

National Research Ethics Advisors' Panel

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

Date: 09 March 2011

Time: 14:00 – 17:00

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

MINUTES

1. Apologies: Jeremy Butler
2. Declarations of Interest
There were none.
3. Minutes of meeting held on 09 February 2011
Minor revisions were requested by Frank Wells and John Saunders.

4. Matters Arising

4.1 JW Letter to General Dental Council re Fitness to practice pending enquiry and research activity

Received for information only:

- Letter to the GDC from Janet Wisely (following similar letter to the GMC)

The panel suggested that JW may also wish to send a similar letter to the Health Professions Council.

4.2 Any Other Business: NREAP Open Letter Expressing Concerns over delays to the implementation of the Recommendations from the AMS Review - Andrew George

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

AG explained that upon reflection he did not think it was sensible to write an open letter to the Prime Minister expressing the panel's concerns as this was likely to be counterproductive. He proposed that the draft letter tabled at the meeting be sent round to all NRES staff and NRES committee members explaining the difficulties being faced by the Service at present and expressing the panel's thanks to all staff and volunteers involved in NRES who are working so hard to maintain the service.

The panel agreed that a letter to be sent to all NRES staff and committee members.

FW suggested that AG should draft a parliamentary question which he would be willing to pass on to the BMA for advice on the appropriate form of words and then might be passed to a suitable MP. It was agreed that this would be a sensible way forward to express the panel's concerns and to seek clarification regarding the implementation of the AMS recommendations.

Action: AG & FW

4.3 The SMILE Study

JW explained that there had been a formal complaint made to the NPSA regarding the handling of the review of the favourable opinion for the study by the main REC following new information. JW pointed out that the complaint focused on the review of the “appeal” but that the second review carried out by the main REC was not an “appeal” but rather a review of its favourable opinion in the light of new information as per NRES SOPs:

“9.86 The main REC may review its favourable ethical opinion of a study at any time. In particular, this might be prompted by safety reports, progress reports or any other information received about the conduct of the study. The Chief Investigator or sponsor may ask the main REC to review its opinion, or seek advice from the REC on any ethical issue relating to the study.” (Standard Operating Procedures for Research Ethics Committees - Version 4.1, May 2010)

The panel expressed their concern that research into M.E. was becoming increasingly difficult for researchers and that consequently less research was being undertaken in this important disease area. Given the potentially vexatious nature of correspondence and complaints it was agreed that AG should contact ‘Understanding Animal Research’ to explore areas of common ground in handling correspondence with regard to conducting research in contentious areas..

Action: AG

4.4 MODREC

AG informed the panel that he met with the MODREC last week to discuss the provision of the panel services to them. It was agreed that formal links between MODREC and NREAP might be difficult to put in place given their different lines of accountability. However, both parties agreed that informal links would be mutually beneficial. AG offered the services of the NREAs to help with interview panels for recruitment to MODREC and this offer had been gratefully received.

4.5 NREA Hosted Chairs Network Meetings

SD asked whether Joan Kirkbride had got back to the panel regarding the issue of feedback from Chairs’ regarding panel guidance/statements. CC he had not received any communication on this and would contact Joan Kirkbride to chase up.

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

JS informed the panel that following JW’s response to the RCP Committee for Ethics in Medicine that the RCP would not be pursuing this matter further.

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

SiWo explained that he and David Neal had met with the ICU team at St Thomas’ Hospital and that the ICU doctors there indicated that they felt it would be useful for them to arrange a national meeting of ICU specialists to discuss this issue with a view to formulating national standards.

5. NRES Update : Janet Wisely

JW explained that NRES continued to face a number of on-going difficulties. The NPSA were still planning to close by September and reduce staff and services through the period through to closure, there was a possibility that they may be asked by the DH to close at a later date in order that the hosting arrangements for NRES might continue during an extended interim period. In addition, JW was exploring with DH a number of options regarding future accommodation for NRES staff currently located at Maple Street.

It was explained that during this continuing period of uncertainty that both JW and Joan Kirkbride were focusing on internal communications involving meetings with chairs, open sessions with staff in London and the use of webinars in order to keep all staff and volunteers fully informed.

The panel continued to be concerned that the delay in the implementation of the AMS recommendations was having a significant effect not only on the NRES but on the conduct of medical research in the UK.

The panel agreed that a letter should be sent to Sir Michael Rawlins expressing the panel's support for the recommendations contained in the AMS report but indicating their concerns regarding the delay to their implementation. The panel wished to ask Sir Michael Rawlins for his understanding of how the AMS recommendations were being taken forward. The panel's concerns focussed on the delay in the acceptance of the recommendations and the fear that the primary concern raised by the review, regarding the difficulties caused by local NHS Trust's R&D procedures, may not be fully addressed. In addition, NRES who were largely praised by the report, is now being damaged by the continuing uncertainty regarding the future of research governance in the UK and the place of NRES within this. It was agreed that the letter should be copied to Dame Sally Davies.

Action: AG

JW invited the panel to attend a strategic meeting with the NRES NMG on the 13th July in London to discuss broad issues related to finance, RECs remit and the proportionality of ethical review. The panel welcomed the invitation and it was agreed that the agenda for this meeting should be reviewed at the panel's meeting in either May or June.

6. Expert review of research and the role of Research Ethics Committees (RECs) - Meeting Report – Hugh Davies

Received for discussion/advice with a view to issuing NREAP guidance:

- Meeting Report: "Scientific review of research and the role of NRES Research Ethics Committees (RECs): what should these committees ask of the review they receive?"

HD explained that he was seeking the panel's comments on the meeting report with a view to the panel adopting the final report as an NREAP paper for publication.

There was lengthy discussion on the role of scientific or peer review in the REC approval process, and the limitations and benefits of scientific/peer review and of REC, There was a concern that any process should be proportionate to the study, and that it should not generate an unnecessary additional hurdle for researchers. HD emphasised that RECs would benefit from a practical tool to help them focus on what it is they should be looking at and what questions they should be asking and to provide a consistent approach across committees which would also be communicated to researchers. .

The panel agreed that the paper formed a useful starting point to develop guidance to be issued by NREAP. AG asked CW to work with HD to produce draft guidance for future discussion by the panel.

Action: HD & CW

7. NREA-Hosted Chairs' Network Meetings – arrangements protocol v2.0

Received for information only:

- NREA-Hosted Chairs' Network Meetings Protocol v 2.1

FW informed the committee that he had recently hosted a chairs' network meeting and felt that the term "NREA-hosted" set the right tone for the meetings i.e. the NREA 'hosts' them but that it was appropriate

that the meeting was 'chaired' by one of the local chairs. FW noted that the next meeting of the East Midlands network meeting had now been confirmed as 27th September 2011.

8. 'Going Beyond Proportionate Review' – How Should RECs Review Research with 'Limited Ethical Issues' – Hugh Davies

Discussed:

Currently where a research study presents "no material ethical issues" it can be reviewed and approved by a proportionate review sub-committee on behalf of the REC. At present, this service is run as a pilot and only available in certain areas with plans for full roll out of the pilot. The draft harmonised Governance Arrangements for Research Ethics Committees (GAfREC) published for comment by the Department of Health makes provision for Proportionate Review to be introduced by NRES. When the harmonised GAfREC is finalised, it is envisaged that the service will be formally adopted.

The panel were asked to broadly discuss the following issues regarding the review of research with 'limited ethical issues' rather than 'no material ethical issues':

- What research should RECs be reviewing
- How should they review such applications

HD explained that the PRS pilot had been positively received but that it still depended upon the coordinator to be able to screen out suitable applications. Once this had been done, however the application could be reviewed quickly and easily. Currently applicants still needed to complete the full IRAS form for PRS but he wondered whether the documents required for proportionate review might be scaled down to simply include the protocol, information sheets/consent forms along with the summary of the research and the ethical issues. HD stated that it was more his intention to look at the information really required by RECs to conduct an ethical review with a view to reducing the amount of information required in the IRAS form. The information required for proportionate review would then be extracted from the IRAS form and sent to the committee. It was his hope that NRES might lead on the review of the information required in the IRAS form so that it might be simplified and reduced.

It was also suggested that RECs might give approval to programmes of research in the same way that generic ethical approval is given to tissue banks. As long as any proposed research under the generic approval was within the approved "template" then there would be no need for further ethical review.

It was agreed that both "protocol only" review for research with 'limited ethical issues' and approval of generic 'template' research were worthy of further consideration. JW said that following assessment of current pilot and wider policy issues a series of 'models' for discussion at the strategic meeting of the NMG and the panel on the 13th July would be developed.

9. Public consultation on a concept paper on the revision of the 'Clinical Trials Directive 13 May 2011 - David Neal

Received for discussion:

- Revision of The 'Clinical Trials Directive' 2001/20/EC - Concept Paper Submitted for Public Consultation (deadline for response: 13 May 2011)

The 'pharmaceuticals' Unit of the Health and Consumers Directorate-General, European Commission have published a concept paper on the revision of the 'Clinical Trials Directive' 2001/20/EC for public consultation It contains:

- a 'preliminary appraisal' of which option appears to be the Most suitable one to address some of the key concerns of the Clinical Trials Directive, on the basis of the current state of the impact assessment; and

- the main figures that are being used to evaluate the impacts of the different policy options.

It is not the purpose of this consultation paper to repeat the 2009/10 public consultation. Topics which have been explored extensively during that consultation are not again put forward for discussion. Rather, the purpose of this public consultation is

- to seek views on more concrete ideas on the issues that have been presented in a rather general way during the 2009/10 public consultation. Consequently, some issues looked at in this paper are of a more detailed and technical nature; and
- to verify with stakeholders the core data which forms the basis of the impact assessment.

The consultation document is also available at: http://ec.europa.eu/health/human-use/clinical-trials/developments/index_en.htm

David Neal gave a presentation on the 'Clinical Trials Directive' 2001/20/EC - Concept Paper Submitted for Public Consultation.

The panel noted a number of issues identified by David Neal and endorsed his proposed responses to these issues on behalf of NRES. The panel did not feel that any of the issues identified were of direct relevance to the remit of NREAP and thus would not be submitting their own response to the consultation.

10. Action Register

Received:

- NREAP Action Register

11. Any Other Business

RT proposed that the panel should formally write to Dame Sally Davies to congratulate her on her recent appointment as Chief Medical Officer (CMO) for England.

The panel agreed.

Action: AG

12. Date of Next Meeting:

The next meeting of the National Research Ethics Advisory Panel will be held on 13 April 2011.

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