National Research Ethics Advisors' Panel

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

Date: **08 December 2010**
Time: **14:00 – 17:00**

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

MINUTES

Present:

Andrew George (Chair)
Jeremy Butler
Peter Heasman
John Saunders
Nalin Thakker
Art Tucker
Charles Warlow
Frank Wells
Simon Woods

In attendance:

Dr Janet Wisely (NRES Director)
David Neal (NRES Deputy Director (Policy)
Clive Collett (NREAP Manager)

1. Apologies: Hugh Davies; Sarah Dyer; Caroline Harrison; Richard Tiner; Sue Wilson

2. Declarations of Interest

   There were none

3. Minutes of meeting held on 10 November 2010

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

4. Matters Arising

4.1 The 'SMILE' Study

JW informed the panel that the main REC had now reviewed its favourable opinion in the light of new information (as per current NRES SOPs).

The main REC had voted unanimously to confirm the favourable opinion of the application with the following additional conditions:

1. PIS for Teenagers and PIS for Parents: Please add the fact that the Lightening Practitioner is

not clinically (medically) qualified (trained).

2. PIS for Teenagers and PIS for Parents: Please include the following text in the 'Are there any disadvantages to taking part' section:
"Teenagers with CFS/ME can get worse with any intervention offered. There is no data in teenagers, see tables 1 and 2 for data in adults."

3. PIS for Teenagers and PIS for Parents: Add the figures for GET, CBT and the LP from the Parliamentary Inquiry into NHS Service provision for ME/CFS include Data taken from Action for ME (AfME) and Association of Young people with ME (AYME) joint report "M.E. 2008: What progress" and reference it.

4. PIS for Teenagers and PIS for Parents: Add the figures for GET, CBT and the LP from the 2008 MEA survey and reference this.

The main REC also suggested (not as an additional condition) that in future Dr Crawley should consider using Lightening Practitioners who were additionally clinically qualified.

5. **NRES Update : Janet Wisely**

JW informed the panel that there was no further progress on specific arrangements for NRES after NPSA closure, and also that the option of hosting staff through a PCT had fallen through. Plans now for operational staff focussed on temporary arrangements through the Foundation Trust in Bristol, and some staff interviewed for permanent posts had taken the opportunity of working on a temporary basis pending NRES being able to offer contracts through a host.

JW explained that AREC had approached her to discuss how they could assist with lobbying relevant individuals concerning the current difficulties faced by NRES. JW felt that as AG had already communicated with both Sally Davies and Michael Rawlins on behalf of NREAP, and had received sympathetic replies, further lobbying would not necessarily be beneficial. However, she welcomed the support of AREC and their help in communicating the difficulties faced by NRES to their members. The panel agreed that the offer of further lobbying from AREC was welcome but would not be necessary given the assurances received from the Department of Health (DH) regarding the future of NRES.

JW suggested that the panel might begin to receive more detailed reports from NRES regarding business plans, appeals, complaints, breaches etc (all of which are currently supplied to the panel for information/advice). A panel agreed that they would be happy to receive such reports.

JW had attended a recent stakeholder event to hear the headline findings of the Academy of Medical Sciences (AMS) review ahead of the publication of the full report in January 2011NRES and the IRAS system were both highlighted as strengths of the current research governance system.
The panel were informed that the recent Chairs national training day attended by members of the panel had been very successful and well received by attendees.

6. **Time-critical research in intensive care – compliance with the Mental Capacity Act : David Neal & Simon Woods**

Received for discussion:

- Time-critical research in intensive care – compliance with the Mental Capacity Act
- Appendix A: Time-Critical Research in Intensive Care at Guy's & St Thomas' Hospital - Compliance with the Mental Capacity Act
- Appendix B: Request for Advice from Relatives about Patient Participation in Intensive Care Unit Research Studies
- DH Guidance on nominating a consultee for research involving adults who lack capacity to consent

The panel discussed the documents regarding a proposed pilot scheme at St. Thomas' Hospital to facilitate increased recruitment of acutely ill patients lacking capacity into time-critical research undertaken in the Intensive Care Units by inviting relatives to indicate in advance whether they believe the patient would be willing to participate in studies for which they were eligible.

The panel recognised and supported the wish to facilitate increased recruitment into valuable emergency care research with the involvement and support of relatives. However, the panel noted that the proposal excluded the use of nominated consultees. Whilst the panel recognised the practical difficulties of using nominated consultees in the ICU setting, the option appeared to have been excluded for reasons of principle that conflicted with the intentions of the Mental Capacity Act and the DH guidelines and therefore could not be supported given that the involvement of such consultees is provided for in law and statutory guidelines.

The panel noted that the provisions contained within the Mental Capacity Act with regards the recruitment of adults lacking capacity into research were study specific and were intended to be applied to recruitment to research as a generic activity. Section 32(9) of the Act allows for recruitment without prior consultation where it is a matter of urgency: enrolment may take place (a) with the agreement of a doctor independent of the project; or where this is also not reasonably practicable in the time available (b) in accordance with any procedure approved by the REC. Once the emergency is over and more time is available, the researcher must seek consent from the patient (if capacity has been recovered) or consult a consultee on whether the patient should continue in the project. There are, therefore, a number of possible pathways to recruitment depending on the circumstances and the options agreed by the REC. However, these pathways need to have been described and justified in the application to the REC for each specific study where no consultees (personal or nominated) are likely to be available.

Simon Woods indicated that there were difficulties with the requirement that consultees should reflect the presumed wishes of the participant lacking capacity and that, with regard to nominated consultees who would have little or no personal knowledge of the participants wishes, it should be made clear that they need to consult as widely as possible with relatives etc who could shed some light on these presumed wishes. John Saunders explained that previous studies had shown that personal consultees do no better than chance in identifying their relative's wishes with regard to participation in research and that, in his view, the use of consultees was supported more by respect for people than any arguments that the use of consultees ensures the 'right' decision is reached as either decision (to allow recruitment or not to allow recruitment) is statistically likely to be correct. Indeed, research into this area has indicated that people were happy that a process of consultation had been entered into rather than that the 'right' decision had been arrived at.

Art Tucker stated that in around 500 instances of the use of consultees at the Royal London Hospital the recruitment of only 5 patients was refused by personal consultees and no patient had been refused entry into a study by a nominated consultee. Of those 500 patients lacking capacity recruited into research 4 patients subsequently refused to participate once they had regained capacity. The panel found such data extremely useful and informative and felt that it might be sensible to gather further evidence regarding the use of consultees in this context to inform future guidance.

Agreed: Whilst the panel sympathised with the aim of facilitating increased recruitment into valuable emergency care research with the involvement and support of relatives they could not support the current proposal as it was not fully compliant with existing law and statutory guidance. It was agreed that further consideration should be given to the potential for use of nominated consultees, where practicable, alongside other options.

It was agreed that David Neal should informally meet with the intensive care team at the Guys and St Thomas' Hospital Trust to discuss the proposal and the options available to them to ensure compliance with the Mental Capacity Act.

The panel agreed that it would be sensible to gather further evidence and data regarding the use of consultees in this context to inform future guidance (AT and JS agreed to contribute to this) and that a

meeting/workshop should be held involving both researchers and members of RECs along with other stakeholders to further reflect on the issues involved in the recruitment of adults lacking capacity into emergency care research with a view to producing future guidance on this issue.

Action: AT & JS (provision of data)

7. NRES Policy and 'Foreign Policy': David Neal

The panel received a presentation by David Neal (NRES Deputy Director (Policy))

During the presentation it was suggested and agreed that the service of the panel might be informally offered to the MODREC. AG agreed to write to the committee accordingly in order to establish relations.

Action: AG

8. Consultation on Draft BPS Code of Human Research Ethics

The panel were asked to review the draft BPS document and provide any comments they might have.

Received for discussion:

- Consultation on Draft BPS Code of Human Research Ethics
- Response form

Agreed: It was agreed that comments on the draft BPS code should be forwarded to CC for collation and discussion with AG before submission to the BPS.

9. NRES Operational Issue: Inclusion of REC reference number on study documentation (including participant information sheet)

The panel were asked to advise on an NRES operational issue regarding the inclusion of REC reference numbers on study documentation (including participant information sheets).

The panel were asked to consider endorsing the NRES position that the inclusion of the REC reference on study documentation is not necessary and should not be insisted upon as a condition of approval.

Received for discussion:

- Email Correspondence

The panel discussed the matter of the inclusion of REC reference numbers on study documentation (including participant information sheets) and felt that whilst it may help organise internal filing this was not a sufficiently compelling reason to require applicants to include REC reference numbers on documents.

Whilst it was recognised that there may be potential benefit from the inclusion of the REC reference number on documentation as an assurance mechanism for participants, journals etc that REC approval was in place, the panel supported current NRES guidance for the name of the REC to be included and felt that this should provide sufficient assurance of such approval. It was agreed the reference number could be seen as helpful but it was felt that it would not be appropriate for NRES or NRES RECs to insist upon its inclusion in study documentation. If the sponsor or investigator wished to include the REC reference number in their documentation then they were of course free to do so.

The panel fully supported the current NRES position that RECs should NOT require the internal REC reference number to be included on documentation as a condition of approval.

10. **Action Register**

To receive for discussion:

- NREAP Action Register

The panel reviewed the action register and discussed options for further action. The register would be updated accordingly.

Action: CC

11. **The EU Clinical Trials Directive in 2011: Tweaks or Transformation?**

Received for information only:

- The EU Clinical Trials Directive in 2011: Tweaks or Transformation? (Pharma IQ)*

FW referred to the committee to the EFGCP report on the ICREL project which he felt would be of interest to the panel. The ICREL project measured the influence of the EU directive on clinical research in Europe.

This would be circulated to the panel by e-mail.

Action: CC

12. **Any Other Business**

12.1 'RECs in the News'

JW informed of the panel that the NRES email newsletter "RECs in the news" would resume publication. The newsletter contains articles of interest to research ethics committees and would be compiled by Carla Denneny. If NREAs knew of any suitable articles suitable for inclusion they should be e-mailed to carla.denneny@nres.npsa.nhs.uk.

12.1 Shared Ethical Debate (SED5: Phase 1 studies)

Jeremy Butler gave a brief update on the recent SED workshop which focused upon issues surrounding phase 1 studies (HD would present a full report to the panel in January). JB noted that there was some heterogeneity amongst the views and practices of the committees taking part in the workshop particularly with regard to:

i) Understanding of the role of the MHRA
ii) Responsibility to review the science of a study
iii) Use of IRAS
iv) Attendance of investigators

He agreed that further training and dissemination from the exercise would be useful to share learning points arising from such debates. JW noted that with regard to the issues of the committee's responsibility to review the scientific validity of a study that this was being addressed by a 'Peer Review Workshop' taking place on the 11th January 2011 in Oxford.

13. **Date of Next Meeting:**

The next meeting of the National Research Ethics Advisory Panel will be held on 12 January 2011.

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