Minutes of the sixth meeting of the National Research Ethics Advisors' Panel held on Wednesday the 10th of March at Oulton Hall, Leeds LS26 8HN

MINUTES

Present:

Andrew George (Chair)
Jeremy Butler
John Saunders
Nalin Thakker
Richard Tiner
Frank Wells
Sue Wilson
Simon Woods

In attendance:

Dr Janet Wisely
Mr Clive Collett (NREAP Secretary)

1. **Apologies**: Hugh Davies; Sarah Dyer; Peter Heasman; Art Tucker; Charles Warlow
2. **Declarations of Interest**

   There were none
3. **Minutes of meeting held on 10 February 2010**

   The minutes of the previous meeting were agreed as a true record.
4. **Matters Arising**

   NRES Communications/Local Chairs Network Meetings

   Janet Wisely (JW) informed the panel that NRES was concerned that some REC members did not always appear to fully understand the reasons behind the ongoing change programme and the pace at which it was being conducted. NRES was aware that this was resulting in a certain level of disquiet in some regions and was anxious to work with the REC community to greater collective understanding of the drivers and necessity for change. She felt it was important that NRES should think about producing constructive, positive messages regarding the changes which could be disseminated amongst the REC community. She welcomed any suggestions from the panel that could be forwarded to the communications team.

   Jeremy Butler (JB) noted that some REC members did not have e-mail addresses whilst others did not wish to be contacted directly by e-mail resulting in contact through coordinators only. He felt that this could often diminish the effectiveness of communications with REC members. JW agreed, NRES have historically relied upon chairs and coordinators to disseminate material to members. NRES have tried to compile a full list of all members' e-mails but this has proven to be difficult. NRES has consulted on a change to terms and conditions which will be implemented later in the year to require an e-mail address be provided to NRES for such communications, with alternatives for existing members considered on a case by case. John Saunders (JS) commented that this was a

long-running issue where the "independence" of committees was rolled over into a feeling of not being responsible to NRES in any way. Andrew George (AG) felt that there was a need to make chairs feel part of the organisation and there was general agreement that the NREAs could have an important role in facilitating this, particularly through the chairing of local chairs network meetings. He noted that the panel have already discussed a number of topics and many of these should be further discussed at local meetings with chairs.

Agreed: It was agreed that AG and Clive Collett (CC) should further develop the proposed NREA role in chairing the local chairs network meetings and formulate a list of topics for discussion at these meetings.

Action: AG & CC

Clinical Genetics and Research

Nalin Thakker informed the panel that following their agreement to the procedure for facilitating research in clinical genetics, using the scheme of generic ethical review Research Tissue Banks that he had started taking it to the relevant professional bodies and was disseminating the agreed procedure to colleagues who have been "delighted" by the procedures.

Equality and Diversity Training

JW notified the panel that the online training currently available to REC members identified by Hugh Davies (HD) at the last meeting is also available to NREA panel members

Action: NREA panel members to contact HT if they require such training

5. NREA Guideline Issues:

5.1 "When do multiple approaches for recruitment become unacceptably intrusive?"

Received: Email from Geraldine Brown (Head of Clinical Research, AstraZeneca)

Richard Tiner (RT) explained that following personal communication with Geraldine Brown that the issue she had highlighted related to the follow-up of potential participants by telephone after they had been informed of the research and after an appropriate "cooling off" period to consider their participation. The investigators simply needed to know, in the absence of a response, whether the individual was willing to take part or not.

AG commented that this e-mail was merely indicative of the general issue of follow-up contact and that the panel's discussion should be focused on the general issue rather than the specific e-mail brought to the attention of the panel.

JW explained that this general issue had been raised at a senior level with regards to the competitiveness of the UK in securing commercial clinical research. If such approaches to participants were not allowed by RECs then commercial research was increasingly likely to be hosted in other countries resulting in UK patients being denied access to potentially useful research whilst at the same time adversely affecting the economic and strategic benefits commercial research brings to UK plc.

The panel agreed that whilst every case would need to be taken on its own merits, RECs could often be overprotective of patients' rights in this regard. The panel did not consider that follow-up phone calls by investigators were in themselves coercive but that it was up to RECs to ensure that appropriate procedures were detailed in the research protocol to ensure such contact was indeed noncoercive. The panel further noted that maximising patient access to and participation in research was a good thing and that noncoercive communication aimed at facilitating this was desirable. SWi commented that not all research was *clinical* research, with its attendant expectation of some direct or indirect therapeutic benefit, and therefore it would be important to highlight this distinction in any

guidance, perhaps by using different research scenarios highlighting the acceptability or otherwise of follow-up contact in different types of research.

Agreed: It was agreed that, in principle, follow-up contact by telephone calls or other methods of communication were reasonable but would need to be performed within the context of a detailed protocol approved by a REC.

The following initial principles were agreed:

- Initial contact with the potential participant must be made by an individual with the right to access their personal information who is also known to the potential participant1.
- If relevant, potential participants should be informed that they would be contacted again and given the opportunity to disagree
- Follow-up communication with potential participants must not be persistent.
- RECs should be assured that if an individual indicates that they do not wish to take part in research they would not be contacted again or have pressure put on them to reconsider their decision in any way.

It was envisaged that the guidance produced by the panel could be relatively brief but should be "fleshed out" by a number of scenarios. AG, CC and HD would draft initial guidelines on this issue to be circulated to the panel for comments. In addition the draft guidelines would be sent to Geraldine Brown for her comments as an individual (i.e. not as a representative of the ABPI)

JW asked the panel if they were happy for her to quote the minutes of this discussion in further correspondence. The panel were happy for her to do so but made the proviso that the final decision on these matters was a matter for individual RECs.

Action: AG, HD & CC

During the discussion Sue Wilson (SWi) noted that "gatekeepers" who control the access to patients and patient data were often the primary barrier to conducting research and that it was an issue that the NREAs should perhaps address at a later date. It was agreed that SWi would draft a paper for consideration by the panel at a future meeting.

Action: SWi

5.2 i) Disclosing Information about a Research Participant without Consent and

(ii) Appropriate Action for a Researcher when Seeing Poor Practice.

Received: Draft Letter to be sent to REC Chairs

AG explained that HD was currently working on guidelines regarding disclosure of information without consent but that there was a need for a holding letter to the sent to REC chairs highlighting currently available guidance on this issue.

The panel noted information received by NRES indicated that RECs appeared to be occasionally overcautious in their interpretation of legal requirements on disclosure of information without consent.

[1] The following guidance from the Academy of medical sciences was considered useful in relation to this principle:

"4.5.2 Consent for consent…If the first approach to the patient is made after prior checking, it will be clear that the person making the approach must have had access to a patient's personal medical information. Some patients may be offended, not by the invitation to take part in research, but by the knowledge that someone has had access to their personal medical records". (Academy of Medical Sciences*: Personal data for public good: using health information in medical research*, January 2006)

The currently available guidance on this issue from the GMC[2]; the British Psychological Society[3]; the British Sociological Association[4] and the UK Data Archive[5] all agree that disclosure of information without the participants consent should only occur in exceptional circumstances where failure to inform would expose others to the risk of serious harm or where the information is subpoenaed by relevant police investigations or court proceedings. In addition some researchers are members of professional groups such as teachers and social workers who have a legal duty to report suspected child abuse. Doctors are also required to disclose information to satisfy a specific statutory requirement, such as notification of a known or suspected case of certain infectious diseases.

JW emphasise that correspondence with NRES had not simply raised the issue of criminal activity but also that of 'whistleblowing' with regard to poor practice e.g. lack of hand-washing.

Agreed: The panel agreed the text of the draft letter subject to the following minor revisions:

- The word "complaints" should be changed to "enquiries"
- the reference to the GMC guidance should give more detail rather than simply state the URL of the guidance
- the term "NREA Forum" should be replaced with "NREA panel"

Action: AG & CC

6. **Policy Item**: Mr Marc Taylor, Head of R&D Systems and Governance, DH

NHS Research Facilitators

Received at meeting: Patient and Public Awareness: Approved NHS Research Facilitators (discussion draft 0.5.2, 10 February 2010)

Received for information: Personal Data for Public Good: Using Health Information in Research – The Academy of Medical Sciences January 2006*

Marc Taylor (MT) tabled a draft paper entitled " Patient and Public Awareness: Approved NHS Research Facilitators" for discussion by the panel. He emphasised that this was a draft publication only and was not ready for publication or dissemination in the public domain.

MT asked the NREAs to consider this proposal and advise on the acceptability of the proposed approach and think about ways to appropriately inform the community of this new initiative. MT emphasised that as this scheme requires direct access to patient records there is a need to put systems in place to record a patient's objection to their records being accessed as part of this scheme.

The panel welcomed and supported the initiative but felt that the panel needed time to read the tabled paper and discuss more fully at the April meeting. In particular NREAs would need to consider:

- How it will be ensured that all patients are given the opportunity to object to their records being accessed for this purpose and how this can be achieved for patients both already in the NHS system and for those joining.
- How objections will be sought for the feasibility study in a particular area where people will join and leave during the study.

[2] http://www.gmc-uk.org/guidance/ethical_guidance/confidentiality.asp
[3] http://www.bps.org.uk/document-download-area/document-download$.cfm?file_uuid=092B7E1C-1143-DFD0-7EA4-6235165A3BA8&ext=pdf
[4] http://www.britsoc.co.uk/equality/Statement+Ethical+Practice.htm
[5] http://www.data-archive.ac.uk/sharing/confidfaq.asp#illegal

MT indicated that he would be happy to email the draft document to CC for dissemination to the panel.

Action: CC

7. Response to Research Ethics Review Case Study: AREC Research Ethics Review (2009) Vol 5, No 4, 129-166

Received: *The role of the REC in considering changes to the protocol: commentary*. AREC Research Ethics Review (2009) Vol 5, No 4, 129-166

Received: Draft response letter

The panel noted the draft response letter to be issued by the NRES operations team.

8. Data Monitoring Committees in Clinical Trials: Guidance for Research Ethics Committees

- Data Monitoring Committees in Clinical Trials: Guidance for Research Ethics Committees - Matthew R Sydes & David Neal*

The panel welcomed the guidance by Matthew Sydes and David Neal (DN) and noted that RECs have a limited role with regards to the setting up of DMCs (the primary responsibility lying with the sponsor and the MHRA).

The panel noted that IRAS presupposes that there should be DMC but that this was not always appropriate for a particular study. However, DN was aware of this issue and that IRAS would be revised in future. Richard Tiner (RT), whilst welcoming the guidance, felt that it tended to concentrate on CTIMPs and that there were other areas where a DMC would also be appropriate e.g. medical device studies and some surgical trials.

JB asked how this guidance would be disseminated. JW explained that it would be available on the NRES website and released as guidance to RECs via REC chairs for discussion at a committee meeting. It was noted that there was currently some variation in the system in how chairs and committees handle these communications. JW stated that once REC centres are firmly established such guidance would be more easily disseminated. In addition, centre managers would be in place to ensure that critical training is attended by members and this would be assessed during accreditation.

Agreed: The panel agreed that the suggestion is made to DN that the guidance be amended to emphasise that DMCs may also be desirable in some medical device studies and surgical trials.

Action: CC

9. Christopher Roy-Toole - email correspondence "Quality Assurance enquiry: Framework for Working Partnership 2010"

Received and noted: Email Correspondence between Christopher Roy-Toole and Janet Wisely/Sandra Holley

The panel noted that Christopher Roy-Toole indicated in his e-mail that he had sent communications to NREAP regarding REC indemnity and the operational guidance in place regarding appropriate insurance and indemnity arrangements for clinical trials at the time of the TGN 1412 trial. The panel were not aware of these e-mails and asked CC to contact Roy-Toole to ensure that the panel receive these.

10. **Any other business**

Membership

AG felt that the panel should consider membership at the next meeting. In particular the following issues needed to be discussed:

- Is the current number of members sufficient or should membership be increased?
- Comments have been made that the panel has a bias towards medical practitioners/scientists as well as being male dominated.

The panel noted that a barrister with expertise in the legal and ethical processes relating to biotechnology, especially gene therapy, and medical research had expressed an interest in joining the panel. It was agreed that her details would be circulated to the panel before the next meeting for consideration. In addition panel members were asked to provide CC with any suggestions they might have for any categories of member or individuals that they felt would be useful as a member of the panel.

Action: CC

Public Presentations as an NREA Panel Member

SWi explained to the panel that she had been asked to co-present a workshop for a 'Philosophy in Research Ethics' meeting that aimed to stimulate discussion by proposing that RECs should be abolished in favour of trust and deterrence.

She asked the panel whether there was any relevant guidance or advice as to what NREAs should/should not say in public?

AG stated that he felt that any panel member was free to publish or say anything they wished as an individual but where their view as an individual might conflict with the established view of NRES or the panel then this might put them in a difficult position but that this was still very much a matter for personal judgement. Panel members would not be deemed to be speaking on behalf of NREAP unless explicitly authorised to do so.

Process for Dissemination of NREAP Guidance

JB asked what process was in place to ensure that NREA guidance was disseminated and acted upon within the NRES system. JW explained NREAP guidance would be published on the NRES website but that there was also a whole governance framework within NRES that NREAP needed to link in with. JW suggested that CC establish links with Sheila Oliver (NRES Manager Quality Assurance/Operations) and Gill Habicht (NRES Business Unit Manager) in order to ensure the NREAP minutes are published on the web and to disseminate NREAP guidance and ensure such guidance and communications were subject to proper document control with appropriate review dates and systems for adding and removing guidance from the NRES website at the appropriate times.

AG stated that he would discuss with HD processes for presentation and dissemination of NREAP guidance.

Action: CC & JW

11. Date of next meeting: The next meeting of the National Research Ethics Advisors' Panel will be held on 14th April 2010. Time: 14:00 – 17:00 at Friends House, 173 Euston Road, London NW1 2BJ