Health Research Authority

National Research Ethics Advisors' Panel

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

Date: **11 January 2012**
Time: **14:00 – 17:00**

Venue: Health Research Authority
National Research Ethics Service (NRES)
Ground Floor, Skipton House,
80 London Road,
London SE1 6LH

MINUTES

Present:

Andrew George (Chair)
Jeremy Butler
Hugh Davies
Sarah Dyer
Peter Heasman
Caroline Harrison
Nalin Thakker
Richard Tiner
Art Tucker (until 3pm)
Frank Wells
Simon Woods

In attendance:
Mr Clive Collett
Janet Wisely (until 2.30pm)
Candy Morris (Senior Responsible Officer for the establishment of the Health Research Authority)(until 3pm)

1. Apologies: John Saunders; Charles Warlow; Sue Wilson
2. Declarations of Interest

   There were none
3. Minutes of meeting held on 09 November 2011

   The minutes were approved subject to the correction of some minor typographical errors and a further minor amendment under item 5. 'NRES Update': the minutes needed to be expanded to indicate that "Joan" referred to Joan Kirkbride, NRES Head of Operations.

4. Matters Arising

4.1 Use of FOI Requests for the Purposes of Research

At the meeting in October the panel supported the drafting of a rapid response to the BMJ article "Use of Freedom of Information Act to produce research on the cheap?". This response was published in the BMJ on the 10th November 2011: http://www.bmj.com/rapid-response/2011/11/10/re-use-freedom-information-act-produce-research-cheap

5. NRES Update : Janet Wisely

Andrew George and the panel congratulated all those involved in the successful launch of the Health Research Authority.

Janet explained that as much of her update had been presented during the HRA board meeting, at which several of the NREAs were present, that the HRA board minutes would be circulated to the panel once finalised.

- JW explained that the HRA now had an updated policy regarding the reimbursement of HRA committee members expenses which included a new provision whereby employers may be paid an appropriate backfill rate where participation in additional duties on behalf of the HRA would lead to them taking time away from their normal work:

  "7.4Should an HRA Committee Member be formally requested by the HRA to undertake additional duties on its behalf, backfill may be paid through their employer, or, alternatively a participation fee may be paid in accordance with the HRA policy "Reimbursement of professional participation in HRA activities". Arrangements for payment must be approved in advance of undertaking such duties by either the Director of Finance or the Head of Operations."

- JW explained that there had recently been some concerns in the system regarding the appointment of REC chairs. She emphasised that the position of REC chair was a critical appointment which demanded that the right person for the REC, researchers, NRES and the HRA was always appointed to the role. Jeremy Butler agreed that the appointment of chair was indeed "critical" and stated that, in his experience as an interviewer of potential REC chairs, the appointment process still needed managing as he felt there was still some variation in marking scales used. Peter Heasman, who has also been involved in the interviewing of REC chairs, stated that the interview process is now extremely good but felt that the fundamental problem that had been encountered was that potential applicants for the role of chair would attend interview expecting a somewhat informal "chat" rather than a formal interrogative interview. This had occasionally resulted in the underprepared applicant not being found suitable for appointment. Andrew George wondered whether the interview letter needed to make it clear the nature of the interview there were being invited to attend. JW said this had been identified as an issue and the interview correspondence has been appropriately updated to indicate the formal nature of the interview.

- Following the announcement that the Appointing Authority for Phase 1 Ethics Committees (AAPEC) would be closing Janet explained that the former Reading Independent Committee had now been moved into NRES to become the NRES Committee South Central - Berkshire B and was functioning well. It was further explained that only one commercial company had been identified as using AAPEC committees exclusively and she would shortly meet with this company in order to discuss any remaining issues with them face-to-face.

- The number of full applications to NRES was reducing, largely due to the success of the proportionate review system. Whilst this did not necessitate immediately a series of planned mergers and closures In the light of these reductions it was explained that it would be irresponsible to recruit new members to RECs at this time. Member recruitment had thus been suspended except where a business case can be made on an individual basis to recruit and appoint to a "special category" such as a lay member.

- The HRA would be seeking to instigate a comprehensive involvement strategy for both staff (via a 'staff partnership forum') and members. To this end the HRA would be holding a workshop together with the Association of Medical Research Charities on the 28th February in London.

Candy Morris, attended the meeting and gave a talk on her dual role as Senior Responsible Officer for the establishment of the Health Research Authority and as a 'Research Champion' supporting the embedding of a positive and proactive research and development culture across the depth and breadth of the NHS. She explained that she was responsible for steering the HRA into its final form as a Non Departmental Public Body (NDPB) which will enable it to take on more functions. There will be a consultation on the future of the Human Fertilization and Embryology Authority to determine if its research-related functions should pass to the HRA. In addition she explained that the HRA would take on responsibility for Section 251 approvals, on behalf of the Secretary of State, under the NHS Act 2006 (originally enacted under Section 60 of the Health and Social Care Act 2001). Such approvals allow the common law duty of confidentiality to be set aside in specific circumstances where anonymised information is not sufficient and where patient consent is not practicable.

Candy Morris also spoke of her role as 'Research Champion' in which she has been meeting with various stakeholders including The NIHR Comprehensive Clinical Research Network (CCRN), investigators, PCTs, patient groups etc to discuss the embedding of a positive and proactive research and development culture throughout the new NHS system. She emphasised that she wished to make good quality ethical research easier to undertake and the "normal" thing to do. Candy Morris referred the panel to the January edition of the Department of Health publication "The Month" (soon to be available at: http://www.dh.gov.uk/health/category/publications/bulletins/the-month/) in which she writes further on the role of Research Champion.

6. Disruption of Research - Caroline Harrison

Unfortunately Caroline Harrison had not been able to prepare the presentation in time for the meeting. This item would be discussed at the February NREA Panel meeting.

7. Presentation of Precedents to RECs (Payments to Participants) – Hugh Davies

Received for discussion:

- Email correspondence relating to decisions taken by RECs regarding payments to participants in clinical trials

The Panel were invited to agree with the following statement:

> "NRES would encourage researchers to seek and present precedent to RECs.
>
> In this case (of payment and different opinions)
>
> If previous similar studies have been conducted we would recommend that researchers indicate what they've paid participants before and that subsequent RECs should take this into consideration and if they wish to change this, we ask they give clear reason, grounds and guidance they've referred to and used"

Caroline Harrison commented that, whilst she thought this statement was a good idea and would help to achieve greater consistency amongst RECs, there was a slight risk that, with regard to payments to participants, that it might inadvertently result in a tariff of payments which might not be equally applicable across all regions. PH stated that he felt the problem was often that RECs could not always decide whether an amount was in fact too much. If applicants were required to state clearly exactly how the amount had been calculated, with reference to time, discomfort, inconvenience etc and the hourly rate used along with the justification for this amount then this would help RECs in reaching a decision regarding the proposed payment.

FW did not agree with the proposed statement as he felt, that patients should not be paid for taking part in 'therapeutic' research, a view that he felt was supported by existing ABPI guidance[1]. He felt that the only

[1] "So it is right to pay subjects – healthy subjects and patients - who volunteer for phase I trials more than just any expenses that they incur. The amount should be related to the duration of residence on the unit, the number and length of visits, lifestyle restrictions, and the type and extent of the inconvenience and discomfort involved. As a guide, payments should be

exception to this was in circumstances where there was no expectation of benefit at all to the patient (e.g. phase I studies). PH explained that he had some sympathy with FW's viewpoint and expressed his surprise that the level of payments indicated in the studies brought to the panel's attention in the e-mail correspondence had been proposed as they appeared to be therapeutic studies. The panel agreed with this view and PH said he would discuss this with Joan Kirkbride and feedback to the panel.

SiWo explained that he felt that the key issue was whether an individual's free and voluntary consent to take part in research would in any way be compromised by payment. Any payment should not be so great so as to induce a participant to take part in research where they wouldn't otherwise have made that decision for themselves.

Recommendation:

The panel agreed that the proposed statement was to be welcomed but required some revision before it could be endorsed by the panel. The following revised statement was proposed and recommended:

> "Where it is acceptable, in line with published guidance, to pay participants in excess of expenses, then where similar ethically approved studies have been conducted previously we would recommend that applicants clearly indicate this along with the amounts paid to the participants in these studies. Applicants should also present a justification for these payments including a detailed description of how they had been calculated.
>
> RECs should consider both the justification and the stated precedents presented to them and if they wish to ask for changes to the proposed payments, as part of their opinion, they should give clear reasons and, where appropriate, references to any published guidance used to reach this decision"

8. Annual Review of NREAP Guidance: NREAP/03 (published: 23 November 2010) Addenda to Participant Information Sheets

All panel guidance/statements are reviewed one year after publication along with any feedback received, to consider whether they require revision:

Received for discussion:

- NREAP/03 Statement from the National Research Ethics Advisors' Panel (Published 23 November 2010)

Simon Woods felt that the current statement should be revised in such a way as to stand as a statement on its own rather than as a response to a concern.

Agreed:
The panel agreed that the statement should be revised in line with Simon's comments and published. It did not need to return to the panel before publication.

Action: CC & SiWo

9. NRES Appeals/Complaints and Breach of GCP/RGF/Potential Fraud & Misconduct Registers

Received for information only:

- The NRES Appeals Register dated 08.11.2011
- NRES Complaints Register - April to September 2011

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based on the minimum hourly wage and should be increased for procedures requiring extra care on the part of the subject or involving more discomfort. Payment must never be related to risk." - Guidelines for Phase 1Clinical Trials 2007 edition" http://www.abpi.org.uk/our-work/library/guidelines/Documents/phase1-trial-guidelines.pdf:

- Breach of GCP/RGF/Potential F&M dated 08.11.2011

AG commented that in a number of cases the box headed "original REC advised" had not been completed in the appeals register and it was not clear whether this meant that the original REC had not been informed of the outcome of the appeal. AG asked CC to ask Joan Kirkbride whether this was in fact the case.

RT commented that for some breaches entered into the Breach of GCP/RGF/Potential F&M register it appeared that no response had been received from the relevant Trusts for almost 2 years. FW agreed that he would discuss this directly with Joan Kirkbride.

It was noted that the Breach of GCP/RGF/Potential F&M contained reports relating to a number of pharmacy errors. Whilst it was acknowledged that these were so few in numbers that no definite trend could be reliably established it was commented that under the newly established HRA it needs to be made clear exactly who has responsibility for the governance of this data and for the analysis and spotting of such trends.

Action: CC & FW

10. **Action Register**

Received for discussion:

- NREAP Action Register

The panel were asked to review the action register and to discuss options for further action where required.

PH noted that his comments quoted from the minutes of the panel meeting held on the 13 April 2011 regarding "incidental findings in imaging research" were incorrect and asked that the action register and minutes be updated to reflect his true understanding of the matter i.e. "that all images produced by ionising radiation must have a clinical evaluation and be reported by a competent individual".

NT explained that the HTA had recently issued a position statement which addressed the issue identified by the panel i.e. "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.":

> "**HTA publishes position statement on extending existing licences to cover the removal of tissue from the deceased for research.** (Issue date: 9 November 2011)
>
> The Human Tissue Act 2004 requires that the removal of tissue from the deceased for research within the scope of the Act must always be licensed, on specified premises, and that specific minimum requirements are met. 90% of establishments in the post mortem sector hold the appropriate removal licence that for example would enable a person who wishes to remove relevant material from a deceased organ donor for the "research 'in connection with disorders, or the functioning, of the human body'. The HTA has highlighted the options available to establishments to empower Designated Individuals to take appropriate action.
>
> The HTA has been working with individual establishments to extend existing removal licences where there is a local need. We have worked with transplant professionals, the Department of Health and partner organisations to identify and evaluate possible options within the legal framework. Extending existing licences is the swiftest and most light touch approach we can take while we explore options, which include the possible introduction of a new type of licence specifically for the removal of tissue from the deceased."[2]

[2] http://www.hta.gov.uk/newsandevents/htanews.cfm/1029-HTA-publishes-position-statement-on-extending-existing-licences-to-cover-the-removal-of-tissue-from.html

It was noted that the action point regarding "the ethics of transplantation research: current guidance and a framework for review" which asked that "UKDEC should be approached to explore the possibility of joint training on transplantation research" was still outstanding. AG indicated that he would contact Professor Anthony Warrens to discuss ways to take this forward.

11. **Involve/NRES Public involvement in research applications to the National Research Ethics Service (October 2011)**

Received for information only:

- Involve/NRES Public involvement in research applications to the National Research Ethics Service (October 2011)

The panel welcomed the publication of this important document. It was felt that this should be widely distributed and its use strongly encouraged. Whilst the panel felt that it would be useful for RECs to have access to this document as hardcopies that could be handed out to researchers it was noted that restraints imposed upon the HRA prevent printing of further hard copies for distribution in this manner. However, the document is being actively promoted by INVOLVE and in addition has been brought to the attention of RECs through 'NRES News' and will also be an item on the next NRES information exchange. It has also been discussed with the Department of Health communications team.

RT suggested that the document should go to the next UKCRC Board meeting with the recommendation that it be disseminated to all bodies involved in medical research in the UK. He suggested it should be sent to Professor Dame Sally Davies (Chair of the UKCRC Board). The panel agreed that this would be a good way to disseminate the publication but felt that the explicit agreement of INVOLVE and NRES should be sought before any such action. In addition any approach to the UKCRC Board would need to be explicitly agreed by DH Communications. JB stated that he would seek the agreement of INVOLVE/NRES on behalf the panel.

Agreed:

The panel agreed that this was an important document and its distribution throughout NRES and to other stakeholders should be encouraged. JB would seek the explicit agreement of INVOLVE and NRES to the further distribution of the document. Once all necessary agreements had been secured AG would contact the UKCRC Board.

Action: JB & AG

12. **An Ethical Framework For Controlled Donation after Circulatory Death (December 2011)**

Received for information only:

- An Ethical Framework For Controlled Donation after Circulatory Death – Full Report
- An Ethical Framework For Controlled Donation after Circulatory Death – Executive Summary

The panel noted the above documents

13. **Any Other Business**

13.1 REC Membership – Recognition of role

The issue of the recognition of the REC member role was raised, particularly with respect to expert members and the difficulty in obtaining sufficient official recognition and time to carry out the role form NHS Trusts. It was felt to be important that Trusts see REC membership as part of their research activities. The panel noted that the HRA have an agreed action to ask DH permission to write to Trusts about the HRA role and the need to

support their staff volunteering for RECs. It was suggested that Candy Morris, in her role as "Research Champion" might be the appropriate person to seek support for the work NRES are undertaking regarding this issue. AG offered to contact Candy Morris to discuss this.

Action: AG

14. **Date of Next Meeting:**

The next meeting of the National Research Ethics Advisory Panel will be held on 08 February 2012.

Time: 14:00 – 17:00
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