

National Research Ethics Advisors' Panel

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

Date: 09 June 2010

Time: 14:00 – 17:00

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

MINUTES

Present:

Andrew George (Chair)
Jeremy Butler
Hugh Davies
Peter Heasman
Nalin Thakker
Art Tucker
Charles Warlow
Sue Wilson
Simon Woods

In attendance:

Dr Janet Wisely
Mr Clive Collett (NREAP Manager)

1. Apologies: Sarah Dyer, John Saunders, Frank Wells, Richard Tiner
2. Declarations of Interest
There were none
3. Minutes of meeting held on 12 May 2010
The minutes of the previous meeting were agreed as a true record.

4. Matters Arising

4.1 Withdrawal of Data Following Participation in a Study.

Janet Wisely explained that following the Panel's discussion of this item at the last meeting the Information Commissioner has insisted that the study participant's data be removed from any analysis in the study that prompted the initial discussion of this issue.

It was noted by the Panel that this is likely to mean that the study will now not be published. The Panel noted that the decision taken by the Information Commissioner might have been constrained by the existing data protection law, but strongly indicated that the consequence was that a study might be wrecked and that the autonomy of other participants in the study harmed

Simon Woods (SWo) suggested that NRES might consider providing a template for researchers as it has done in other instances such as the MCA so that researchers have an example of appropriate wording to use when raising the issue of data retention at the time of consent to a study.

The Panel felt that it would be beneficial to seek the views of other interested parties, e.g. the MRC, to mount a coordinated response to this decision. It was agreed that Andrew George (AG) should contact Professor Janet Darbyshire (Head of the MRC Clinical Trials Unit and Joint Director of NIHR CRN CC) about the Panel's concerns regarding the removal of valuable data from research studies.

Action: AG

5. "Gatekeepers" – Sue Wilson

- Received and considered: A paper from Sue Wilson, Sarah Damery, Sally Warmington & Janet Jones describing two case studies where processes and procedures associated with seeking approval for research to commence, have either delayed research or prevented it.

The Panel agreed that the issues highlighted by the paper presented a major barrier to the conduct of research in the UK and that they chimed with the issues identified in the Joint NREAP/AREC Response to Independent Review of the Regulation and Governance of Medical Research.

Sue Wilson (SWi) explained that even within a single NHS Trust there were various levels of "clearance" that were required even down to the departmental level and this proliferation of internal approval processes often were the cause of significant delays. In addition, the NIGB secretariat would often make information requests in addition to those asked for by the NIGB itself and SWi wondered whether it might be possible in future to centrally coordinate the different approval processes.

JW stated that IRAS should hold the complete data set for a research project. If other bodies required more information than this then they should flag this up to the IRAS board for consideration. The Panel noted that there was currently no mechanism to broker any difference in opinion between an ethics committee and another gatekeeper such as the NIGB. JW stated that there would shortly be a Memorandum of Understanding between NRES and the NIGB which should greatly facilitate communication between the two bodies and facilitate a swift resolution in the event of any disagreement.

SWi asked the rest of the Panel whether it would be useful for her to submit version of this paper to the Academy of Medical Sciences Independent Review in her capacity as an academic researcher. The Panel agreed that this would be sensible.

Hugh Davies (HD) highlighted the need to provide 'solutions' to the AMS review Panel as well as incidences of specific problems. He suggested the need for better education and training for 'gatekeepers', a single insurance policy for research involving NHS patients to be provided via the NIHR, the setting of targets within NHS trust contracts to conduct research and the setting of regulatory approval timelines for gatekeepers.

AG also pointed out that the NIGB and other gatekeeping bodies do not have appeals processes in place such as those available to researchers who wish to appeal against the decision of a REC.

JW commented that it was a greater risk for the NHS not to perform and facilitate ethical research than the attendant risks of carrying out research. The Panel agreed.

6. Nuffield Consultation on Ethics of Human Bodies in Medicine and Research – Simon Woods

It was agreed at the May meeting that the Panel should respond to the consultation.

- Received and considered: the Nuffield Council on Bioethics consultation document “Human Bodies in Medicine and Research”.

Simon Woods (SWo) presented an initial response to the consultation for discussion by the Panel. He explained that he had couched the initial response in general language avoiding substantive "ethical" arguments.

The Panel thanked Simon for his work on the initial document and made a number of suggestions and revisions. SWo would use these to produce a second draft of the document which would be circulated to the Panel in order to prepare the final NREAP response for submission to the Nuffield Council.

7. NREA Guidelines: Educational Projects and Research

The Panel were invited to consider whether they would like to issue any guidance to Universities, or support a letter from NRES management to Universities potentially regarding educational research projects.

Received for Information:

- Email correspondence between Janet Wisely and a REC Chair
- Email correspondence between Janet Wisely and an attendee at the Southern Conference
- Current online NRES guidance regarding educational projects

The Panel felt that it was important to acknowledge the educational benefit of undertaking a piece of student research even if there was little or no scientific value to be gained from that research, or if it had been conducted previously. However it was emphasised that there needed to be ‘real’ educational value to be gained from the conduct of the research.

The Panel noted that the level of support provided by supervisors to students in undertaking research was variable and could often be inadequate. It was suggested that an ethics committee might refuse to give an opinion or give an unfavourable opinion if the supervisor did not attend the REC meeting with the student, however it was pointed out that students and supervisors are only “invited” to attend the meeting at which their project is being reviewed and RECs would be going beyond their remit to issue an unfavourable opinion in this case.

AG felt that there were two aspects to the question under consideration:

1. The provision of guidance and training on this issue to REC members
2. What action should be taken by RECs/NRES where poor supervision is identified?

With regards to the first point the Panel agreed to restate previous NRES advice on student research which reiterates that, notwithstanding the scientific value, the educational value of student research is an important and worthwhile goal in itself. The current induction and other training available to REC members should be checked to ensure that it adequately addresses the issue of student research.

With regards to the role of supervisors, the Panel agreed that they should be strongly encouraged to attend alongside the student for the meeting at which the research is reviewed. Where a supervisor does not attend the committee felt that the REC could note this in their opinion letter and state that they were concerned that the supervisor did not attend. It was considered that such attendance was an essential part of the supervisor's responsibilities. Furthermore, it was suggested that, in cases where the REC also had concerns over the general quality of the proposed research, the supervisor's Head of Department should be either copied into the letter or have a specific letter written to them pointing out the non-attendance of the supervisor and the poor quality of the application. The Panel discussed whether such action involving the notification of a third party of the outcome of the REC review was in contravention of the Data Protection Act. The committee asked JW to investigate whether this was the case.

Action: CC to liaise with David Neal

JW re DPA

8. NREA-Hosted Chairs Network Meetings – Discussion Document – Clive Collett

At the February meeting the Panel agreed in principle that NREAs would facilitate and host chairs network meetings in their local patches.

- Received and considered: NREA-Hosted Chairs Network Meetings – Discussion Document

The Panel broadly agreed the proposals set out in the discussion document but made the following suggestions:

- **Attendees:** the Panel felt that Vice-Chairs should be invited in addition to Chairs. Alternate Vice-Chairs (or if unavailable another REC member) should be invited to attend where only one of either the Chair or Vice-Chair can attend.
- **Agenda:** HD felt that the agenda should be set locally and then passed up to the NREA. However, JW felt it would be preferable if the agenda could be set by both the NREA and the local Chairs. She emphasised that it was important to ensure that national issues can be discussed by all Chairs at these meetings and these would need to be set by the NREAs in discussion with NRES. It was agreed that a central agenda would be prepared but additional items could be added by local Chairs/Vice-Chairs.
- **Network Meeting Groups:** the Panel agreed that the current groupings appeared sensible but also felt that the initiative should be offered to RECs in Scotland, Wales and Northern Ireland. It was felt that Wales could be combined with either the 'South West' or 'West and East Midlands' network group. Scotland and Northern Ireland would each form a single network group.
- **Minutes:** the Panel agreed that the minutes would be circulated to the attendees and their committees. NREAs could bring minutes/specific items from the minutes to the attention of the Panel, and if applicable to NRES, where necessary.

Once the network groupings were finalised then NREAs would need to be mapped to their appropriate group.

It was agreed that it would be sensible to pilot the Chairs network meetings initially before rolling out across the country. It was proposed that the pilot should take place in the following network groups:

- **London** (Proposed REC Centres: London Bridge & Northwick Park)
- **North West** (REC Centre: Manchester)
- **Yorkshire and the Humber** (REC Centre: Leeds) & **North East** (REC Centre: Jarrow)

Action: CC in liaison with NRES Operations Team

9. Draft Proposal for Local Service Evaluation Governance - Andrew George

- Received and considered: A draft proposal "Developing Local Clinical Governance of Service Evaluation Inquiries" from Dr Bernie Colaço (Chair, North London REC 1)

The committee welcomed any local initiative aimed at developing the clinical governance of service evaluation enquiries. There was a clear need for service evaluation projects to be sensibly governed in a way which did not place an undue burden upon clinicians carrying out this important work. However, the Panel noted that 'service evaluation' was, by definition, not 'research' and therefore not within the remit of NRES or NREAP and thus the Panel could not comment upon this local initiative.

Action: CC

10. Joint NREAP/AREC Response to Independent Review of the Regulation and Governance of Medical Research - Andrew George

- Received: The Final version of the Joint NREAP/AREC Response to Independent Review of the Regulation and Governance of Medical Research submitted to the AMS Review Panel

11. Email from David Neal to Marc Taylor re: Meeting of the Commission Ad Hoc Working Group on Guidelines on the Clinical Trials Directive, 11 May 2010

- Received: An email from David Neal to Marc Taylor in his capacity as Chair of UKECA, reporting on the Commission Ad Hoc Working Group for the Development of Implementing Guidelines for the Clinical Trial Directive. This was the first time David had attended the working group. Until this year the group has been attended only by Competent Authority leads, but Member States are now invited to send ethics committee representation, and he attended on behalf of UKECA.

12. Follow-up contact of potential participants who have not responded to an initial invitation to take part in research – Draft Letter – Andrew George/Clive Collett

- Received and considered: draft guidance on the follow-up contact of potential participants who have not responded to an initial invitation to take part in research.

The Panel welcomed the document but agreed that an additional paragraph needed to be added to the section detailing the "principles" that should be taken into consideration when reviewing research involving the follow-up contact of potential participants which explicitly stated who should be allowed to make this follow-up contact.

The Panel agreed that the follow-up contact should only be undertaken by an individual with the right to access their personal information who is also known to the potential participant.

Action: CC

13. The pharmaceutical industry and Q A14-1 – Jeremy Butler

- Received and considered: An e-mail sent to Janet Messer (Deputy Director NHS R&D Forum) from an individual working for a contract research organisation (CRO) asking for advice on the appropriate response to Q.A14-1 in the IRAS form. Janet Messer passed the request on to Jeremy Butler for his view.

Question A 14-1 asks the applicant to state:

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

- Design of the research
- Management of the research
- Undertaking the research
- Analysis of results
- Dissemination of findings
- None of the above

Give details of involvement, or if none please justify the absence of involvement.

The Panel noted that the individual from the CRO considered that it was not appropriate to involve patient groups or the public in any of these aspects due to issues of confidentiality and intellectual property but also because they felt that such individuals would not have sufficient knowledge to contribute to the design of the research.

The Panel disagreed strongly with the sentiments expressed in the e-mail from the CRO and noted that such views were not representative of the pharmaceutical industry in general.

It was noted that specific guidance on this question was already given within IRAS:

“Question A14-1 - Patient, service user and public involvement

Public involvement includes consultation with or working alongside members of the public, patients, service users or carers in the choice of research topic, and the design, planning, conduct and dissemination of research. The UK health departments are committed to active patient and public involvement in all stages of research. For more information see INVOLVE (<http://www.invo.org.uk/>) or, in Wales, see Involving People (<http://www.wales.nhs.uk/sites3/page.cfm?orgid=580&pid=14773>)

This question does not refer to the involvement of patients, members of the public or service users or carers as participants in the research.”

Furthermore, the Panel endorsed the aim of INVOLVE to support and promote active public involvement in NHS, public health and social care research. It was agreed that the pharmaceutical industry should, where appropriate, endeavour to involve patients, service users and/or their carers, and members of the public in the design, planning, conduct and dissemination of research.

Action: JB

14. Memorandum of Understanding between MHRA, NRES, GTAC and AAPEC

- Received and noted: Memorandum of Understanding between MHRA, NRES, GTAC and AAPEC

15. Institute of Clinical Research Response to Call for Evidence - Academy of Medical Science review of the regulation and governance of medical research

- Received and noted: ICR Response to Call for Evidence - Academy of Medical Science review of the regulation and governance of medical research

16. Any Other Business

13.1 Translation of information sheets:

During the meeting SWi raised the issue of the translation of information sheets, particularly for student research, or for a pilot study. She explained that RECs would often insist upon such translation even where the researcher had no budget to fund this. The Panel agreed that, whilst it acknowledged the importance of providing translated information documents and interpreters to non-English speakers and the importance of making access to research available to all members of society, there may be occasions where it would not be appropriate to insist upon this. The Panel agreed to discuss this issue at the next meeting.

17. Date of Next Meeting:

The next meeting of the National Research Ethics Advisory Panel will be held on 14 July 2010.

Time: 14:00 – 17:00.

Venue: Conference Room

Indian YMCA

41 Fitzroy Square

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