

National Research Ethics Advisors' Panel

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

Date: 13 April 2011

Time: 14:00 – 17:00

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

MINUTES

1. Apologies: Caroline Harrison; Art Tucker; Sue Wilson
2. Declarations of Interest:

Item 6.0 The Ethics of Transplantation Research: current guidance and a framework for review:

Prof John Saunders is the Chair of the Organ Donation Committee and a member of the Aneurin Bevan Health Board.

Prof Andrew George is actively involved in transplantation research.

3. Minutes of meeting held on 09 March 2011

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

4. Matters Arising

4.1 Letter from AG to Professor Sir Michael Rawlins

Received for information only:

- Letter from Andrew George to Professor Sir Michael Rawlins

AG Informed the panel that he had not yet received a response to this letter.

4.2 Letter from AG to Professor Dame Sally Davies

Received for information only:

- Letter from Andrew George to Professor Dame Sally Davies

AG informed the panel that Professor Dame Sally Davies had e-mailed him to thank the panel for their congratulations on her appointment as Chief Medical Officer.

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?”

As some members of the panel had not received the revised document in time for the meeting it was agreed that it would be circulated to the panel by e-mail for comments and an updated version would be presented to the panel at the meeting in May.

4.4 The SMILE Study

AG had contacted ‘Understanding Animal Research’ who were happy to explore areas of common ground in handling correspondence with regard to conducting research in contentious areas.

4.5 GTAC

AG informed the panel that he had been invited to attend a future GTAC meeting.

4.6 Public consultation on a concept paper on the revision of the 'Clinical Trials

JW informed the panel that the UK response to the public consultation was about to be submitted. FW asked whether the panel could have sight of the submitted response. JW would forward the response to the panel for information.

4.7 Fitness to practice pending enquiry and research activity

Janet wisely informed the panel that she had met with the General Dental Council who had agreed to amend their paperwork regarding research interests and fitness to practice enquiries.

5. NRES Update : Janet Wisely

JW informed the panel that NRES had now received three formal complaints regarding the ethical review of the SMILE study, JW has completed the NRES investigation as per NPSA complaint policy and as per this policy if subsequent complaints are received, and it is deemed they have been fully investigated through the initial investigation, a further investigation is not undertaken, those raising complaints are advised of the investigation that has been completed. Those not satisfied with the response at that stage have options to take their complaint to a further stage, the NPSA Chief Executive, and a third stage to the Parliamentary and Health Service Ombudsman.

Accommodation has been made available for NRES on the ground floor of Maple Street whilst refurbishment of the premises is carried out in readiness for the arrival of the NHS Commissioning Board. In addition, IT services will continue to be supplied at Maple Street and an application for extension to the IRAS contract is being progressed.

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

Received for discussion with a view to issuing NREAP guidance:

- The Ethics of Transplantation Research: current guidance and a framework for review
- Letter from AG to Prof Anthony Warrens (Chair, UKDEC Research Sub-Group)
- Letter from Prof Anthony Warrens to AG including:
 - Extracts from the Report of the UKDEC Transplantation Research workshop
 - Report of the UKDEC/NRES workshop on ethics of transplantation research

HD explained that originally the UKDEC were concerned that transplantation research appeared to require submission to an MCA flagged REC for review. However, this misunderstanding appeared to be the result of incorrect advice and such research did NOT require to be submitted to an MCA flagged committee.

The panel wondered whether the IRAS form required review in case it appeared to push applicants conducting research in this area towards submission to an MCA flagged REC. JW explained that they had checked the IRAS form and the associated guidance and were content that the form did not appear to suggest that MCA flagged committee review was necessary.

The panel discussed whether it was desirable to flag appropriate RECs for review of transplantation research. There was general agreement that there was sufficient understanding of the issues amongst RECs to deal with the issues involved in this type of research and that adding another “flag” was unnecessary. However, it was suggested that whilst such research did not need to be the subject of mandatory flagging it might be best reviewed by RECs currently flagged to review ‘research tissue banks’ as they would have expertise in this area and knowledge of the Human Tissue Act and applicants could be encouraged to submit to such RECs.

NT felt that it would be sensible to expand current HTA training for RECs to include transplantation. The panel agreed. SiWo suggested that it would also be sensible to conduct during training between REC members and UKDEC. The panel also agreed that this would be beneficial to both parties.

The panel noted that the ‘Report of the UKDEC/NRES workshop on ethics of transplantation research’ identified an issue regarding the need for hospitals where blood (or other “relevant material” under the HTA) is taken from the deceased to be licensed for research under the HTA. If correct, the panel felt that this was unnecessarily obstructive to the conduct of ethical research. NT volunteered to take this issue up with the Human Tissue Authority (HTA) and report back to the panel.

JS raised the issue of “non-heart-beating donors” and expressed concern that whilst there is currently no statutory definition of death in the UK there appeared to be a shift in the accepted definition of death from the ‘brain-stem’ definition of death to a ‘cardiac’ definition. AG agreed that he would write to Prof Anthony Warrens to seek his understanding of this issue.

Agreed:

- 1. AG would write to Prof Anthony Warrens regarding the issue of a perceived move to a ‘cardiac’ definition of death.**
- 2. NT would contact the HTA regarding the need for hospitals, where “relevant material” under the Act is taken from the deceased for research, to be licensed under the HTA.**
- 3. Current HTA training for REC members should be expanded to include training on transplantation research.**
- 4. UKDEC should be approached to explore the possibility of joint training on transplantation research.**
- 5. The draft document “Ethics of Transplantation Research: current guidance and a framework for review” would be revised and reviewed at a future panel meeting.**

7. Incidental Findings in Imaging Research: a framework for considering the ethical issues – Hugh Davies

Received for discussion with a view to issuing NREAP guidance:

- Incidental Findings in Imaging Research: a framework for considering the ethical issues

HD explained that the impetus for this document came from a meeting organised by the Wellcome Trust last year and that a similar meeting was scheduled for June of this year. HD would attend this meeting and will revise the document following this.

PH pointed out that the document made no reference to the Ionising Radiation (Medical Exposure) Regulations which incorporate the use of images for research. It was his understanding that all images produced by ionising radiation must have a clinical evaluation and be reported by a competent individual. It should be ensured that the final version of the document under discussion should be fully

compatible with this guidance.

Agreed: HD would further revise the document for circulation by email and consideration at the panel meeting in June

8. Training Syllabus for REC Members – Hugh Davies

HD explained that NRES have produced a training CD for members which includes both induction material and topic-based training. He welcomed the views of the NREAs on this. HD would arrange for the distribution of the CD to all panel members.

9. Any Other Business

9.1 Advertising materials and inclusion of payment amounts

NT had received an e-mail from a committee in the North West regarding the issue of the inclusion of payment amounts on advertising materials. The REC had decided that the sums of money should not be included on such materials (both at sub-committee and full committee meetings) and had been asked to review this decision by the applicants.

It was noted that the 'ABPI guideline on advertising for subjects for clinical trials' (2002)¹ states that there should not be "undue emphasis on reimbursement but mention of reimbursement is permitted" whilst the ABPI 'Guidelines for Phase 1 Clinical Trials' (2007)² states that "advertisements must never over-stress payment".

JW stated that this issue had been addressed by the phase I advisory group who had encouraged RECs to comment upon generic adverts whilst recognising that they could only make such comments part of their ethical opinion if the advertisements were study specific. The Panel agreed this issue should be referred to the phase I group for their view.

9.2 European textbook on ethics in research

FW informed the panel that the recently published "European textbook on ethics in research" was available free of charge from the EFGCP and could be downloaded from their website (http://www.efgcp.be/Downloads/textbook-on-ethics-report_en.pdf)

CC agreed to forward an electronic copy to all NREAs

9.3 Future meeting venue

JW explained that once NRES had moved to the ground floor at Maple Street a meeting room would be available for future NREAP meetings. The panel agreed that it would be sensible to use this meeting room and future meetings would be held at Maple Street from June.

9.4 Adults Lacking Capacity

SiWo informed the committee that he was about to collaborate with the NIHR on a project regarding adults lacking capacity.

10. Date of Next Meeting:

The next meeting of the National Research Ethics Advisory Panel will be held on 11 May 2011.

¹ http://www.abpi.org.uk/our-work/library/guidelines/Documents/Guideline_advertising_ClinicalTrialsSubjects.pdf

² <http://www.abpi.org.uk/our-work/library/guidelines/Documents/phase1-trial-guidelines.pdf>

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