

National Research Ethics Advisors' Panel

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

Date: 09 February 2011

Time: 14:00 – 17:00

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

MINUTES

Present:

Andrew George (Chair)
Hugh Davies
Peter Heasman
John Saunders
Nalin Thakker
Charles Warlow
Frank Wells
Sue Wilson
Simon Woods

In attendance:

Dr Janet Wisely (NRES Director)
Clive Collett (NREAP Manager)

1. Apologies: Sarah Dyer; Jeremy Butler; Caroline Harrison; Richard Tiner; Art Tucker
2. Declarations of Interest:
 - 6. The SMILE Study

Janet Wisely (NRES Director) and Hugh Davies (NRES Ethics Advisor) left the room during the discussion of this item.

- 7. "Letter from RCP Committee for Ethics in Medicine re Wakefield et al."

John Saunders is the Chair of the RCP Committee for Ethics in Medicine and acted as an expert witness in the GMC's Fitness to Practice Panel consideration of the cases of Dr. Wakefield, Professor Walker-Smith, and Professor Murch.

He left the room during the discussion of this item and did not participate in the panel's decision.

3. Minutes of meeting held on 12 January 2011

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

4. Matters Arising

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

AG informed the panel that he had written to Sally Davies on behalf of the panel to thank her for the support given to NRES by her and her office.

4.2 NIHR Research Support Services – Communication between JW and Marc Taylor

AG informed the panel that he had written to Marc Taylor

4.2 GTAC and MODREC

AG explained that whilst he had contacted GTAC to offer the services of the panel to them he had not yet received a response. He further informed the committee that he would be meeting with the MODREC later this month along with David Neal.

5. NRES Update : Janet Wisely

JW informed the committee that the AMS recommendations for both interim and long term hosting of NRES were still awaiting formal response from DH. This continued uncertainty was having a direct impact upon the ability of NRES to continue its provision of a robust ethical review service and in particular was causing significant problems with regards to the retention and employment of staff. The panel expressed their concern and asked JW for sight of the NRES risk register. JW agreed to supply this.

The panel reiterated their support for the recommendations made in the AMS report and saw it as an opportunity to restructure research governance in the UK for the good of both researchers and patients. However, further delay regarding any decision to implement these recommendations was having a deleterious effect on the ability of NRES to plan appropriately for the future and was likely to cause serious damage to the competitiveness of the UK as a place to conduct medical research.

Agreed: The panel agreed that an open letter expressing their concerns should be drafted by AG for review by the panel before publication.

Action: AG

6. The SMILE Study: Charles Warlow

Received for discussion:

- Report for the National Research Advisors Panel - Charles Warlow

JW and HD left the room whilst the panel discussed this item.

Following the verbal report from CW the panel agreed that:

- Whilst the panel did not feel that any "material issues" had been raised to categorically require a second review by the main REC it was felt that NRES had acted appropriately and reasonably in asking the main REC to review its favourable opinion in the light of the 'new information' (in line with NRES SOPs).
- Whilst the panel were not in a position, nor had the remit, to comment upon the initial and subsequent review provided by the main REC they considered the REC's opinions to be entirely appropriate.
- If any further studies involving the lightning process are to be reviewed by an NRES REC then the panel felt it would be appropriate for the main REC involved to be appraised of the history of the ethical review of the SMILE study.

- The panel supported the NRES operational view that the correspondence received after the REC meeting, in response to the REC decision not to suspend the ethical opinion, does not raise new issues that require a further review by the REC at this time.

7. Letter from RCP Committee for Ethics in Medicine re Wakefield et al.

Received for discussion:

- Letter from Prof. Danny Shickle, Acting Honorary Secretary of the Committee for Ethics in Medicine (RCP) and Professor of Public Health at the University of Leeds
- Draft Letter from Janet Wisely

The panel were asked to comment and advise on the draft response letter.

John Saunders explained to the committee that the ramifications of the Wakefield case were still with us. The claims made by Wakefield et al in their 1998 paper published in The Lancet had led to a significant drop in vaccination rates around the world and had seriously jeopardised public health. He stated that he considered the case to be a major scandal. John Saunders stated that in his opinion this protocol should never have been approved, in which case the ensuing events would never have happened.

He pointed out that various editorials have questioned the quality of the ethical review of Wakefield's study protocol. JS pointed out that at the time of the ethical review there was guidance available to the RECs to inform their ethical review e.g. HSG(91)5 Local Research Ethics Committees ("The Red Book") and the RCP's own 'Guidelines for Research Ethics Committees' first published in 1984 and in its third edition in 1996.

JS left the room during the discussion of this item and did not participate in the panel's decision.

AG pointed out that the review of the research was undertaken at a time when RECs were not subjected to the oversight of COREC (later NRES) and that standards, consistency of ethical review and the quality control of RECs had all improved immeasurably since that time. Indeed FW was of the opinion that the current research ethics governance framework in the UK was second to none in Europe.

The committee were in agreement that there was little to be gained from NRES expending considerable time and effort in investigating the events of over 14 years ago regarding a committee that they did not have operational responsibility for at that time. In particular they wished to point out that the GMC had made no criticism (explicitly or implicitly) of the REC and that the blame for failure to obtain or adhere to ethical approvals was placed firmly with Dr Wakefield. Furthermore, Dr Wakefield had clearly misled the REC with regards the nature of the lumbar punctures, which he had said were clinically indicated, and was found by the GMC to have behaved unethically in failing to seek Research Ethics Committee approval where it was required.

The panel acknowledged that this case has had, and continues to have, a major negative impact on vaccination rates which in turn poses a serious threat to public health both in the UK and worldwide. It was clear that the research had been carried out in an unethical manner and that there are considerable concerns about the conflict of interest of the Chief Investigator. However, they wished to point out that research ethics committees have never been, nor ever would be, able to guard against a maverick researcher working outside of the terms of their ethical approval and that the ethical review system is only one part of a wider research governance framework.

Agreed: The panel endorsed JW's draft letter with minor suggestions.

8. NRES Pilot of the Personal Development Process and Paperwork for REC Chairs - Sandra Holley

Received for discussion:

- NREAP Paper: NRES Pilot of the Personal Development Process and Paperwork for REC Chairs
- NRES Outline Process for Taking Forward the Personal Development of REC Chairs

The Panel were asked to support a pilot of the NRES Personal Development Process and paperwork for REC chairs.

Sandra Holley attended the meeting to give a short presentation to the Panel.

The panel welcomed and supported the proposed pilot process. In discussion the following suggestions were made:

- The section headed "knowledge and experience required by REC chairs" should make reference to the need for an awareness of ethical principles and ethical analysis and also a working knowledge of the Data Protection Act.
- The document should make reference to the need for all members to conduct themselves appropriately. It could reference the current NRES member terms and conditions regarding "Business Conduct" which states that:

"You are required to conduct yourself in a manner which positively reflects the activities of the NRES and to treat colleagues, applicants, employees of NRES and other key stakeholders with respect and in an appropriately courteous way. In all circumstances you will be required to work in a way which upholds the reputation of NRES."

Sandra Holley explained that she would like to pilot the scheme in one network meeting area for six months whereby local chairs would observe each other's meetings. John Saunders volunteered to conduct the pilot in Wales.

9. NRES Shared Single Issue Ethical Debate: Participants in research who may have difficulties in adequate understanding of English - Sandra Holley

Received for discussion:

- NRES Shared Single Issue Ethical Debate: Participants in research who may have difficulties in adequate understanding of English

Sandra Holley attended the meeting to give a short presentation to the Panel of the report of the shared single issue ethical debate.

Sandra Holley stated that she felt proud of the RECs involved in this shared single issue ethical debate as she felt that this issue had resulted in good, considered debate resulting in well-balanced advice. It was explained that there was currently little external guidance regarding this issue and what was available tended to simply state a general principle of equality and the need to be as inclusive as possible with regards to recruitment for research. JS pointed out that the current edition of the RCP 'Guidelines on the Practice of Ethics Committees in Medical Research with Human Participants' (fourth edition) did include an extensive section on this issue under the heading 'Language' (paras 5.50 to 5.58).

The panel discussed the difficult issue of the use of family members as translators. It was acknowledged that many RECs have adopted a blanket policy that no family members may be used as translators for the purposes of research, however it was felt that such a blanket policy may not always be appropriate and that each case would need to be decided on its relative merits. Where the proposed research is only minimally invasive, say the taking of a few extra mls of blood for non-genetic research, then it may be appropriate to involve a family member as a translator. However, HD pointed out that the use of family members to translate for clinical purposes was generally frowned upon. The panel felt that if any guidance is produced based on this report then this issue would need to be carefully thought through in order to provide precise advice.

Sue Wilson asked what the focus of this report and any subsequent guidance was. Did it focus on ethnic groups alone or on the more general issue of disadvantaged groups? She pointed out that often literacy levels are more important in terms of disadvantage than ethnicity. She felt that any guidance should also address such issues faced by disadvantaged groups who represent a significant percentage of the population.

HD pointed out that Sarah Dyer had previously agreed to work with Sandra Holley to explore existing guidance on this issue. The panel agreed that this would be an important first step before considering whether to issue any future guidance.

Agreed: HD would contact Sarah Dyer to ask her to work with Sandra Holley to explore existing guidance with a view to producing a paper for future consideration by the panel.

Action: HD

10. NREAP MEETING DATES 2011

For information:

09 March 2011 (14:00 – 17:00) Jubilee Room, YMCA
13 April 2011 (14:00 – 17:00) Jubilee Room, YMCA
11 May 2011 (14:00 – 17:00) Jubilee Room, YMCA
08 June - venue tbc
13 July - venue tbc
10 August - venue tbc
14 September - venue tbc
12 October (**Birmingham** - venue tbc)
09 November - venue tbc
14 December (**Manchester** – venue tbc)

The panel noted the meeting dates and confirmed that they would be happy to hold meetings in both Birmingham and Manchester. Sue Wilson indicated that the issue would be happy to help arrange accommodation for the panel in Birmingham.

11. NRES Appeals Register for April 2010 – March 2011

Received for information only:

- The NRES Appeals Register for April 2010 – March 2011

12. NRES Complaints and Breach of GCP/RGF/Potential F&M Registers for April 2010 – March 2011

Received for information only:

- NRES Complaints Register - 01 April 2010 to 31 March 2011
- Breach of GCP/RGF/Potential F&M 1 April 2010 – 31 March 2011

FW informed the panel that he had regular meetings every six months with John Kirkbride to discuss breach of GCP/RGF/potential fraud and misconduct and both he and Joan felt that these meetings were extremely useful.

13. Any Other Business

13.1 NREA Hosted Chairs Network Meetings

Simon Woods informed the committee that he had hosted the first chairs network meeting for the North West REC Centre on the 24th of January. He stated that the meeting had gone well and that he had received a lot of positive feedback from the attendees. The issue of the recent AMS report dominated the meeting but there was also discussion of other items including post-trial access and local appeals. There was not enough time at the meeting to discuss recent NREAP guidance but it was noted that many chairs had indicated they had provided feedback on the guidance which had did not seem to have reached either NRES or the Panel manager. Joan Kirkbride had indicated that she would investigate this further.

13.2 MIST Trial

JW informed the panel that she had recently had discussions with Dr Peter Wilmshurst regarding the issue of disclosure by investigators that they were currently under investigation. She had referred him to the minutes of the panel's discussion on these issues.

JW asked the panel if they could consider the issue of conflict of interest as a priority.

Agreed: It was agreed that this was an important issue that should be a priority for the panel as it had been highlighted in several of the meeting items. HD was currently in the process of putting together a discussion paper for the panel and this would be discussed as soon as possible.

13.3 Review of NREAP Guidance

Simon Woods asked whether the panel had agreed a process for the ongoing review of published NREAP statements and guidance. JW explained that NRES currently review all guidance yearly and had processes in place to alert the panel for the necessity of review. SiWo expressed the opinion that he felt the panel's guidance regarding the '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) might be returned to discuss whether it should be revised to be more emphatic regarding individual's responsibilities.

Agreed: It was agreed that this would be brought back to the panel for review shortly after the first anniversary of its publication

13.4 Public Involvement in Research Applications (IRAS Q. A14-1)

JW explained that Infonetica have been asked to trawl through all the answers to Q A-14 and present this data to INVOLVE who would report back to NRES. She informed the panel that a joint meeting between INVOLVE and NRES to discuss this issue would take place on Tuesday 15 February 2011, 12.30 - 2.30pm at the NIHR CRN Coordinating Centre.

14. Date of Next Meeting:

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

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