near final" draft of GAfREC on 8th March, however the forthcoming general election is likely to hold up the final publication of the document until at least June 2010.

6.2 NHS Research facilitators

DN explained that this item would be postponed until the March agenda where Marc Taylor would attend to present this DH business. DN briefly outlined the proposals to create research facilitator roles which would sit alongside the care team to generate patient lists of suitable patients for research. The method of approach to these patients would still need to be agreed by RECs.

John Saunders (JS) noted that a very good document on the issue of the use of health information for medical research had been produced by the Academy of Medical Sciences[1]. It was agreed that this would be circulated to the panel.

Action: Clive Collett (CC)

6.3 Clinical Genetics

DN presented the "clinical genetics and research" paper produced by himself and Nalin Thakker (NT) which presented a suggested procedure for facilitating research in clinical genetics, using the scheme of generic ethical review Research Tissue Banks.

The panel fully endorsed the proposed method and felt that it was a neat and practical solution to the problem. The panel felt that the RECs who are likely to see such applications for clinical genetics research should be pre-warned and educated about the proposed method. DN agreed that this was desirable and would take place. NT agreed to publicise the proposed approach through the Genetics Society.

[1] *Personal data for public good: using health information in medical research*, January 2006 http://www.acmedsci.ac.uk/download.php?file=/images/project/Personal.pdf

Agreed: The panel agreed the proposed approach.

7. Quality Assurance – Shared Ethical Debate (SHED) – Sarah Dyer (SD)

QA Shared Ethical Debate Procedure

SD explained that she and Peter Heasman (PH) had discussed changes to the shared ethical debate procedure with Sandra Holley (Head of Quality Assurance) including the role of NREAs and the QA Shared Ethical Debate Procedure document was updated accordingly.

The NREA Panel were asked to:

1) **Consider and agree the suggested role established for the Panel and NREAs with a special interest in QA**

The panel considered the role for the panel and NREAs suggested in the SHED document. Sue Wilson (SWi) made the suggestion that paragraph 10.3.12 should be amended to state that NREAs will occasionally attend meetings of a REC in order to support training and development around the SHED, rather than use the existing phrase that members of the NREA panel "may attend a meeting of a REC" as attendance might then be seen to be triggered by poor performance in the SHED and could be seen as confrontational. SWi was concerned that NREAs might be seen as policing the committee rather than being the facilitator of further debate around issues that arose from the SHED. The committee agreed the proposed role subject to the revision to the QA Shared Ethical Debate Procedure document proposed by SW.

2) **Begin to discuss and establish the key ethical themes to be prioritised for the programme for 2010/2011 as suggested in 7.1.**

SD and PH initially made a number of suggestions for future SHED ethical themes:

- Confidentiality
- Vulnerable groups - what constitutes a vulnerable group?
- Mental Capacity Act - procedures for consultation with nominated consultees
- RECs and their view of the distinction between ethics and law

However the panel were invited to also put forward more themes.

Themes suggested at the meeting were:

- 1st use in Man studies (Phase 1)
- Stem cell research
- Clinical drug trials in children
- Dementia and consideration of existing living wills/advance directives with regard to medical research

Agreed: The panel agreed the proposed role for the panel and NREAs as set out in the QA Shared Ethical Debate Procedure subject to the revision to para 10.3.12 proposed by SWi.

8. Fraud and Misconduct - Janet Wisely (JW)

- Breach of GCP/RGF/Potential Fraud & Misconduct Register 1 April 2009 - 31 March 2010

JW explained that NRES has no remit to investigate alleged cases of fraud and misconduct but could raise concerns with the appropriate NHS body/University/SHA for them to take appropriate action. JW also identified an issue with regards to the alleged fraud/misconduct of a Sponsor. In such cases it was not clear that there was any appropriate body to forward the concern to.

The panel discussed the suggestion put forward by JW that applicants would be asked to declare whether they were subject to a pending GMC or equivalent investigation by any professional body as part of the application process. JW also wished to explore links with the GMC to facilitate the exchange of information.

Agreed:

- **It was agreed that the issues raised by JW needed future discussion, and that JW would produce a paper around these issues.**
- **The panel agreed that they should receive the Register of Breach of GCP/RGF/Potential Fraud and Misconduct on an annual basis**

Action: JW

9. Equality & Diversity Training

The panel were informed that they are required to undertake equality and diversity training if they have not already done so. HD informed the group that there was online provision for such training and that he would investigate this further and inform the panel how they can access this training.

Action: HD

10. NREA Leads for Summary of Ethical Opinion and Proportionate review service

The chair asked the panel for volunteers to provide the NREA lead on either the summary of ethical opinion work or the proportionate review service.

Frank Wells offered to lead on the summary of ethical opinion whilst Andrew George would take the lead on proportionate review.

11. Any other business

NRES Forum for Public Consultation

Jeremy Butler (JB) updated the committee on the formation of a standing group to consult more widely with the public. JB had a meeting with AG, JW, CC and Sam Wigand. At this meeting it was agreed that the name for this group should be the “NRES Forum for Public Consultation”. JB informed the panel that it was initially thought that there should be recruitment by interview through identified organisations of individuals meeting the person specification. Individuals would contribute their background, knowledge and skills to the Forum. They would be supported by their organisation but not be representatives of it.

The role and person specification need to be refined, recruitment methods considered and who and how to approach organisations and people.

A proposal should be available for discussion and ratification by NREAP at the April meeting.

Action: JB

NREA Panel Strategic Themes

Andrew George (AG) explained that the committee was now in a position to start to develop strategic themes/main issues that the panel want to debate and influence. There also needed to be agreement on how to take these themes forward.

Panel members made the following suggestions:

- **Consent for research use of tissue – DN/NT**

  DN explained that there had been a reduction in research using archive tissue and there was scope to provide a more consistent and proportionate approach regarding consent requirements for research use of archived tissue. While it was acknowledged that there were already HTA codes of practice it was felt that there was a need for *ethical* guidance on these issues for REC. There was also scope for involvement of the proposed NRES Forum for Public Consultation in this work.

  SWi offered to work with DN and NT on this theme.

  DN also explained that there needed to be an agreed interface between NRES and NIGB and that he was working on the provision of a Memorandum of Understanding. DN would prepare a working draft for future discussion by the panel.

Action: DN

- **Accountability/Transparency of RECs - JS**

  JS put forward this theme in the wake of high profile cases such as the ongoing GMC investigation of Dr Wakefield, Prof John Walker-Smith and Prof Simon Murch over allegations of serious professional misconduct. How can RECs be made more transparent and publicly accountable particularly with regard to such high profile cases which have involved a REC's favourable opinion of such research?

  HD felt that the panel needs to discuss how best to draw together issues and arguments, guidance and legal advice related to these and other themes so that they can be disseminated to RECs.

Agreed: The panel agreed that they needed to develop a methodology into which any issue such as those above could be slotted into and be used to generate useful guidance.

Requests for NREA/NRES advice

JB explained to the panel that the Brompton REC had recently brought an issue to the attention of NRES that they felt required their advice. The issue was one of confidentiality and when that confidentiality might be breached for legal reasons and how this was to be explained in a patient information sheet.

The panel agreed that there should be a mechanism for RECs to obtain advice on minor application-specific issues in a reasonably rapid manner.

Action: HD to produce a draft framework for RECs to obtain NREA/NRES advice on specific issues

The committee also discussed the issue of how NRES and NREAP react to issues such as the MMR research detailed above, the TGN 1412 phase I trial etc and what lessons can be learned from them. DN stated that there was a clear role for NREAs to be involved in the prospective discussion of "difficult" cases as they arise.

JS was asked whether he can look at what information was in the public domain regarding the Dr Wakefield case and present a paper for future discussion detailing what lessons might be learnt to inform how NRES should react to such high profile cases in the future.

Action: JS

12. **Date of next meeting**

The next meeting of the National Research Ethics Advisory Panel will be held on 10th March 2010 in the Rothwell Room, Oulton Hall, Leeds LS26 8HN. Time: 14:00 – 17:00