

National Research Ethics Advisors' Panel

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

Date: 11 August 2010

Time: 14:00 – 17:00

Venue: Room 6,
NRES, NPSA
4-8 Maple Street,
London W1T 5HD

MINUTES

Present:

Andrew George (Chair)
Jeremy Butler
Hugh Davies
Peter Heasman
John Saunders
Richard Tiner
Frank Wells
Simon Woods

In attendance:

Dr Janet Wisely
Mr Clive Collett (NREAP Manager)

1. Apologies: Sarah Dyer; Charles Warlow; Sue Wilson; Nalin Thakker; Art Tucker
2. Declarations of Interest

MIST trial – update

Richard Tiner explained that as a non-executive director of MedicoLegal Investigations Ltd he was party to information regarding an investigation conducted by this company into one of the investigators involved in the MIST trial although he did not participate in the investigation itself. The Panel considered that this did not constitute a major conflict of interest and that Richard Tiner should participate fully in the discussion of this item (6. MIST trial – update).

3. Minutes of meeting held on 14 July 2010

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

4. Matters Arising

4.1 New Panel Member

Andrew George (AG) informed the panel that Caroline Harrison had been interviewed prior to the meeting and would be recommended for appointment as a National Research Ethics Advisor.

4.2 Withdrawal of Data Following Participation in a Study.

AG informed the panel that he had received further confirmation from Professor Janet Darbyshire (Head of the MRC Clinical Trials Unit and Joint Director of NIHR CRN CC) that they had received a response from the Information Commissioner's Office which they have interpreted as meaning that they do not need to withdraw the individual's study data from the PACE trial.

4.3 Patient Information Sheets

Hugh Davies (HD) informed the panel that NRES would be seeking comments next year on the current information sheet guidance and template with a view to issuing updated guidance.

5. ALB Review/AMS Review and implications for NRES – (Janet Wisely)

JW updated the panel on recent announcements regarding the Arm's-Length Body (ALB) review and the Academy of Medical Sciences (AMS) review.

Following the ALB review it was announced that the NPSA would be abolished and the safety functions of the NPSA transferred to the national commissioning board that is being formed as part of a wider NHS reform. The ALB review referenced the continued requirement for a coordinated ethics service. The future arrangements for the National Research Ethics Service are currently being considered as part of the wider review of research regulation conducted by the AMS. As part of this review the AMS has now issued a second call for evidence on the function and scope of a proposed "single research regulator" and the future arrangements for the National Research Ethics Service (NRES); and research regulatory activities of the Human Fertilisation and Embryology Authority (HFEA) and the Human Tissue Authority (HTA). The ALB review stated the Medicines and Healthcare products Regulatory Agency is to be retained, but "with the expectation that it will undertake its regulatory duties in the most cost-effective way".

JW said that DH have assured that the future of NRES was secure but that there were considerable practical issues which need to be resolved, such as hosting for staff and contracts, including IRAS. In addition she hoped that the issue of who would host NRES would be decided soon as prolonged uncertainty may lead to the loss of experienced staff which could compromise the continued provision of the professional service provided by NRES.

In terms of the panel response to the second call, AG felt that it would be important to decide the role of R&D departments with regards to research governance so that functions which were not dependent upon local knowledge could be transferred to a single central body, perhaps leaving R&D with only the oversight of the fiscal aspects of research governance. The panel were broadly supportive of this suggestion.

It was agreed that the panel should respond to the second call for evidence from the AMS. It was noted that the submission date for written evidence was Tuesday 31 August. However, respondents unable to meet this deadline could notify the Academy by 31 August of their intention to submit evidence and to highlight substantive issues that will form the basis of their submission and could then submit their evidence by 5pm Tuesday 14 September. AG stated that he would talk to AREC regarding the submission of evidence and would start work on the draft response. In addition, he would contact the AMS in order to notify them of the intention to submit evidence by the 14th September.

Action: AG

6. MIST trial – update (Janet Wisely)

NREAP were asked to consider and comment on this matter, particularly the general learning points. NREAP support was sought for the proposed joint NRES/SHA letter.

- **Discussed:** Lessons from the MIST trial

AG felt that there were two main issues for the discussion of the panel in this case:

- 1) How to provide oversight of a category of sponsors for which there is no overarching body effective ; and
- 2) Should investigators indicate on their application to a REC that they were currently under investigation by the GMC?

It was considered that the issue of the "oversight of commercial sponsors" was a difficult issue. In the MIST trial it was noted that the sponsor was an American company and thus did not fall under any UK industry bodies such as the Association of British Healthcare Industries (ABHI). In addition the device used in this trial was CE marked and thus the study did not fall under the jurisdiction of the MHRA.

The panel discussed whether investigators should indicate in their application whether or not they were under investigation by the GMC and felt that this raised a number of difficult issues.

John Saunders (JS) explained that doctors are becoming more and more likely to be the subject of an investigation by the GMC, often for relatively trivial issues following a complaint. In fact he stated that a doctor was more likely to be investigated by the GMC than they were to be sued during their career. Given this he felt it would be quite wrong to prevent a doctor from carrying out research whilst under investigation particularly given the length of time that this could take (often several years).

It was acknowledged that an admission that an applicant was currently under investigation may unfairly have an adverse effect on the outcome of the REC's review. Simon Woods (SiWo) expressed the view that if this approach were to be adopted then there would need to be very clear guidance on how this information should be used by committees.

AG considered that it might be preferable to have a third party make the decision whether NRES should be informed of an ongoing investigation into an applicant. Perhaps the GMC could make this decision and inform NRES where it was considered to impact upon the ability of the doctor to conduct research or where participants may be put at risk.

The panel agreed that the GMC should consider any ongoing role as a researcher during an investigation and/or when a decision to suspend is made. The GMC should be encouraged to set up a system for informing NRES where it is considered that research participants might be put at risk by allowing an investigator to either continue their involvement in ongoing research or by conducting new research.

Agreed: The panel fully supported the proposed joint NRES/SHA letter.

7. NRES Finance Overview and update - Debbie Corrigan (NRES Deputy Director)

- The panel received and noted a presentation from Debbie Corrigan

8. Proportionate Review Service Report - (Hugh Davies)

- **Discussed:** Proportionate Review Service: an assurance framework

JS pointed out that the reference to the 1990 RCP guidelines was out of date and should be removed. In addition he pointed out that the RCP definition of minimal risk concurred with that of the Council of Europe. The panel felt that the term "everyday risk" was too subjective as it represented a different risk for different people depending on their particular "everyday" activities. It was felt that the term "minimal risk" would be preferable. AG commented that there were very few examples in life of activities that presented "no risk" and suggested that the term "no or negligible risk" would be preferable.

HD would revise the document and bring back to a future meeting for endorsement by the panel.

Action: HD

9. Scientific or peer review of research and the role of Research Ethics Committees: guidance and a framework for review – (Hugh Davies)

- **Discussed:** Scientific or peer review of research and the role of Research Ethics Committees: guidance and a framework for review; and
- 'W London REC 1 Scientific Review': a breakdown of applications to the West London REC 1 over a 4 month period and the status of their peer review/justification of review process.

JW noted that data from RED indicated that for the last year 4.16% of non-CTIMP applications had included separate scientific review and that only 2.44% of CTIMP applications had included separate scientific review. RECs had requested scientific review where none had been submitted on only six occasions, all for non-CTIMP applications. JW further advised that analysis by University of Leicester found that RECs often raised issues with the science – 68% of letters analysed had raised issues with science in this work. JW hoped that if an increase in the number of scientific review documents submitted to RECs could be achieved then this might lead to RECs raising fewer questions regarding the science/methodology of studies.

HD raised the question of what RECs should be doing with any scientific review that they receive. Should they simply be checking who had conducted the review and if, for example, it was an organisation such as the MRC then simply be content that adequate review had taken place or should they be assessing the review process against published standards? HD commented that the guidance for reviewers is variable and so there was a need to set out the issues that any robust peer review should have covered so that RECs can properly assess the submitted review. If these criteria are then published then applicants to RECs would know that these questions will be asked by the REC which should in turn lead to the submission of scientific review that met these published standards.

HD suggested that these issues should all be discussed at a workshop involving interested parties and NREAs interested in this area. The panel agreed that this was a useful way forward

Action: HD

10. Appointment Process for REC Chairs (Janet Wisely)

The Panel were asked to discuss a proposal to change the way in which NRES recruits REC Chairs. NREAP endorsement was requested prior to consultation with REC Community and SHA as Appointing Authority

- **Discussed:** Appointment Process for REC Chairs

JW explained that this proposal was driven by the fact that too often experienced REC Chairs are lost to the service when their term of office comes to an end. This process would allow NRES to advertise for members who are interested in being appointed to committees in the role of Chair. Suitable applicants would be placed on a waiting list to be appointed to committees as and when suitable vacancies arise.

Jeremy Butler felt that there may be some nervousness amongst RECs who might perceive that Chairs were being imposed upon them. In addition, he felt that they needed to be some sort of process or "batting order" for deciding who should be appointed in the event that more than one candidate was suitable. JW explained that in all cases there would be an appointment panel and if there were more than one potential candidate they would appoint the most appropriate candidate. The opinion of RECs would be taken into consideration.

Agreed: The panel supported and endorsed the proposed appointment procedure for REC chairs.

11. Proposed guidance for NREAP to issue to RECs regarding Medical Device Review and CI conflict of interest.

The panel were asked to consider issuing the following NRES document from Joan Kirkbride (Head of Operations) as NREAP guidance:

- **Discussed:** Ethical Review of Medical Device Studies – Financial Interest of Chief Investigator

The panel discussed the draft guidance and agreed that simply having a financial interest in the outcome of the research should not prevent an individual from being an investigator in that research nor result in that application receiving an unfavourable opinion purely for this reason. It was noted that investigators involved in any research project would have a vested interest in its outcome which may or may not give rise to a significant conflict of interest. Whilst RECs should always consider the potential for a conflict of interest each case should be considered on an individual basis.

It was considered that the interests of investigators, financial or otherwise, were not restricted simply to medical device studies and felt that the NREAP guidance document should address the broader issue of conflict of interest in all studies.

Agreed: The panel agreed to issue advice on this subject using the submitted document as a starting point. AG and CC would amend the document accordingly prior to its issue as NREAP guidance

Action: CC & AG

12. The rights of children to benefit from clinical research – (Hugh Davies)

HD informed the group that he would be attending a meeting organised by Professor Neena Modi regarding the “rights of children to benefit from clinical research” and would report back to the panel.

13. 2nd World Conference on Research Integrity 2010 Leadership Challenges and Responses – (Frank Wells)

FW explained that he had recently attended the “2nd World Conference on Research Integrity 2010”. He stated that it had been extremely good meeting and a “Statement on Research Integrity” rising from the conference was likely to be published soon. FW hoped that the panel would review the statement at a future meeting and consider formally endorsing the document. The panel agreed to review the statement following its publication.

14. Proposed change to the way RECs handle applications at meetings which are not considered to be research.

- Received for information: NRES document: “Applications submitted for REC review and considered by the REC not to be research”

The panel welcomed and endorsed the proposed change.

15. Christopher Roy-Toole – Email correspondence

- Received for Information: Email correspondence from Christopher Roy-Toole

The e-mail correspondence was received and noted

16. Any Other Business

16.1 Action Register

Jeremy Butler asked how items that required future action by NREAP would be monitored. JW suggested that an "action register" of open items should be kept but that this should be restricted to NREA-specific action points as all other items would be monitored by NRES and the DMG. It

was agreed that CC would maintain an active register which would be monitored by CC and AG at their monthly meetings.

16.3 Research Ethics Review (RER)

JW explained that NRES had noted that a number of recent articles published in the RER contained some inaccuracies with regards to NRES policy. She felt that it would be helpful to have some form of "sanity check" on any articles for publication that made reference to NRES procedures or policy. With the panel's agreement she wished to approach the RER to suggest that a member of NRES sat on the editorial board or failing that some other form of checking system put in place to ensure that such articles correctly represented NRES procedures and policy.

Agreed: The panel agreed that JW should approach the RER with the suggestion.

It was further suggested that NREAs might offer their services as peer reviewers for articles to be published in the RER regarding NRES and/or NRES policy.

16.4 EFGCP report on ethical review systems in non-EU countries

FW explained that the European Forum for Good Clinical Practice (EFGCP) had been commissioned by NRES to compile a report on ethical review systems in non-EU countries. He stated that the report would shortly be available on the EFGCP website (www.efgcp.be) and that its conclusions were that the UK system was both robust and fit for purpose.

17. Date of Next Meeting:

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

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