National Research Ethics Advisors' Panel

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

Date: **10 August 2011**
Time: **14:00 – 17:00**

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

MINUTES

Present:

Peter Heasman (Acting Chair)
Jeremy Butler
Sarah Dyer
Nalin Thakker
Art Tucker
John Saunders

In attendance:
Debbie Corrigan
Clive Collett

1. Apologies: Andrew George; Hugh Davies; Charles Warlow; Caroline Harrison; Richard Tiner, Frank Wells; Simon Woods; Sue Wilson; Janet Wisely
2. Declarations of Interest

   There were none
3. Minutes of meeting held on 13 July 2011

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

4. Matters Arising

5. Annual Review of NREAP Guidance:

NREAP/02 - Follow-up contact of potential participants who have not responded to an initial invitation to take part in research (published 2010/07/12)

Received for review/discussion:

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

The panel felt that the original document might benefit from editing to make the document shorter and less fragmented. In addition it was felt that the document should be identified as "guidance" rather than as a "Letter from NREAP Chair".

JS felt that the term "coercion" was an overused term which should be revised in this document.

Agreed:

The panel agreed that the original document should be identified as "guidance" and revised to be shorter and more focused. PH volunteered to edit the original document which would then be ratified at the September meeting.

Action: PH

6. NRES Update – Debbie Corrigan (NRES Deputy Director)

Debbie Corrigan explained that the scoping document has now been approved and signed off by the HRA Steering Group and the Transition Programme Board. The HRA Establishment Group has been further developing the implementation plan to assign lead personnel for each workstream and agree and finalise timings with the specific details of the plan examined in greater detail. Debbie reported that a recent meeting with SHA leads meeting had been held and was felt to be very helpful with the SHA leads being supportive of the plans for the HRA Establishment.

She explained that there was some concern that NRES may need to move from their current office accommodation sooner than had been anticipated. It was hoped that this could be avoided and NRES was currently in negotiations to address this issue.

It was explained that there were challenges for NRES to continue "business as usual" as there were difficulties in moving forward with converting temporary posts into permanent posts as the NPSA did not wish to recruit to more permanent posts at a time when they were moving towards closure. As a result of this NRES has negotiated with other staff hosts (University Hospitals Bristol NHS Foundation Trust and East of England Strategic Health Authority) to arrange recruitment to 14 posts. In addition Further negotiations are underway with NPSA for them to recruit to a minimum of 11 posts.

Debbie was pleased to inform the panel that following an audit of the quality assurance department they have successfully retained their ISO 99001 certification.

7. SOPs and GAfREC Update – David Neal (NRES Deputy Director, Policy)

Version 5.0 of the SOPs will shortly be issued together with guidance on the changes to REC remit in the harmonized GAfREC from 1 September. David Neal attended to brief the panel on the changes contained in these documents.

Received for Information:

- Briefing document for REC Chairs and members
- Full summary of the changes to SOPs
- Guidance on changes to REC remit under GAfREC

During the presentation DN mentioned that he had created an algorithm entitled "Does my project require review by a Research Ethics Committee?" which it was hoped would go some way to reduce the number of queries directed to NRES and coordinators. He would send this to CC for distribution to the panel for their information.

8. Proposal for NREAP Meeting Format

Received for discussion:

- Proposal for NREAP Meeting Format

The panel were broadly supportive of the proposed meeting format. However, there was some concern that the option to assign individual NREAs to lead on specific issues and task them with producing a paper for fuller discussion at a meeting might result in quite an arduous workload without the appropriate

support to facilitate this. NT pointed out that any such paper would only be used as a starting point for discussion by the panel and used to inform the formal guidance document, and thus the original discussion paper may not necessarily need to be extensive.

Agreed:

The panel supported the proposed meeting format and agreed to trial it over the next year and review its effectiveness at the end of that period.

9. National Blood Service and Consent for Research Use

Received for discussion:

- Email correspondence regarding the "National Blood Service and consent for research use"

The panel were asked to consider whether they would wish to recommend to the National Blood Service that more information should be given to donors regarding the possibility that their blood could be given to animals for research purposes. This issue was raised by a REC regarding a study in which the researchers proposed to transfuse human blood (from the National Blood Service) into pigs.

PH informed the panel that whilst he could not find any specific document related to the research use of blood on regional National Blood Service websites in England, he did find information from the Scottish National Blood Transfusion Service which informs donors that their blood may be used for research purposes[1]. It was noted that this did not specify that this may include infusion into animals. The National Blood Service website confirms that the information given to donors states "that occasionally blood that is not needed for transfusion maybe used for research and development work to benefit patients. All such use is carefully controlled, ethically approved where appropriate and no donor is identified"[2].

Whilst the panel were aware that many people would not wish their blood to be used in this way it was felt that the current practice, whereby donors are informed that their blood may be used for research purposes, was sufficient and alerted them to the broad nature and purpose of the donation. To go into specific detail about use in human research vs. animal research in the leaflets would be possible but the introduction of such a system by which blood could be designated as being 'available for research', 'not available for research' or 'not for animal research' (for example) would be complex and expensive to set up and administer. Furthermore, it was envisaged that this might deter a number of potential donors from giving blood in the first place, which would be detrimental to society as a whole.

The panel were unaware of the how much donated blood is currently used for 'research' purposes, whether any donors currently ask about the possible use of animals in research, and how much blood is specifically used for research involving animals.

SD was of the opinion that whilst the current information given to donors would not require updating she felt that the National Blood Service should take note of any complaints/concerns from donors around the use of their blood for animal research and should be constantly assessing whether their current information adequately deals with donors' concerns over the use of their blood.

Recommendation:

The panel do not recommend any change to the current information given to blood donors and therefore advise against writing to the National Blood Service requesting such a change.

10. Participant Recruitment and Commitment to Complete Research Studies

Received for discussion:

[1] http://www.scotblood.co.uk/pubdocs/donor%20information%20leaflet2.pdf
[2] http://www.blood.co.uk/giving-blood/faqs/

- Email correspondence regarding the issue of “Participant Recruitment and Commitment to Complete Research Studies”

The panel noted that the REC chair’s e-mail was primarily concerned with sponsors, and commercial sponsors in particular, not funding studies through to completion. Whilst the panel empathised with the chair’s concerns over this issue it was felt that, unfortunately, there was very little that the panel/NRES can do to prevent this from happening. It was noted that whilst sponsors/funders will start a study in good faith there would always be occasions, particularly with longer CTIMPs conducted by commercial organisations, where the study may simply cease to be commercially viable for the pharmaceutical company.

The panel noted that The Medicines for Human Use (Clinical Trials) Regulations 2004 require that both the licensing authority and the main REC are notified of the early termination of the trial within 15 days:

> PART 3 Regulation 27: **Conclusion of clinical trial**
>
> 27.—(1) Subject to paragraph (2), within 90 days of the conclusion of a clinical trial the sponsor shall notify the licensing authority and the relevant ethics committee in writing that the trial has ended.
>
> (2) If a trial is terminated—
>
> (a) before the date for the conclusion of the trial specified in the protocol for that trial, or
>
> (b) before the event specified in the protocol as the event which indicates the end of the trial has occurred,
>
> the sponsor shall notify the licensing authority and the relevant ethics committee in writing of the termination of the trial within 15 days of the date of termination.[3]

Furthermore, it was noted that the Standard Operating Procedures for Research Ethics Committees (Version 5.0 September 2011) also require that “An explanation of the reasons for early termination should be given.”[4]

Recommendation:

The panel recommended that RECs should, where they consider it to be necessary, ensure that participants are informed that the study may be terminated by the sponsor/funder for commercial reasons at any time. For most studies the use of the phrase included in the NRES information sheet and consent form guidance would be sufficient:

“If the study is stopped for any other reason, we will tell you and arrange your continuing care.”[5]

11. Consent and Foetal and Embryonic Material for Stem Cell Research

Received for discussion/advice:

[3] http://www.legislation.gov.uk/uksi/2004/1031/regulation/27/made

[4] Standard Operating Procedures for Research Ethics Committees (Version 5.0 September 2011) para. 9.80

[5] http://www.nres.npsa.nhs.uk/EasySiteWeb/GatewayLink.aspx?alId=4757

- Email query from Professor Martin Gore – Chair GTAC
- Code of Practice for the Use of Human Stem Cell Lines (Issued:15 Apr 2010)
- HFEA Guidance: "Research and Training"

The panel noted and welcomed the e-mail from Professor Martin Gore.

It was noted that the questions asked in the e-mail were primarily concerned with legal and procedural issues surrounding consent for research using embryos and foetal tissue. The panel felt that such issues were not within their remit to advise upon and, furthermore, were not adequately constituted to provide such *legal* advice. However, it was noted that extensive guidance on the consent requirements for such research was available online e.g. the MRC's "Code of Practice for the Use of Human Stem Cell Lines (Issued: 15 Apr 2010)[6]" and the HFEA "research and training" code of practice[7] and they referred Professor Gore to them.

Whilst the NREAs did not feel able to provide specific advice on what constitutes valid consent for such research they would be happy to receive and advise upon any specific *ethical* issues related to the use of foetal and embryonic material for stem cell research.

12. NREA-Hosted Chairs Network Meetings – National Items for future meetings

Discussed:

The NREAs were invited to suggest "national items" for future NREA-Hosted Chairs' Network Meetings in accordance with the terms of reference for these meetings:

Item 1 – National issue:

National issues for discussion will be identified by the Panel or by senior NRES management and notified to the Operations Business Manager.

The designated NREA and a local representative Chair will choose which issue to include on the agenda from those identified

The NREA's present suggested the following national items:

- "Equipoise" vs. "uncertainty"
- Research into complementary medicines
- Incidental findings
- Scientific review
- Feedback of study results to participants
- Discussion of Shared Ethical Debates

13. Any Other Business

14. Date of Next Meeting:

The next meeting of the National Research Ethics Advisory Panel will be held on 14 September 2011.

Time: 14:00 – 17:00

Venue: Ground Floor

[6] http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC003132
[7] http://www.hfea.gov.uk/3468.html

National Research Ethics Service
National Patient Safety Agency
4-8 Maple Street
London W1T 5HD