National Research Ethics Advisors' Panel

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

Date: **11 May 2011**
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
Caroline Harrison
Peter Heasman
John Saunders
Art Tucker
Charles Warlow
Frank Wells
Simon Woods

In attendance:

Dr Janet Wisely
Mr Clive Collett

1. Apologies: Sarah Dyer; Nalin Thakker; Richard Tiner, Sue Wilson
2. Declarations of Interest: None
3. Minutes of meeting held on 13 April 2011

   Minor changes were requested to the minutes.

4. Matters Arising

4.1 The Ethics of Transplantation Research – Letter from Prof Dame Sally Davies to Prof Anthony Warrens (UKDEC)

Received for information only:

- Letter from Prof Dame Sally Davies to Prof Anthony Warrens (UKDEC)

4.2 Advertising materials and inclusion of payment amounts

Janet Wisely confirmed that this issue has now been referred to the phase I group for their view.

5. NRES Update : Janet Wisely

Janet Wisely informed the panel that NRES had now moved to the ground floor of Maple Street. JW also advised that she had been asked to Chair an Establishment Group for the Health Research Authority, which would have a joint NRES / DH secretariat. The Establishment Group will be accountable through a Steering Group, Chaired by Dr Russell Hamilton, to the ALB Transition Board. Further information will follow after preliminary meetings in late May / early June and will be communicated to REC community.

6. **The Ethics of Transplantation Research: current guidance and a framework for review (updated) –** Hugh Davies

Received for information:

- The Ethics of Transplantation Research: current guidance and a framework for review (updated)

The panel noted the revised document and agreed that it should be sent to UKDEC for their input and would be revisited once their response had been received.

Action: HD

7. **NRES Report on the Shared Single Issue Ethical Debate: "How should RECs consider and decide about the inclusion or exclusion of participants in research who may have difficulties in adequate understanding of English?"** – Hugh Davies

Following discussion of this item in February the document has been revised.

Received for information/advice:

- NRES report on the Shared Single Issue Ethical Debate: "How should RECs consider and decide about the inclusion or exclusion of participants in research who may have difficulties in adequate understanding of English?"

Agreed: Further comments on this document should be sent to Hugh Davies. The final document would then be published in four weeks time on the NRES website.

During the panel's discussion the issue of access to participation of foreign nationals in NHS-based medical research was raised. Simon Woods explained that some commentators felt that as such research was embedded within the NHS and utilised valuable NHS time & resources that participation should be limited to UK nationals, whilst others felt that provided the potential participant fulfilled the entry criteria for the study this was the only important factor to be considered. It was agreed that this issue should be further explored via e-mail correspondence between John Saunders, Simon Woods and Frank Wells to decide whether this should be discussed as an agenda item at a future NREA panel meeting.

8. **NRES Report on the Shared Ethical Debate March 2011: an analysis of 17 Research Ethics Committees' review of a research project entitled "How can art assist in the recovery and promotion of mental health?"**– Hugh Davies

Received for information/advice:

- NRES Report on the Shared Ethical Debate March 2011: an analysis of 17 Research Ethics Committees' review of a research project entitled "How can art assist in the recovery and promotion of mental health?"

The panel welcomed the report. JS noted that the application raised issues regarding the ethics of cluster randomisation and that not all REC members may be fully cognizant with this particular method and its attendant ethical and methodological difficulties. The panel agreed that this was a complex issue and felt that it was something that they will consider returning to at a future date. PH felt that the current document included far too much detail of the committees' comments that are unlikely to be read by

everyone and that it would be preferable to summarise this data in a more digestible manner which highlights the main issues. JB commented that this exercise had resulted in 8 unfavourable, 7 provisional and one favourable opinion and wondered how greater consistency amongst RECs might be achieved, perhaps through identifying the areas of particular difficulty in this exercise and instigating training in these areas. HD acknowledged that there was a diversity of opinion coming out of this exercise but referenced, as way of explanation, that the RECs in the exercise did not have the benefit of being able to ask the research questions and that given the somewhat artificial nature of the review (i.e. all RECS were aware that the application was a "dummy", no researchers were present to discuss the application and there was a tendency for RECs to search for issues to comment upon in these training exercises no matter how trivial) it had only limited interpretability.

During the discussion HD drew the panel's attention to a recent article published by Roberts et al. in the Lancet entitled "Effect of consent rituals on mortality in emergency care research"[1]. It was agreed that CC would circulate this to the panel by e-mail.

9. **Review of NREAP Guidance: 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) -** Simon Woods

At the February meeting of the panel it was agreed that published NREAP guidance should be reviewed annually, along with any feedback received, to consider whether it requires revision.

Received for discussion:

- NREAP/01 Correspondence from the National Research Ethics Advisors' Panel (Published 22 April 2010)

  (i) Disclosing Information about a Research Participant without consent and
  (ii) Appropriate action for a researcher when seeing poor practice.
- Email feedback from Mrs Claire Ramsden regarding the published guidance.

Simon Woods echoed the e-mail from Mrs Claire Ramsden in stating that the responsibility for the safeguarding of children was incumbent upon everyone working with children and not just professionals with statutory obligations. He felt that all RECs should consider whether the researcher has made an appropriate declaration about the extent of, and any limits to, the principle of confidentiality within the information sheet. In some circumstances it may be necessary for the researcher to include an explicit declaration about the circumstances in which confidentiality will not be honoured e.g. where the research participant discloses information that leads the researcher to believe there is a danger to self or others. Furthermore it should be emphasised that no breach of confidentiality occurs when the participant gives consent for disclosure and therefore seeking consent for disclosure must be an element of their strategy.

CH expressed their concern that, whilst she agreed that RECs should insist upon a clear strategy for research where disclosure may be an issue, children might feel that there was an expectation that they will disclose information regarding others conduct and that it was *their* responsibility to disclose such information when what was required was a purely *voluntary* provision of information. JB commented that perhaps, whilst the researcher must always understand and adhere to moral and statutory requirements of disclosure, it might not always be appropriate to inform the child of these requirements.

FW expressed the opinion that the original NREAP guidance had been warmly welcomed by REC chairs as evidenced by the feedback he had received from the NREA hosted Chairs Network Meetings and he did not feel that the guidance needed to be revised as the issues discussed by the panel were all adequately addressed. SW felt that whilst this might be the case it should be emphasised that the RECs should always insist upon a strategy for dealing with potential disclosure, as many researchers were not

[1] The Lancet, Volume 377, Issue 9771, Pages 1071 - 1072, 26 March 2011 (http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(11)60317-6/fulltext)

subject to the existing professional codes of conduct identified in the current guidance.

Agreed: The panel agreed that SWo should suggest revisions to be made to the existing NREAP guidance in collaboration with AG and CC. The revised document would then be email to all NREAs for comment.

10. **"Research Ethics CD" "A research ethics syllabus for Research Ethics Committee members (Version 1, April 2011) –** Hugh Davies

Discussed:

- Research Ethics CD: "A research ethics syllabus for Research Ethics Committee members – V1 April 2011. (The CD has been posted to NREAs)

HD asked for any comments on the CD to be e-mailed to him.

11. **Guidance sheets for REC Coordinators/Chairs and members**

The Panel were asked to consider the possibility of the provision of brief guidance sheets on various issues that would be made available primarily to coordinators and REC Chairs

Received and discussed:

- Brief proposal paper for "Guidance sheets for REC Coordinators/Chairs and members"

JS expressed the view that there was already a large amount of guidance available but the problem was that no-one reads it. Furthermore, he felt that the RCP "Guidelines on the practice of ethics committees in medical research with human participants" and MRC guidance documents were the prime reference materials needed by RECs as he felt they covered the majority of issues faced by committees. CC explained that whilst volunteer REC members didn't always have the time or inclination to read such guidance or were not always aware of the various regulations pertaining to ethics committees, the coordinators should be empowered to be aware of these and act as a "clerk of court" advising members of the statutory and ethical context to the research they were reviewing. The provision of brief one page guides highlighting the "headline" issues for various topics that could be quickly referred to at meetings, primarily by the coordinator and Chair, might go some way to ensure that committees are aware of relevant guidance and legal considerations. SWo stated that as someone who teaches research ethics that it was useful to produce summaries consisting of around four bullet points with links to online guidance. CH stated that in her experience on GTAC that the input of the GTAC secretariat was invaluable as they produced a summary of the each application along with a thumbnail sketch of the issues associated with it.

JW explained that one of the key rationales for the development of REC centres was to enable senior and more experienced staff to develop roles to further support the RECs, including advising on relevant guidance for consideration on a particular study. This was linked to recent initiatives such as 'Information Exchange' and the use of the Extranet to further improve reference to relevant guidance.

12. **NRES Appeals Register for April 2010 – March 2011**

Received and noted:

- The NRES Appeals Register for April 2010 – March 2011

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

Received and noted:

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

14. **INVOLVE – IRAS Question 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?" Analysis of responses -** Sarah Buckland & Maryrose Tarpey (INVOLVE - http://www.invo.org.uk/) **(attending at 4pm)**

Sarah Buckland and Maryrose Tarpey attended the meeting and gave a short presentation on their analysis of responses to QA14-1

Received for information only:

- Involving users in the research process, a 'how to' guide for researchers. (King's College/Guy's and St Thomas' NHS Foundation Trust leaflet: http://www.guysandstthomas.nhs.uk/resources/education_research/biomedicalresearch/transcripts/step-by-step-user-involvement-guide.pdf)

The panel congratulated INVOLVE, NRES and Infonetica on this collaborative research and felt that this was an excellent use of IRAS application data that had yielded extremely useful information. The panel encouraged INVOLVE and NRES to publish this preliminary data as it was felt that this would help to encourage a wider discussion of this issue amongst all stakeholders.

The panel commented that it appeared that many researchers failed to adequately understand Question A14-1 and that they appeared not to have consulted the available guidance on this question provided in IRAS. One purpose of the activity had been to inform the rewording of question 14 and it was agreed that the wording of this question may need to be revised in order to make it clearer to researchers exactly what is being asked for. It was noted that researchers might assume that the tick box for "dissemination of findings" refers to how results will be disseminated "to" participants and the public rather than disseminated "by" participants/public, even though the initial question referenced service user involvement. It was also agreed that perhaps question A14-1 should not be a "tick box" question at all but rather one requiring a free text answer.

It was commented that this research highlighted the problem that many applicants appear not to read or do not adhere to the available IRAS guidance, which is currently provided through a question specific link to guidance on every question, and that the IRAS website may require revision to help ensure it is not overlooked or ignored.

15. **4.3 Expert review of research and the role of Research Ethics Committees (RECs) - Meeting Report – Hugh Davies**

Received for information/discussion:

- Updated "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 final comments on this document. JS commented that the recently published "Governance arrangements for research ethics committees: a harmonised edition[2]" would need to be taken into account. JW explained that in terms of content this document already incorporated the harmonised GAfREC, and DH had specifically agreed this to be the case, and thus would only need to be revised to update references to the new document.

Agreed: The panel endorsed the document subject to the minor changes identified above being made.

[2] http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_126474

16. **Governance arrangements for research ethics committees: a harmonised edition**

Received for information:

- The "Governance arrangements for research ethics committees: a harmonised edition" published 9 May 2011

17. **Any Other Business**

15.1 **Incidental Findings in Imaging Research – IR(ME)R regulations**

At the last panel meeting PH raised the issue that the IR(ME)R regulations appeared to require all radiological images taken for research purposes to be subjected to a clinical evaluation. HD confirmed that following discussions with Joanna Wardlaw (Professor of Applied Neuroimaging, Centre for Clinical Brain Sciences, Edinburgh University) this interpretation of the regulations did appear to be correct. PH explained that there was a widespread misconception that such evaluation would need to be carried out by a radiologist or other registered Health Care Professional, however this was not the case and the evaluation merely needed to be conducted by an individual who had been adequately trained for the purpose. CH wondered whether the requirement for a "clinical evaluation" necessarily implied certain minimum standards of care, and this may be outside the scope of researcher's intentions. She offered to research this further and discuss her findings with HD. HD informed the panel that there would be a further meeting of the incidental finding group organised by the Wellcome Trust in June which he would be attending.

18. **Date of Next Meeting:**

The next meeting of the National Research Ethics Advisory Panel will be held on 08 June 2011.

Time: 14:00 – 17:00

Venue: Ground Floor
National Research Ethics Service
National Patient Safety Agency
4-8 Maple Street
London W1T 5HD