National Research Ethics Advisors' Panel

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

Date: **30 July 2015**
Time: **14:00 – 17:00**

Venue: HRA 1
Skipton House
Health Research Authority
Skipton House,
80 London Road,
London SE1 6LH

MINUTES

Present:
Andrew George (AG) (Chair)
Malcolm Boyce (MB)
Peter Heasman (PH)
Ros Levenson (RL)
John Keen (JK)
Mark Sheehan (MS)
Simon Woods (SW)

In attendance:

Clive Collett (HRA Ethics Guidance & Strategy Manager)
Observer: Bill Davidson (BD), HRA Policy Projects Lead, attended the meeting for item 5.

1. Apologies: Søren Holm

2. Declarations of Interest

3. Minutes of meeting held on 18 May 2015

RL felt that the phrase words "right to a fair trial" in the sentence "*… RL questioned whether the proposed procedures would be compliant with Article 6 (Right to a fair trial) of the Human Rights Act*" should be revised to say "right to a fair hearing".

[Post meeting note: Article 6 of the Human Rights Act 1998 is correctly stated as being the "*Right to a fair trial*", however it states that:

> "1. In the determination of his civil rights and obligations or of any criminal charge against him, *everyone is entitled to a fair and public hearing within a reasonable time by an independent and impartial tribunal established by law*. Judgment shall be pronounced publicly but the press and public may be excluded from all or part of the trial in the interest of morals, public order or national security in a democratic society, where the interests of juveniles or the protection of the private life of the parties so require, or to the extent strictly necessary in the opinion of the court in special circumstances where publicity would prejudice the interests of justice." [My italics]

4. Matters Arising

AG and CC informed the panel that they had attended the HRA board meeting held on 22 July to update them on the work carried out by NREAP over the past year.

RL suggested that, in the light of the Board's interest in whether the panel represented value for money, that there was a need for the panel to develop metrics/proxy measures regarding the output of the panel and whether behaviours were changed as a result. SW wished to emphasise the fact that the NREAs own institutions invested in the work of the panel by allowing them to take part in its work. Furthermore, it was important to note that the institutions involved did this because they perceive the work of NREAP as a valuable activity. SW also noted the work done by the NREAs outside of the meetings, such as the recent contribution to the Nuffield Council on Bioethics report on children and research, to which both MS and SW contributed. SW explained that this had provided him with the opportunity to correct a number of misunderstandings regarding the work of the HRA and their research ethics committees.

The panel agreed that CC should contact the HRA Board Secretary to offer the opportunity for the recently appointed non-executive directors to attend a future meeting of the panel.

Action: CC

5. Mental Capacity Act: Revision of HRA guidance – Simon Woods

Received for Discussion/Review:

- MCA Guidance - Loss of capacity – (draft guidance)

SW explained that he had produced a number of simple vignettes which were grounded in both the common law and the Mental Capacity Act (MCA) but also echoed the questions contained in the IRAS application form regarding the inclusion of adults lacking capacity in research.

The MCA does not prescribe a statutory process for assessing or monitoring capacity. SW noted that it was difficult to be specific regarding how often researchers might reasonably check on the capacity of those participating in a research study. Such monitoring would need to be negotiated with the research ethics committee and be proportionate to the research in question. It would be reasonable to assume capacity if there was no continuing contact with the participant.

PH noted that there was a tendency for some people to be very "MCA driven" requiring researchers to monitor capacity even in studies where the likelihood of any participant losing capacity during the research was very low.

MS felt that the MCA did not currently get the balance right between the interests of research and the protection of adults lacking capacity: the act was too restrictive regarding the circumstances under which research involving adults lacking capacity could be undertaken.

SW also pointed out that the 'Guidance on nominating a consultee for research involving adults who lack capacity to consent' issued by the Secretary of State and the Welsh Ministers made it difficult to use a nominated consultee as that function could only properly be fulfilled where a 'personal consultee' was also involved i.e.

"The nominated consultee may not know the person who lacks capacity. In determining what the person's wishes and feelings about the research would be if they had capacity, the nominated consultee should attempt to seek views from any family, friends or carers who may not be willing or able to act as a consultee."

He felt that this document would benefit from review and revision and, as it was not a statutory instrument, it would be easier to lobby for such review. SW also wondered whether the "Mental Capacity Act 2005 Code of Practice" (originally issued in 2007 by the Department for Constitutional Affairs which is now part of the Ministry of Justice) might also be subject to lobbying for review.

It was agreed that CC and BD would liaise to investigate whether opportunities exist to influence changes with regard the inclusion of adults lacking capacity in research in either guidance or legislation.

BD stated that he would take this item forward liaising with NREAP as necessary regarding the revision of the HRA's MCA guidance and opportunities available for lobbying for changes to existing third-party guidance/codes of practice.

6. Consistency in REC Review - Response from Operations Management Group (OMG)

Received for Discussion:

- Consistency in REC Review - Response from OMG

The panel noted the OMG response to their recommendations.

It was agreed that Prof Nalin Thacker (HRA Board lead for 'consistency') should be invited to the next NREAP meeting to discuss further ways in which consistency of REC opinion might be improved.

Action: CC

7. Shared Ethical Debate (ShED) 17 Report

Received for Information/Discussion:

- ShED 17 Report: "A feasibility study to develop the Quality of Interactions Schedule (QuIS) for use as an outcome measure in acute hospital care"*

The panel noted the ShED 17 report.

The panel discussed ways in which the shared ethical debate process might be used to further drive consistency of REC opinions. It was felt that the current format was trying to be several things at once i.e. a training, research, and audit tool. MS acknowledged the need for ShED to be used for audit but considered that its primary use was as a training tool to promote reflection on behalf of the REC about their decisions.

AG suggested that it might be helpful for a facilitator to be present at the time the REC considers the ShED application so that they can provide immediate feedback to the REC and help them to discuss and explore why they had arrived at their opinion. SW felt that might work but it would require a very skilled individual and there would be a need to decrease the number of applications slots for that meeting in order to provide sufficient time

for this. MS wondered whether considering an opinion immediately after having reached it would be the best time for reflection. He preferred a specific training session shortly after the opinion which would be used as a springboard for self reflection, part of which might be reflection upon committee dynamics and how this had affected the opinion reached.

RL felt that it was important to engage with the REC community to get feedback on how the ShED process could be improved from their perspective.

CC explained to the group that he would shortly be meeting with Jane Thompson (HRA Head of Learning) to discuss how ShED might be incorporated more usefully into training. CC would feedback the outcome of these talks to the panel at the next meeting.

8. Information Provision

Received for Discussion:

- Discussion paper
- Flory J, Emanuel E (2004) Interventions to improve research participants' understanding in informed consent for research: a systematic review. JAMA; 292(13): 1593-1601.
- Current HRA "Participant Information Sheet (PIS) Template"

NREAP has identified that the provision of information in support of the informed consent process is an area that might usefully be taken forward by the panel as a major item over the forthcoming year.

The panel noted that the issue of informed consent and the provision of information to support this was a very large issue and the panel would need to be very specific about what it could practically and usefully do in this area.

SW noted that REC members would not necessarily have expertise in how to present information in order to facilitate understanding, but could ask researchers to justify the approach they have taken and the evidence that it would facilitate informed consent. He felt that producing more templates, rather than being useful, would simply compound the existing problem. He noted that increased use of patient and public involvement in the production of information documents was a good way of improving them.

MS noted that in reviewing information documents the RECs are only looking at a theoretical description and not the actual process involved in seeking consent. This being the case, he felt that RECs would not be the primary target for any guidance; the target should be the researchers.

MB noted that information sheets had become far too lengthy and tended to overload the potential participant with information and thus were counter-productive. He felt that it would be important to champion much shorter information sheets. In his experience potential participants simply wanted to know what the risks and benefits involved were.

SW noted that it would not be useful to focus on what goes on within the potential participant's head i.e. it would be difficult to ensure that participants actually *understood* what they were being presented with. It would be better to focus on the information provided and make that as simple and clear as possible i.e. 'provision' not 'understanding'.

SW felt that the issue could be broken down into three elements:

1. information processing
2. legal issues
3. ethical issues

MS considered that the fundamental question here was whether it matters, and if so why, that potential participants *understand* what is involved in participation. He noted that RECs are primarily there to ensure that potential participants are being presented with an acceptable offer, i.e. an offer that would be reasonable for anyone to accept. This being the case the issue of whether potential participants fully understand what is involved becomes less important and information sheets can be much reduced as a result.

AG put forward the idea that there might be three categories of information that potential participants "ought" to be provided with:

1. Information that is essential for them to be given and provided within the PIS;

2. Less important but useful supporting information which would be available elsewhere (for example online or in a separate document).

3. Information contained in the study protocol but written from the patients' perspective i.e. a type of "user manual" for the trial detailing the practical information regarding the participant pathway.

AG noted that any work looking at this would necessarily require the involvement of patients, the public and also industry. RL added that any work in this area would also need to engage with RECs.

MS suggested that the main questions that would need to be answered for any potential participant were:

1. What is going to happen to me?
2. Why are you doing this research?
3. What are the risks involved?
4. What are the benefits?

All of this could be contained on one or two pages at most and everything else could be provided elsewhere.

AG and CC agreed to produce a more detailed proposal for this work on information provision.

It was noted that this proposal would need to be formally approved through HRA processes before being taken forward.

Action: AG & CC

9. Seeking Informed Consent for Simple and Efficient Trials in the NHS Draft Guidance: For Comment - Summary of Responses

Received for Information;

- Seeking Informed Consent for Simple and Efficient Trials in the NHS Draft Guidance: For Comment - Summary of Responses

Following the release of the HRA's 'Seeking Informed Consent for Simple and Efficient Trials in the NHS - Draft Guidance' the summary of the responses received has now been published.

The responses, in conjunction with feedback obtained from parallel public dialogue workshops, will inform the development of future HRA guidance concerning seeking consent in a proportionate manner, not just in simple and efficient trials, but also other types of research.

The panel noted the report.

RL considered that the information provided regarding the respondent "type" and "category" was not particularly helpful.

10. Research without prior consent (deferred consent) in trials investigating the emergency treatment Of critically ill children: CONNECT study guidance Version 2 updated July 2015

Received for Information:

- CONNECT study guidance "Research without prior consent (deferred consent) in trials investigating the emergency treatment of critically ill children"

This guidance has been developed to assist the design, review, and conduct of clinical trials investigating the emergency treatment of children (under 16 years of age) and young people (16-18 years) with life-threatening conditions.

The panel noted this "guidance" but felt that there were a number of problems with it. MS questioned on what grounds something that was essentially an empirical study could be said to be "guidance" or in any way normative.

MS offered to look more closely at the guidance in order to provide an opinion to the panel.

Action: MS

11. Nuffield Council on Bioethics: Ethical challenges in bioscience and health policy for the new UK Parliament

Received for Information:

- Ethical challenges in bioscience and health policy for the new UK Parliament

The panel noted the document.

12. Declaration of the End of a Study

Received for Information:

- CTIMP End of Study Declaration Form
- IRAS Application Form

A REC Chair felt that NREAP should be aware of a recent end of study declaration as the reasons patients gave for not taking part in this study might provide useful information on patient perspectives regarding this type of research.

The panel noted the information provided and the reasons for not taking part in the study given by patients detailed in the end of study declaration form.

The panel thanked the REC chair for making this information available to the panel.

13. Testing Treatments Interactive

Received for Information:

- Testing treatments interactive (TTi): helping to equip the public to promote better research for better health care*

The Testing Treatments Interactive website: http://www.testingtreatments.org/

It was noted that the HRA is currently collaborating on development of the TTi website, specifically a section on helping RECs review such work.

14. Chairs network meeting minutes

Received for Discussion:

- London and S.E. Coast (19/05/2015)
- East Midlands (15/05/2015)
- N.E. Yorkshire & The Humber (15/10/2014)
- West Midlands (07/05/2015)

The panel noted the minutes.

The panel were concerned that neither the London and S.E. Coast nor the East Midlands minutes had been seen by the relevant NREA before being finalised.

It was also noted that some Chairs network meeting minutes was still outstanding and had not yet been presented to the panel.

15. HRA Year in Review 2014/15

Received for Information:

- The Year in Review: How our work benefits the lives of patients

The panel noted the document.

It was noted that, on page 10, there appeared to be two different percentage figures given for the same statement i.e.

"74% researchers think it is important that they involve patients and the public in the design and development of their research. (Assessing professional and public opinion of the HRA, January 2015)

82% of researchers think it is important that they involve patients and the public in the design and development of their research."

CC agreed to notify HRA comms of this.

16. Identifying and recruiting participants for health research: A public dialogue for the Health Research Authority Report (July 2015)

Received for Information:

- Identifying and recruiting participants for health research: A public dialogue for the Health Research Authority Report (July 2015)

The panel noted the report

17. Any Other Business

TGN1412/TAB08

MB notified the panel that the experimental drug TGN1412, which had caused a cytokine storm, an extreme autoimmune reaction leading to multiple organ failure, in six healthy volunteers in 2006 has been acquired by a Russian biotechnology company TheraMAB. The drug has now been renamed TAB08 and is being used in new trials to evaluate it as a potential treatment for rheumatoid arthritis.

Children and Research

CC informed the panel that he had been approached by Professor Neena Modi (President of the Royal College of Paediatrics and Child Health) asking whether the HRA might require the inclusion of infants and children in clinical trials by default in the absence of clear justification for their exclusion. Professor Modi had offered to liaise with other bodies (Academic Paediatric Association, Neonatal Society and the BMJ Ethics Committee) in order to produce a briefing paper for the panel to consider this issue.

The panel agreed that if Professor Modi could submit a briefing paper to the panel then they would consider this issue at a future meeting

18. Date of Next Meetings

Tuesday, 13 October 2015
Thursday, 26 November 2015