National Research Ethics Advisors' Panel

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

Date: **13 October 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)
Søren Holm (SH)
John Keen (JK)
Simon Woods (SW)

In attendance:

Clive Collett (HRA Ethics Guidance & Strategy Manager)
Prof. Nalin Thakker (NT) (HRA Board member and consistency lead)
Dr Jane Thompson (JT) (HRA Head of Learning) attended the meeting for item 7.0.
Jim Elliott (JE)(HRA Public Involvement Lead) and Andrea Horwood (AH) (HRA Public Involvement Coordinator) attended the meeting for item 8.0.

1. Apologies: Peter Heasman; Mark Sheehan; Ros Levenson

2. Declarations of Interest

3. Minutes of meeting held on 30 July 2015

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

4. Matters arising

4.1 NREAP Terms of Reference

Received for Information:

- Revised NREAP Terms of Reference v2.5 – previously ratified by email.

4.2 Information Provision

AG asked the panel whether the issue of what is said to potential participants during the consent interview is something that could be usefully taken forward by the panel as a

specific project. SW said that it would be hard to get this aspect of the consent process into a form that could be evaluated by a REC because the REC can only see the formal documented part of the process and not the actual consent process which should include a discussion and an opportunity for potential participants to ask relevant questions.. He pointed out that the Mental Capacity Act code of practice encourages clinicians and researchers to provide information in a way that is most appropriate to help potential participants to understand what is proposed:

"Understanding information about the decision to be made

4.16 It is important not to assess someone's understanding before they have been given relevant information about a decision. Every effort must be made to provide information in a way that is most appropriate to help the person to understand. Quick or inadequate explanations are not acceptable unless the situation is urgent (see chapter 3 for some practical steps). Relevant information includes:

- the nature of the decision
- the reason why the decision is needed, and
- the likely effects of deciding one way or another, or making no decision at all."[1]

SW further noted that the process to be used in seeking consent i.e. providing the information sheet, asking the potential participant to read it and subsequent discussion including questions could be documented and presented to the REC for review. The REC would also need to know that the right people were undertaking the interview process and that the process was reasonable.

AG noted that further thought would need to be given to this issue to focus any project working on this area. Any project taken forward in this area would also need to be aligned to the needs of the HRA and other projects looking at information provision/consent.

5. Chief Executive Update

Received for Information:

- Chief Executive Update

6. ShED 18

Received for Information/Discussion:

- ShED18 Report: *Duration of Intravenous antibiotic therapy for Septic Arthritis or acUte osteomyelitis in a paediatRic population (DINOSAUR): Qualitative Substudy*

The panel noted that it could be said that there was a level of consistency displayed by the RECs taking part in this shed in that no REC was prepared to give a favourable opinion. It was also noted that the majority of RECs (8 out of 14) felt that the application was not suitable for PRS despite the fact that it was originally reviewed under the proportionate review procedures.

[1] Mental Capacity Act 2005 Code of Practice Issued by the Lord Chancellor on 23 April 2007 in accordance with sections 42 and 43 of the Act. London: TSO (https://www.gov.uk/government/publications/mental-capacity-act-code-of-practice)

7. HRA Head of Learning – Jane Thompson

Dr Jane Thompson (JT) attended to discuss her role and how NREAs might inform and contribute to HRA training (including how ShED outcomes might better feed into and inform training).

JK expressed the view that there was very little training provided that was specific to REC chairs. He was of the view that chairs should be subjected to an annual appraisal. SW noted that the fact REC chairs were now paid through the HRA payroll and that this represented a shift in their status which might provide an opportunity to revisit appraisal mechanisms for REC chairs.

AG asked the question "what are we training for?". JK felt that it was to keep REC members up-to-date with initiatives such as 'HRA Approval' but also to provide opportunities for case analysis i.e. looking at why some RECs reject applications when others do not in order to promote consistency by reflecting upon each other's decisions.

SH stated that there needed to be more thought given to providing specific information for chairs and REC members which was tailored to their needs rather than their being presented with communications that were generic.

AG suggested that facilitating exchange of members amongst RECs would provide good training and further promote consistency. For example, if a member cannot attend a meeting of their own REC then they should be encouraged to attend another REC meeting instead.

SW noted that the mentoring of new members was very resource intensive and needed a lot of time if it was to be done well. In addition, the mentoring process needed to be more consistent amongst RECs.

MB expressed the view that training of REC managers was extremely important so that they were aware of applicable regulations and were provided with sufficient training and information to ensure RECs were operating within SOPs. SW agreed: REC managers needed to know the legal limits placed on REC review but also where there was room for committees to exercise judgement.

AG noted that the shared ethical debate (ShED) process was a useful tool but one which involved an unresolved tension between its use both as an audit tool and as a training tool. He noted that there was currently too long a gap between the REC taking part in the ShED and receiving feedback. There needed to be more thought about how to improve this.

8. HRA Public Involvement Team - Jim Elliott and Andrea Horwood

Jim Elliott (Public Involvement Lead) (JE) and Andrea Horwood (Public Involvement Coordinator) (AH) attended the meeting to discuss their work and how they might assist NREAP.

Jim Elliott explained to the panel that he was currently finalising the latest report regarding public involvement in research applications to the Research Ethics Service which shows an

increase in the level of PPI reported in answer to QA14-1 of the IRAS Ethics Application compared to the previous report which looked at data from 2010 and 2012[2].

SH noted that encouraging greater levels of patient and public involvement was part of a wider project of culture change. It is important that applicants know RECs will challenge them on the level of patient and public involvement undertaken in their research.

AG asked how NREAP and the public involvement team can work together, particularly with regards seeking access to the patient voice. JE noted that the HRA has a network of around 70 experienced patient advocates who could be quickly and easily accessed to provide feedback to the panel.

It was agreed that there may be some pieces of research where public and patient involvement was not necessary nor desirable; PPI needed to be encouraged where it added meaningful value to the research. RECs might benefit from guidance on how to spot "good" PPI that adds to the research. In addition to this more work needed to be done to promote the benefits of PPI to sponsors and researchers who need to be encouraged to access PPI early on in the research design process.

9. Consistency – Nalin Thakkar (Non-Executive Director (NED))

Professor Nalin Thakkar NED, 'consistency lead' for the HRA Board, and former member of NREAP, attended to discuss how the panel's document on 'consistency' is being, and will be, taken forward.

SH pointed out that consistency is one of the main things that all researchers talk about in relation to research ethics committee review. It was therefore an important issue for the HRA which needed to be taken seriously and needed a well thought out action plan or policy aimed at promoting consistency amongst RECs.

It was agreed that much of the inconsistency seen within the REC community was related to process and as such should be amenable to further improvement. It was noted that REC managers were integral to the improvement of procedural consistency and, with sufficient training and support, can support the work of the committee with professional advice to ensure that that the appropriate decision category is reached for appropriate reasons.

In terms of the NREAP recommendation that "*contextualisation requires broader engagement with researchers, patients and the public regarding the values, standards and practicalities of current clinical practice in specific parts of medicine*" It was suggested that applicants might be asked whether they are aware of relevant clinical guidelines or other community benchmarks that apply to their research, preferably as part of the IRAS application form - these could then inform REC review and help to ensure that RECs did not impose unnecessarily restrictive conditions on research that were not in line with accepted clinical practice

NT assured the committee that he would ensure that the issue of consistency is kept on the Board's agenda.

10. NREAP and Devolved Administrations (DA)

[2] Tarpey M. and Bite S. (2014) Public involvement in research applications to the National Research Ethics Service: Comparative analysis of 2010 and 2012 data, INVOLVE Eastleigh. www.hra.nhs.uk/documents/2015/02/involve_nres_report_2014.pdf

The panel noted that CC had attended the four nations meeting in July where it was agreed to explore attendance at hosted meetings in the Devolved Nations. CC informed the panel that he has not yet received details of chairs meetings being held in the devolved nations and would update the panel once these are known.

11. Request for Advice: Is it acceptable to design a trial that would have, as one of the inclusion criteria, the ability to pay for the biological agent that is being assessed?

Received for Discussion:

- Email correspondence regarding request for advice

The panel considered an emailed request for advice regarding the ethical acceptability of asking participants to pay for the biological agent under investigation.

N.B. currently, The Medicines for Human Use (Clinical Trials) Regulations (2004) specifically prohibit payment by participants for the investigational medicinal products used in a clinical trial:

> "PART 4
> GOOD CLINICAL PRACTICE AND THE CONDUCT OF CLINICAL TRIALS
> Good clinical practice and protection of clinical trial subjects
> 28.
> (3) Subject to paragraphs (4) and (5), the sponsor of a clinical trial shall ensure that—
> (a) the investigational medicinal products used in the trial, and
> (b) any devices used for the administration of such products,
> are made available to the subjects of the trial free of charge.
> (4) The restriction in paragraph (3) shall not apply in relation to any charge payable by a subject
> under regulations made under—
> (a) the National Health Service Act 1977(a);
> (b) the National Health Service (Scotland) Act 1978(b); or
> (c) the Health and Personal Social Services (Northern Ireland) Order 1972(c)"

The panel debated the wider ethical issues of payments by participants.

SH felt that there were two main difficulties with such an approach:

1. The acceptance of payment by participants in relatively simple and benign cases might represent a 'slippery slope' opening up the acceptance of the practice in future circumstances which are less clearly benign.
2. The principle of justice and equal access to research are important considerations that should not be disregarded lightly without robust reasons for doing so.

In countries where the predominant healthcare system was insurance-based, such as the U.S., SH felt that a case might be made for the acceptability of payment by participants. However, this was not the case in the UK. In addition, he felt that acceptance of payment by participants would open up the possibility that research, of little merit, could be undertaken through direct financing by the participants.

SW considered that the principles of the open market should not apply in the context of drug trials. The fact that the potential participants were willing to pay should not be taken into account.

12. Any Other Business

13. Date of Next Meeting

Thursday, 26 November 2015