NHS
Health Research Authority

National Research Ethics Advisors' Panel

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

Date: **08 February 2012**
Time: **14:00 – 17:00**

Venue: Room 140B
Health Research Authority
National Research Ethics Service (NRES)
Skipton House,
80 London Road,
London SE1 6LH

MINUTES

Present:

Andrew George (Chair)
Sarah Dyer
Caroline Harrison
Peter Heasman
Nalin Thakker
John Saunders (until 3pm)
Richard Tiner
Charles Warlow
Frank Wells
Simon Woods

In attendance:
Mr Clive Collett
Janet Wisely

1. Apologies: Hugh Davies; Jeremy Butler; Art Tucker; Sue Wilson
2. Declarations of Interest

   There were none

3. Minutes of meeting held on 11 January 2011

   The minutes were approved subject to a minor amendment under item 7: 'Presentation of Precedents to RECs (Payment to Participants)'. SiWo asked that the word "volitional" be changed to "voluntary".

4. Matters Arising

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

Received for information:

- NREAP/03 Statement from the National Research Ethics Advisors' Panel (Revised 01/02/2012)

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

Richard Tiner was asked whether FW's assertion at the last meeting that the ABPI position was that patients should not be paid for taking part in 'therapeutic' research could be referenced in existing ABP I guidance. He explained that this was a complicated area as before the ICH GCP Guidelines were adopted in 1997, The ABPI Guidelines on GCP were the accepted model and indeed, as FW stated, payments to patients in Phase II trials onwards was not supported in this document. However this guidance was superseded by ICH GCP which, in turn was superseded by the EU Clinical Trials Directive, both of which are silent on the issue of the payment of patients. RT also explained that the recently updated ABPI website no longer carries the old ABPI Guidelines on GCP (not even as an archived document) and thus they would now be considered by the ABPI to have been truly superseded. RT stated that his own personal view was that although payments should not be encouraged a REC may agree to such payments where it is felt to be appropriate, on a case by case basis. He felt that this was most likely to be at the proof of concept stage i.e. early Phase II where the subject might get therapeutic benefit from the IMP but this was by no means certain as the drug was still very experimental.

FW stated that since the last meeting he had discussed this issue with senior pharmaceutical industry staff who had told him that it made little difference to recruitment whether payments to patients were allowed by RECs or not.

JS felt that there was nothing intrinsically unethical about paying either healthy volunteers or patients for taking part in research and that all objections to payments are contingent and should be considered as such.

JW explained that the issue of payment and incentives to participants had been taken to the phase 1 group for discussion and that they had agreed to set up a working group to report on this issue, with particular reference to healthy volunteers but also to consider patients as far as they are able with their early trial focus. The final report from this group would be brought to the panel for future

discussion.

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

At the panel meeting held in January it was noted that in a number of cases under the box headed "original REC advised" had not been completed in the appeals register. It was not clear whether this meant that the original REC had not been informed of the outcome of the appeal

The panel received an e-mail from Joan Kirkbride, NRES Head of Operations responding to this comment. This explained that NRES had recently introduced a further checking mechanism on the appeal register whereby her office would formally confirm that the original REC had been advised of the outcome of the appeal. The reason for blank columns in the register is that office staff are working through the backlog of old appeals.

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

JW informed the panel that the use of pop-ups on IRAS had now been agreed, where there is evidence to support alerting to guidance, and thus an alert to the guidance on the involvement of the public in research, and how to appropriately answer the relevant question in the IRAS form, would be incorporated. JW also confirmed that the report was being disseminated within the guidance from DH communications, and this was primarily electronic copies as limited printed copies were available.

RT explained that the Academy of Medical Royal Colleges were in the process of bringing this document to the attention of all Medical Royal Colleges.

4.5 REC Membership – Recognition of role

AG informed the panel that he had been in contact with Candy Morris who was supportive of this issue. JW explained that the HRA have an already agreed action to ask DH permission to write to Trusts about the HRA role and need to support staff volunteering.

5. Proposal for National Research Ethics Advisors' Panel (NREAP) – Janet Wisely/Andrew George

Received for discussion:

- Proposal for National Research Ethics Advisors' Panel (NREAP)

JW explained that she had been asked to review all aspects of the way in which the HRA carried out its functions. As part of this review the membership and terms of reference of the panel were being reviewed against the background of imminent recruitment of a Chair and non-executives to the HRA board together with other initiatives such as the possible introduction of 'ethics officers'. JW felt there were currently gaps in the HRA in terms of working corporately with REC Chairs and REC members and that the panel might be best placed to fill this gap particularly with the introduction of full-time administrative support to the panel. It was hoped that with less meetings the panel would work more efficiently and have more time to consult with stakeholders and work up guidance documents. UKECA had welcomed the review but specifically required the proposal to be discussed by the panel before any final approval was given.

AG agreed with Janet and stated that he felt the panel could engage more with RECs, not to tell them how to think, but to consult with them to inform guidance issued by the panel.

JS broadly supported the proposal and felt that the terms of reference were sufficiently broad and that a smaller panel may bring some focus to their work. However, he felt that the proposal should be revised to state that, ideally, there should be representation from each of the devolved nations. However, it was recognised that this may not be practical for a panel of only 8 members. JW acknowledged that this was an issue and agreed that the proposal should incorporate appropriate representation from the devolved nations.

FW supported the increased engagement with RECs and stated that as the NREA host for two Chairs Network Meetings he had found that this forum for engaging with REC Chairs to be particularly productive.

RT questioned the statement in the terms of reference that "Each NREA would be expected to consult with their appropriate stakeholder group via appropriate fora". He was not sure what this meant as not all members would have an easily identifiable "stakeholder group". CH agreed with the concern and noted that it would not be clear who the appropriate stakeholder group would be for the "legal expert" or "individual with academic expertise in the ethics of research". She felt that the statement contained an expectation that the member would act as a "representative" for their "stakeholder group". She felt that this was not appropriate as the member would not be directly elected by that group and thus would have no mandate to speak on their behalf. AG agreed with these concerns and suggested that the sentence be changed to state that:

"Each NREA would be expected to consult with appropriate stakeholders as required."

The panel agreed that this was an appropriate revision.

RT also expressed the concern that, if the current NREA appointments concluded in September 2012 and all new appointments were made at that time for a period five years, there would be a problem when those appointments came to an end as all members would need to be replaced at the same time. RT suggested that if current NREAs were re-appointed that it might be sensible to appoint these members for 2 or 3 years, rather than the full 5 year term. PH agreed and felt there needed to be some flexibility built into the appointments. JW agreed with this and stated that this would need to be managed appropriately to ensure that the membership would not need to be replaced in its entirety every five years.

JW acknowledged that section 8.0 "payment of expenses" needed to be revised to reference the new "Reimbursement of HRA Committee Members Expenses" document recently approved by the HRA Board. All NREAs would be reimbursed in accordance with this policy.

NT commented that the current NREAs encompass a broad range of relevant expertise and experience and that he was concerned that if the panel is reduced to only 8 members that this broad expertise might be diminished. JW acknowledged this concern but felt that there was a huge range of expertise already within the REC community and this expertise could be accessed by the NREAs and specific individuals co-opted onto the panel as and when required.

Whilst it was noted the current proposal incorporated the ability to invite "appropriate expertise, as necessary, to advise the panel and contribute to guidance" it was agreed that the proposal should explicitly include the option to co-opt members to the panel on an ad hoc basis.

CH suggested that the proposal should include a process by which members might be removed from the panel. JW suggested that it might be appropriate, in relation to attendance, that where a member has not attended three meetings in a row, without a reasonable excuse, they would be asked to leave the panel.

FW asked JW how she viewed the relationship between the panel and the HRA/NRES. JW stated that NREAP would be an NRES panel. She thanked the panel for all the help they had given to her and NRES in acting as an informal "Board" over the past two years during this period of intense change. However, as NRES and the HRA moved into a period of greater stability with the appointment of a chair and non-executives to the HRA Board this informal function of the panel was now coming to an end. It was hoped that this proposal would set the template for the future work of the panel in engaging with and consulting the REC community and other stakeholders in order to facilitate the provision of ethical training and guidance to RECs.

Agreed: The panel agreed the proposal subject to a number of revisions identified above. CC would revise the proposal accordingly and e-mail to all NREAs for comment. The final proposal would be ratified at the panel meeting held on 14 March 2012. The ratified final proposal would then be submitted to UKECA at their meeting on 15 March 2012.

Action: CC

6. NRES Update : Janet Wisely

AAPEC

JW informed the panel that AAPEC had now formally closed and that NRES Committee South Central - Berkshire B (previously the Reading Independent Committee (RIEC)) and East of England – Welwyn (previously Welwyn Clinical Pharmacology Ethics Committee (WCPEC)) had now moved into NRES.

RT commented that some AAPEC phase 1 RECs had traditionally worked to shorter timelines regarding the submission of applications than NHS RECs. He noted that for, phase 1 research, any delays introducing the system were extremely expensive for pharmaceutical companies.

JW said that phase I RECs had been asked if they could take applications with shorter cut off dates and there had been an initial positive response. PH noted that most REC members were unlikely to review applications until a few days before the meeting. He suggested that with e-submission shortly coming online it would be possible to dramatically shorten the deadline between receipt of the application and placing on the next meeting agenda for one or two items. He felt that this could be reduced beyond the seven days currently being considered for phase 1 research. JW welcomed his comments and would discuss further with Joan Kirkbride.

Accommodation

NRES and the HRA do not have any delegated authority to enter into leases and any break clauses in current leases must be taken unless Department of Health (DH) agreement is specifically obtained to allow continuation of the lease. A direct consequence of this is that the West Midlands NRES centre will be closed on 31 March 2012.

The need to make efficiencies on accommodation has meant that HRA are currently consulting with staff

to move all London-based staff to the DH accommodation at Skipton House. This will see the closure of both the Charing Cross and Northwick Park sites by autumn this year. Unfortunately, as some staff will be unlikely to see the alternatives as suitable, and also because there may be insufficient space in Skipton House for all the London staff, this may mean some staff are placed at risk of redundancy. All London-based staff had been offered the opportunity to relocate. Further London-based RECs are likely to have staff based outside London providing support after the moves have been completed. JW explained that the HRA would invest in remaining REC centres to provide facilities such as video-conferencing etc.

Communications strategy

JW explained that she had managed to secure the part-time assistance of Shaun Griffin (Director of Communications and Public Affairs at the Human Tissue Authority) in order to help develop the HRA's communications strategy. The NRES identity will be retained for the core REC service and immediate support. Other functions will be positioned within the wider HRA, including training and guidance to demonstrate the wider applicability within a national role for the HRA.

HRA involvement strategy

JW informed the panel that and interim involvement strategy will be considered by the HRA Board at its next meeting. One very important element of this strategy will be patient and public involvement. The HRA has sought external advisors (INVOLVE and AMRC (Association of Medical Research Charities)) to a small project team which is considering how the HRA may effectively engage with patients and the public. There will be a further workshop later in February and the intention is to issue plans for comment and have proposals for the HRA Chair and non-Executives when appointed.

Business planning

JW had received several detailed comments on the plans NRES issued for comment and these will be considered in finalising the HRA business plans which need to be submitted to the DH by the end of February. JW stated that the majority of comments had been positive and supportive of the business plans and that they would move forward to evaluate the proposed "ethics officer' role.

GAfREC

JW explained that the initial, draft version of the Governance Arrangements for Research Ethics Committees (GAfREC) stated that student social care research did not need to be reviewed by NHS RECs if it fell within agreed ESRC framework. Unfortunately this provision was removed from the final published version of GAfREC. DH did not wish to issue a revised version of GAfREC but the following statement correcting this has now been issued:

> February 2012: Erratum
>
> A paragraph was erroneously omitted from the document. The following paragraph has been added:
>
> 2.3.8A This document does not apply in England and Wales if research proposals are reviewed by a committee operating in accordance with the Economic and Social Research Council's Framework for Research Ethics [1], unless:

(a) the research involves withdrawing standard care; or
(b) the research involves NHS patients or service users as research participants (see paragraph 2.3.2); or
(c) the research is a social care research project funded by the Department of Health (see paragraph 2.3.3); or
(d) there is a legal requirement for review by a REC (see paragraphs 2.3.4 and 2.3.5).
With these conditions, the Framework for Research Ethics sets out principles, requirements and standards for review by university committees that are compatible with those set out in this document[1].

The HRA will be issuing further guidance on applicability of GAfREC, in particular to confirm that the requirement for REC review was as described in GAfREC and not RGF with respect to NHS staff research, although Trust approval was of course required i.e.:

> 2.3.13 Employers owe a duty of care to their employees. It is different from the duty of care that care providers owe to users of their services. RECs are not expected to assume employers' responsibilities or liabilities, or to act as a substitute for employers' proper management of health and safety in the workplace. It is for employers to ensure that they are fulfilling their duties as employers when their employees take part in research. Research involving staff of the services listed in paragraph 2.3.1, who are recruited by virtue of their professional role, does not therefore require REC review except where it would otherwise require REC review under this document (for example, because there is a legal requirement for REC review, or because the research also involves patients or service users as research participants)[2].

Delivering a unified approval process from the IRAS

Plans have been approved by the IRAS Board and accepted by the DH to use IRAS to deliver a unified approval process in the UK. This will see full e-submission available for IRAS partners, and implemented by the summer for NRES, MHRA and NHS R&D, and will be a major advance to the system provided. Later developments will include the option of a single application route via HRA, and co-ordinated messaging and notification of approvals to provide a unified system.

Establishing an effective national role for the HRA

JW explained that the HRA has established a senior project team to complete a system review of research in the UK, from idea, through funding, approval, conduct, compliance and inspection, publication and translation to inform and identify an effective national role for the HRA in providing a unified approval process and promoting proportionate standards for compliance and inspection. The HRA has already agreed plans to provide a system for the unified approval process. The use of information provided through this system needs further review to understand the use of information to identify areas of duplication, incompatibility and unnecessary tasks and opportunity, therefore giving further efficiency. Currently, there is little learning across the process from funding, approval, set up, conduct, compliance and inspection. The process needs review as a continuum for the entire research

[1] http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_126474
[2] Governance arrangements for research ethics committees - A harmonised edition (9 May 2011)

event and as one event within a number of linked events, i.e. other projects by the same researcher or sponsor. The project team will be led by Janet Wisely, with project team members Janet Messer (NIHR), Sandra Holley (NRES), Rebecca Stanbrook (MHRA) and Shaun Griffin (HTA). Gavin Grump (HRA) will be providing project support.

The project team will be seeking formal evidence from key stakeholders and selecting a small further linked team to attend events in March to consider the evidence, identify problems and propose solutions. Outputs will include organisational specific actions and objectives within ongoing improvement programmes, as well as proposals for national roles within the HRA on which there will be opportunity for further comment and consideration after a report in April.

7. **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 March NREA Panel meeting.

8. **A consensus statement on research misconduct in the UK - FW**

Received for information:

- Verbal presentation by Frank Wells regarding the joint BMJ/COPE meeting held on 12 January. The meeting brought together institutions, researchers, and funders to address the problem of research misconduct in the UK.
- BMJ News: Scientific misconduct is worryingly prevalent in the UK, shows BMJ survey
- BMJ Editorial: Research misconduct in the UK. Time to act
- A consensus statement on research misconduct in the UK from the BMJ/COPE high level meeting, London, January 12 2012

The panel noted and welcomed the BMJ/COPE consensus statement on research misconduct in the UK. It was noted that the HRA should have an interest in research conduct in general and it was suggested that once the HRA business plans have been agreed then it may be appropriate to enter into a dialogue with the UK Research Integrity Office (UKRIO) on this issue.

9. **Minutes of the Health Research Authority Board meeting, held on 11th January 2012**

Received for information:

- Minutes of the Health Research Authority Board meeting, held on 11th January 2012

10. **NREA-Hosted Chairs' Network Meetings: East of England Minutes**

Received for information:

- NREA-Hosted Chairs' Network Meeting East of England: Minutes of the meeting of 21st December 2011
- NREA-Hosted Chairs' Network Meeting North West: Minutes of the meeting of 21st November 2011

11. **Any Other Business**

12. **Date of Next Meeting:**

The next meeting of the National Research Ethics Advisory Panel will be held on 14 March 2012.

Time: 14:00 – 17:00
Venue: Room 126A Skipton House
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Skipton House,
80 London Road,
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