

## National Research Ethics Advisors' Panel

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

**Date:** 14 September 2011

**Time:** 14:00 – 17:00

**Venue:** NRES  
Ground Floor, 4-8 Maple Street,  
London W1T 5HD

## MINUTES

1. Apologies: Hugh Davies; Caroline Harrison; Peter Heasman; John Saunders; Art Tucker; Sue Wilson. Janet Wisely (joined meeting late)
2. Declarations of Interest
3. Minutes of meeting held on 10 August 2011  
The minutes of the previous meeting were agreed as a true record subject to minor changes (see item 4.3).

### 4. Matters Arising

#### 4.1. Annual Review of NREAP Guidance: NREAP/02 - follow up contact

Ratified:

- UPDATED NREAP/02 - Follow-up contact of potential participants who have not responded to an initial invitation to take part in research

#### 4.2. Consent and Foetal and Embryonic Material for Stem Cell Research

AG informed the committee that he would write to Prof Martin Gore (Chair, GTAC) regarding the questions considered by the panel at the previous meeting. He also informed the panel that he had been invited to attend the next GTAC meeting.

Nalin Thakker commented that whilst the HFEA guidance was clear regarding the need for consent for the use of foetal and embryonic material for research it did not explicitly deal with the use of foetal tissue obtained from a termination of pregnancy. He explained that the HTA requirement for "valid consent" for the use of foetal tissue<sup>1</sup> was in contradiction with the

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<sup>1</sup>HTA Code of Practice 1 – Consent

([http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code1consent.cfm?FaArea1=customwidgets.content\\_view\\_1&cit\\_id=665&cit\\_parent\\_cit\\_id=652](http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code1consent.cfm?FaArea1=customwidgets.content_view_1&cit_id=665&cit_parent_cit_id=652))

**160.** It is recognised that, in the absence of specific legal requirements, guidance on the use of fetuses and fetal tissue for [research](#) has been derived from the 1989 Review of the Guidance on the [Research Use of Fetuses and Fetal Material](#), also known as the Polkinghorne Guidelines. A number of aspects of the Polkinghorne Guidelines are outside the remit of the HTA and of this code of practice. However, it should be noted that guidance within the Polkinghorne guidelines which recommended that in the context of giving consent, women should not know the purpose for which the fetus would be used, or whether it would be used at all, is now superseded by guidance within this code on valid consent, which must be based on the person's understanding of what the activity involves (see section on valid consent [paragraphs 30-34](#)).

principles set out in the 1989 'Review of the Guidance on the Research Use of Fetuses and Fetal Material', also known as the Polkinghorne Guidelines. NT would discuss the current status of the Polkinghorne Guidelines with the HTA.

### 4.3. Participant Recruitment and Commitment to Complete Research Studies

Richard Tiner felt that the minute of the above item discussed at the August meeting seemed to imply that the early termination of clinical trials was a common problem, when in fact it was relatively rare. In addition, he felt that it should be clearly stated that the sponsor has a statutory duty to report the early termination of a trial to both the MHRA and the REC within 15 days. It was agreed by the panel that the minute and recommendation should be amended accordingly.

The panel also felt that it would be useful to find out how common the early termination of both CTIMP and non CTIMP studies was. CC would ask NRES if this data was readily available.

## 5. REC Membership – Recognition of role

The panel were asked to discuss how the contribution of members might be recognised within NRES and other stakeholders/employers.

Received for discussion/advice:

- Email correspondence regarding the formal recognition of REC members

AG stated that he felt there were two issues contained in the recognition of the REC member role:

- 1) The formal recognition and facilitation of NHS staff to participate in the work of RECs/NRES; and
- 2) The recognition of the contribution of lay members to RECs/NRES.

There is considerable evidence that NHS Trusts are increasing reluctant to allow staff to serve on RECs, or to acknowledge the time that they put in. The panel unanimously endorsed the importance of expert members on RECs. The input of expert members is vital for the quality of the review process. It is likely that lack of expertise could subject research to delays. Given the clear importance of research it is very important that the involvement of expert members employed by the NHS is facilitated. The panel noted and applauded the position taken by Barts and The London NHS Trust whereby they formally recognise REC membership as part of an employee's job plan:

"Medical members (both hospital and GP): Any consultant joining the committee will have their commitment formally recognised in their job plan and will therefore have time out for committee work. Involvement in an REC will also be recognised through the appraisal process."

<http://www.bartsandthelondon.nhs.uk/our-services/research-and-development/the-approval-process/ethical-approval/>

RT felt that the impending GMC revalidation of doctors, likely to be introduced in 2013, would help in the formal recognition of their REC role as they would need to declare such membership as part of an appraisal process and show that they were sufficiently up-to-date in order to effectively carry out their role. NT noted that this was also a problem within universities as many clinicians would also have academic posts in addition to their NHS positions.

It was also pointed out that the Government have formally stated that "supporting and promoting research and development will be a core function of the future Department of Health"<sup>2</sup> and thus, by extension, the panel felt that ethical review of research, and membership of RECs, could also be considered to be a "core function". Furthermore, the impending Health Bill would create a new statutory

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<sup>2</sup> <http://www.nihr.ac.uk/about/Pages/LiberatingtheNHS-theGovernmentsresponse.aspx>

duty for the Secretary of State to promote research.

It was suggested that AG discuss with JW various organisations that should be contacted to raise this issue.

The panel noted that it would be more difficult to formally recognise or facilitate the contribution of lay members due to the potentially very large number of individual employers involved, although it would strongly support any move by the HRA, once established, to lobby for the recognition of REC membership as a 'public duty'.

The possibility of nominations for an award through the honours system was discussed but it was felt that it would be extremely difficult, and possibly unfair, to single out individuals within the Service for such nominations. Members at the moment do get a letter of thanks and a token of appreciation to acknowledge their service. The panel felt that (following the setting up of the HRA) lay members leaving the service should receive a letter of thanks from the chair of the HRA.

### **Recommendation:**

The panel recommended that various stakeholders should be contacted to seek their support for the formal recognition of expert members within the NHS and their contribution to NRES and its constituent RECs.

It also recommended that all members leaving the service should continue to have their contribution recognised in the form of a letter; this might be signed by the chair of the HRA or other high standing officer within DH.

## **6. Conflict of Interests**

The panel were asked to comment on the attached "conflict of interests section from NRES induction material", particularly regarding how the table "Questions the REC might raise/Preparations and answers from the researcher" might be developed to assist RECs.

Received for discussion/advice:

- Conflict of interests section from NRES induction material

In discussion, the panel noted with approval that the latest version of the NRES SOPs states that the following should be considered to be a substantial amendment:

"A change to the payments, benefits or incentives to be received by participants or researchers in connection with taking part in the study, or any other change giving rise to a possible conflict of interest on the part of any investigator/collaborator"

SiWo felt that it would be hard to establish a threshold for when an interest becomes a conflict of interest. Most researchers would all have a strong *personal* interest in the successful completion of research they were involved in but society did not consider this personal interest to be incompatible with the proper conduct of research. In addition patient groups could also have a personal interest in the conduct of the research. Even where a researcher has a *financial* interest in the outcome of research it would not necessarily represent a conflict of interests incompatible with their being directly involved in that research. NT felt that the threshold would be reached at the point the research was compromised by the overriding interest. SD felt that it was important that all parties involved in the research should be aware of the interests of the researchers so that they can make a judgement as to whether these interests would endanger the validity of the trial. JB agreed and felt that such interests should be more upfront in participant information sheets.

NT commented that the pressures placed on researchers to successfully conduct research studies were increasing. For example, CLRN funding was dependent upon the number of patients recruited into

research studies. Furthermore, one of the criteria for clinical excellence awards was the number of people recruited into clinical trials. Whilst these all represented examples of competing interests NT felt that the main issue was that such interests were declared so as to ensure that the legitimate aims of the research were not compromised by interests of the researcher/sponsor.

SiWo agreed that researchers should openly declare what their interests were and that these might be judged to be conflicting where they were incompatible with the aims of the research.

FW propose that any guidance on this issue should state that, as a fundamental principle, that all interests must be declared. However, the panel felt that this was somewhat onerous given the large number of explicit and implicit interests that all researchers would have. It was suggested that such a statement might be restricted to 'all interests directly associated with the research'. It was also pointed out that as interests can change and develop over time that researchers should be asked to declare all *foreseeable* interests. This was compatible with the requirement in the NRES SOPs that any change giving rise to a possible conflict of interest on the part of any investigator/collaborator should be submitted as a substantial amendment. Where such changes were foreseeable prior to their becoming an actuality they should be declared at the outset.

CW pointed out that the BMJ has a useful way of looking at whether a non-financial interest is potentially a conflicting interest i.e. individuals seeking publication in the journal should ask themselves whether a competing interest "would embarrass you if it became generally known after publication?"<sup>3</sup> The panel felt that this was a very useful acid test of whether an interest was potentially a conflicting interest.

The panel felt that it would be useful if the IRAS form requested the details of potential conflicts of interests of *all* investigators involved in research and not just those of the Chief Investigator.

#### **Agreed:**

The panel endorsed the tabled "conflicts of interest section from NRES induction material" as suitable guidance on this matter.

## **7. Research into Complementary Medicine and REC Review**

Received for discussion/advice:

- Research into Complementary Medicine and REC Review (HD)
- Web Page: DC's Improbable Science - "Acupuncturists show that acupuncture doesn't work, but conclude the opposite: journal fails" <http://www.dcscience.net/?p=4439>
- Paterson, C., Taylor, R., Griffiths, P., Britten, N., Rugg, S., Bridges, J., McCallum, B., & Kite, G. (2011). Acupuncture for 'frequent attenders' with medically unexplained symptoms: a randomised controlled trial (CACTUS study) *British Journal of General Practice*, 61 (587), 295-305 DOI: 10.3399/bjgp11X572689
- NRES: Issues, Guidance and Evidence: Deception In Medical Research (HD)

The panel considered the questions posed by HD and made the following responses:

1. *What is the role of the REC in assessing the relevance and need for research? In this area when do we say "enough is enough – this complementary therapy doesn't show benefit?"*

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<sup>3</sup><http://www.google.co.uk/url?sa=t&source=web&cd=1&sqi=2&ved=0CBoQFjAA&url=http%3A%2F%2Fresources.bmj.com%2Ffiles%2Ftalks%2Fconflict.ppt&rct=j&q=BMJ%20conflict%20interest%20would%20you%20be%20embarrassed&ei=rWhzTsjWGoWZ8QO09fTRDQ&usq=AFQjCNHFH1SOEx1Fc38immuHESXXrdDK3g&sig2=U1dgEdrI N2Hn3M4vi3upDw>

The panel considered that the question of whether there was a need for the research should be addressed by the peer review of the study. The researchers would need to justify to the REC, with appropriate scientific review, that there was a need to conduct this study in order to add to the data already in existence.

## 2. What role can the REC have in interpretation of the results?

The panel considered that RECs do not have any remit to become involved in the interpretation of study results.

## 3. What is fair to put in the information sheet when researching treatments that fall outside the “Western model” of science-based healthcare?

The panel felt that where the research involved interventions that were based on a paradigm not widely recognised or supported by the established scientific community RECs should be careful not to approve participant information that appeared to unquestionably endorse such unsupported world-views.

## 8. Change in Clinical Practice Foreseen During the Study

Received for discussion/advice:

- Question from REC Chair regarding change in clinical practice foreseen during the study

The panel discussed the following question posed by a REC Chair:

“What is the role of REC if a change in clinical practice can be foreseen during the study time by a due NICE statement? Should we ask the study to be held till then? Continue, knowing it may have to be stopped, therefore invalidating participants? Or do nothing as NICE isn't always followed?

Should we be asking researchers to notify us if NICE issues a relevant change during a study time, should they demonstrate that this does/doesn't alter study?”

The panel noted that the situation identified was not limited to changes brought about by NICE guidance but could be brought about, amongst other things, by the publication of results from other studies involving the drug/intervention in question. The position of equipoise in an ongoing study could be affected by any number of factors and RECs are not required to actively monitor NICE statements/published data from other studies etc. in order to assure themselves that the position of equipoise in a study has not changed.

The primary responsibility for monitoring the safety of participants in clinical trials lies with the trial sponsor. The sponsor along with any data monitoring committee (DMC) should actively monitor relevant data and if they consider that such data materially alters the position of equipoise in the trial then they should submit any changes deemed necessary as a substantial amendment to the main REC.

The panel wished to draw attention to the NRES guidance “DATA MONITORING COMMITTEES IN CLINICAL TRIALS: Guidance for Research Ethics Committees (May 2010)<sup>4</sup> which gives useful information on the function of DMCs.

## 9. NRES Update – Janet Wisely

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<sup>4</sup> <http://www.nres.npsa.nhs.uk/EasysiteWeb/getresource.axd?AssetID=74623&type=Full&servicetype=Attachment>

Received for information:

- NRES at the HRA Considerations for NRES September 2011

JW explained that the establishment of the HRA was still on track and it was expected that it would be established as a Special Health Authority on 1 December 2011.

She informed the panel that the NRES head office currently based at Maple Street would be moving to Skipton House, 80 London Road, London SE1 6LH by 1 October. NRES were currently in consultation with affected staff regarding this move.

It had been agreed that the Appointing Authority for Phase 1 Ethics Committees (AAPEC) would be closing no later than end of this financial year. JW explained that the former Reading Independent Committee had now been moved into NRES to become the NRES Committee South Central - Berkshire B and the remaining IECs wishing to transfer were currently the subject of a gap analysis to determine whether they would also be moved into NRES.

JW informed the panel that Marc Taylor (Deputy Director of R&D; Head of R&D Systems and Governance at Department of Health) would be retiring at the end of September and his role would be split into two separate roles each addressing DH R&D 'policy' and 'systems'.

Candy Morris CBE, currently chief executive of NHS South East Coast, will be taking up a new national leadership role as the Senior Responsible Officer for the establishment of the Health Research Authority.

JW informed the panel that the joint INVOLVE/NRES/Infonetica paper on public involvement in research applications (IRAS QA14-1) was now signed off and Professor Dame Sally Davies had been invited to write the foreword. The paper would then be circulated and placed on the NRES website

## 10. Action Register

Received for information:

- NREAP Action Register

The panel asked CC to enquire about the current status of the Independent Scientific Review paper currently being written by HD.

## 11. NREA-Hosted Chairs Network Meetings - Minutes

Received for information:

Minutes of the following NREA-Hosted Chairs Network Meetings:

- **North West REC Centre - 24 January 2011**
- **Minutes of the East Midlands - 22 February 2011**
- **East of England REC Centre - 31 March 2011.**
- **North East and Yorkshire & the Humber - 20<sup>th</sup> April 2011**

It was noted that the minutes of the North East and Yorkshire & the Humber network meeting proposed that the 'payment of research participants' should be discussed with a view to issuing guidance by the panel. JW explained that this issue would be discussed by the phase one group in November initially, as there were representatives from AAPEC RECs there and then taken more widely after the Phase 1 consideration.

The panel asked that they are sent the outcome of that discussion to determine whether the issue would need to be discussed further by the panel.

## 12. Any Other Business

## 13. Date of Next Meeting:

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

Time: 14:00 – 17:00

Venue: Room 223  
Primary Care Clinical Sciences Building,  
School of Health and Population Sciences,  
University of Birmingham  
Edgbaston  
Birmingham B15 2TT