National Research Ethics Advisors' Panel

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

Date: **15 January 2014**
Time: **14:00 – 17:00**

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

MINUTES

Present:
Andrew George (AG) (Chair)
Peter Heasman (PH)
John Keen (JK)
Simon Woods (SW)
Malcolm Boyce (MB)

In attendance:

Clive Collett (HRA Ethics Guidance & Strategy Manager)
Sue Bourne (Head of Partnerships & Guidance)
Joan Kirkbride (Director of Operations)
Janet Wisely (HRA Chief Executive Officer)

Observers: Kate Donaldson (REC Manager London – Brent & London - Stanmore)

Welcome of new member: AG warmly welcomed Malcolm Boyce to his first meeting as an NREA.

1. Apologies: Søren Holm; Ros Levenson; Hugh Davies; Mark Sheehan
2. Declarations of Interest

   There were none
3. Minutes of meeting held on 09 October 2013

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

4. MATTER ARISING

4.1 Revised National Research Ethics Advisors' Panel Terms of Reference v2.1

- National Research Ethics Advisors' Panel Terms of Reference v2.1

The panel were asked to approve the revised terms of reference which have been updated in line with the comments made at the previous meeting.

The panel agreed the revised terms of reference subject to two minor changes that do not need further approval by the panel:

i) Para. 4.3: The "HRA Training & Development Group" has now been closed and replaced by a small group made up of the Director of Operations, Training and Development Manager, Head of Corporate Service, Training Officer and Quality Assurance Manager plus others co-opted as necessary. The HRA Ethics Guidance & Strategy Manager no longer sits on the new group and so this paragraph should be removed.

ii) The provision for annual review of the terms of reference should be added

Action: CC to re-draft terms of reference accordingly.

4.2 Nuffield Council Consultations

Received for Information:

- Health Research Authority Response to the Nuffield Council on Bioethics Call for Evidence – "Children and Clinical Research: Ethical Issues"

- Health Research Authority Response to Nuffield Council on Bioethics Consultation: "The linking and use of biological and health data: Open consultation" (To Follow)

5. NREA Activity Log

Panel members provided updates to the NREA activity log.

6. Action Register

Received for Review:

- NREAP Action Register

Noted

7. HRA Business Plan - Janet Wisely

Received:

Janet Wisely (JW) provided a verbal update on the HRA's Business Plan for 2014/15

JW informed the panel that a high level business plan had been submitted to DH but some of the detail involved was still being worked up.

Proposals for the 'HRA Assessment and Approval' are currently with DH having been presented to them at the end of September 2013. A decision is still awaited. Thus the HRA are working on two separate versions of the business plan: one which anticipates DH approval of the HRA Assessment proposal and another which does not incorporate this.

The HRA is expected to become a Non-Departmental Public Body (NDPB) within the next financial year. This would be an important step for the HRA, moving it from its current position as a Special Health Authority to a body that is provided for in primary legislation. This will further protect the organisation and its agenda, particularly as the legislation contains clauses regarding research governance and the duties of the HRA and the duties of others incorporating a duty to take heed of HRA guidance.

The Ethics & Confidentiality Committee (ECC) of the former NIGB had now successfully moved in to the HRA to become the Confidentiality Advisory Group (CAG). Six former members of the ECC had moved across to the new committee on one-year contracts to form the core of the new committee augmented by new members. The HRA were now in the process of recruiting further members to replace the original ECC members. The positions would also be open to the current incumbents to apply. CAG will become an operational function under Joan Kirkbride's directorship of Operations.

The first phase of the ethics officer pilot had now completed and phase 2 was now being developed. Applicants involved in the initial pilot found it useful to have early access to advice and felt better prepared for the REC meeting.

As part of the HRA's move to become an NDPB it will be given responsibility for the Research Governance Framework (RGF) in England. In anticipation of this an RGF project group has been set up to oversee a number of projects to inform a future draft of the RGF. These projects include:

- review of responsibility for social care research
- "what research can the NHS support"
- risks in research
- public and patient involvement
- optimised consent processes

All of these strands would involve input from stakeholders and the draft RGF document would go out for consultation before implementation.

JW explained that the last of these (optimised consent processes) would involve NREAP and would copy NREAP into emerging proposals. In addition, JW asked the panel whether they would be willing to issue preliminary advice on applications to a forthcoming NIHR HTA (Health Technology Assessment) call for funding applications involving innovative trials and minimised consent processes. The panel agreed that they would be happy to comment on the issues involved in such applications.

SB asked that the work on consent processes ultimately be linked back to the work that has already been done to provide online consent guidance. JW agreed that whilst this was currently a separate piece of work this would eventually need to be incorporated into the online consent guidance.

8. EU Clinical Trials Regulation – Sue Bourne

Received for Discussion:

- Update on the EU clinical trials regulation

9. Consistency of REC Decisions?

Received for Discussion:

- NREAP ‘Consistency’ Discussion Paper

  The Panel were invited to review this paper and suggest changes for a more concise HRA document highlighting practical recommendations for achieving greater consistency by RECs.

PH noted that the revised document should include reference to the use of ethical domains and the NRES summary of opinion project.

AG wondered whether an insistence that every chair, and possibly every member, attends at least one meeting of another REC would promote consistency. JK felt that all REC members should move to a different committee after their first term of office.

SW commented that MS had produced a very good paper and felt that procedural consistency might be further promoted through the ongoing ethics officer pilot and other future work in this area. He noted that achievement of content consistency amongst REC was the bigger challenge. Content consistency, he felt, was about the quality of ethical reasoning and the way it is supported by substantive values. Whilst we have some idea of what those substantive values are (by reference to guidance etc) they are open to disagreement. It is not entirely clear what level of *reasonable* disagreement should be accommodated. Content consistency may be anchored in certain values expressed in SOPs but it is not clear how we bring critical appraisal to these values and what these values should be, for example with respect to research involving children or adults lacking capacity. RECs might be internally consistent but that consistency might rely upon what others might regard as "bad" values. SW felt that in order to explore the values being relied upon by RECs there was a need for them to more clearly spelt out in their written reasoning.

Joan Kirkbride (JKi) commented that when she has attended REC meetings in the past she has been able to observe and comment upon issues from an operational perspective but could not comment on the quality of the ethical debate. She wondered whether NREAs, or other suitably qualified people, might usefully observe REC meetings to assess the quality of decision making. JK agreed noting that appropriate peer review using REC chairs might be used and explained that he had sent a proposal to Joan regarding chairs appraisals.

The panel agreed that a rigorous chair/REC appraisal process should be explored as this would certainly contribute to greater levels of consistency amongst RECs. The panel agreed that as decisions of such importance are being made by RECs there needs to be a robust appraisal system in place to ensure the competency of the decision-makers.

JKi noted that once HARP (the replacement for the current Research Ethics Database) was operational there would be a requirement for all REC minutes to be written in a standard format using ethical domains. It is hoped that this would promote consistency of review. AG noted that the use of ethical domains would be key to achieving better consistency.

MB felt that any approach would need to consider the views of the "consumers" i.e. the researchers that apply to RECs as they would have important views regarding the performance of individual committees. JKi explained that NRES always asks for feedback from applicants but receives very little.

SW asked what evidence there was regarding procedural consistency of RECs. He noted that Mark Sheehan argues in his paper that we should not be too strict on variability between RECs, within appropriate limits, and commented that we would need to provide evidence that there was an issue with regards inconsistency. What would constitute a legitimate difference of opinion and what would count as "inconsistency"? JK noted that there was

already evidence regarding disparity between RECs with regard the proportion of certain category of decisions (i.e. favourable opinion, favourable opinion with conditions, provisional opinion, unfavourable opinion). JKi noted that Catherine Blewett was currently looking at the ethical reasons provided by RECs when giving unfavourable opinions for clinical trials.

AG summarise that the revised consistency document should include reference to the following:

- use of standard templates and ethical domains (acknowledging mandatory use from 1 April 2014)
- RECs to provide *reasons* for their decisions
- role of REC Managers/ethics officers in ensuring consistent decisions are made particularly with regard use of the most appropriate decision.
- Engagement with research community to contextualise REC decision-making (e.g. the previous HRA workshop held on emergency research involving REC members and other stakeholders)

Action: CC to revise consistency paper to include summary of issues, work already done/in progress to promote consistency and list of proposals for further consideration by the HRA.

10. Collated responses received from RECs after review of the SED12 Report

Received for Information:

- Collated responses received from RECs after review of the SED12 Report
- ShED 12 Report

The panel noted the responses received from RECs who had taken part in shed 12 and commented that they exhibited a reasonable degree of self reflection following the circulation of the report. They noted that only a small number of RECs had provided feedback and asked CC to enquire whether any further comments had been received.

11. NREAP Guidance: Payments & Incentives

Received for Discussion:

- Discussion paper on “Payments & Incentives”

The panel were asked to consider the issue of providing more general guidance on 'payments and incentives' that goes beyond phase 1 studies and encompasses the issue of payments to patients and healthy volunteers in both therapeutic and non-therapeutic research.

CC explained that the current discussion paper had been reviewed at the recent round of NREAP/chairs network meetings and that the majority of attendees had felt that the issue of payment for risk was largely irrelevant given that RECs should only approve studies that did not exhibit excessive risk for participants. The panel agreed that the paper should be revised to focus more on payment for "burden" rather than for "risk" as tackling the ethical issues around payment for risk was not a high priority in the context of RECs.

The panel made the following comments to be incorporated into the revised paper:

- 3.2 - patient volunteers need not always be patients with a "chronic, but stable condition" and this should be removed.
- The Royal College of Physicians guidelines make reference to pro rata payments and the panel's guidance should also comment on such payments.
- The panel agreed that completion bonuses were largely unethical and could be seen as coercive.

CC noted that at the previous meeting Søren Holm had commented on the use of the term "reasonable person" and whether it was appropriate. CC would contact SH to seek clarification and alternative wording if necessary.

Action: CC to revise paper and email to panel for further comment.

12. NREAP Guidance/Statement: Information Sheets for Children Under 8 years old

The panel were asked to consider the statement made by PORT along with the general issue of the provision of information (in any format) to children under 8 years of age along with the seeking of “assent” in this age group with a view to developing NREAP guidance or issuing a statement.

Received for Discussion:

- PORT statement on “under 8 PIS”
- Email from Clive Collett to REC Chair 28/10/2013
- NRES Committee London – Central – Unfavourable Opinion Letter (01/11/2013)
- Response Letter from researchers (13/11/2013)
- NRES Operational Management Email Alert (OMEA #61): Participant Information Sheets and Assent Forms for children under 8 years old (13/11/2013)

Background:

Prior to the submission of this amendment the trials unit took the decision to remove Patient Information Sheets from the Cancer Research UK Clinical Trials Units Standard Operating Procedures for children under 8 and two trials within the portfolio have recently been given a favourable opinion by other research ethics committees without Patient Information Sheets for children under 8 years of age.

A substantial amendment for a paediatric oncology study was recently submitted to a Research Ethics Committee requesting the withdrawal of the previously approved information sheets for participants under 8 years old. The research team had received advice from a paediatric oncology reference group (PORT - www.port.uk.com) that it was unsuitable to provide information sheets for, *or seek assent from*, participants in this age category and that the parents would be best placed to explain the study to the child. The reference group considered that for the child to assent properly, they must fully understand the implications of their illness, their treatment and the deviations from their treatment that the research required. The advice from the group was specifically related to children receiving paediatric oncology treatment.

The REC eventually approved a resubmitted amendment which contained a revised PIS for children under 8.

NRES issued the attached OMEA on 13/11/2013

SW commented that in his opinion PORT had misunderstood the important difference between 'assent' and 'consent' and had provided incorrect advice. He commented that children, if properly informed in accordance with their ability to understand, can take in relatively complex information. Even where a child may not be able to fully understand the complexities of what is being proposed in research it was still important to engage with and calm any fears they might have e.g. a child with a fear of needles can and should be given information in an appropriate format to assuage their fears. He noted that in thinking through these issues it was important to distinguish between 'informing', 'assent' and 'consent' and which would be appropriate to the needs and abilities of the child.

SW noted that many of these issues had been addressed in the HRA response to the recent Nuffield Council on Bioethics consultation "children and clinical research: ethical issues" and suggested that this should be sent to PORT.

AG offered to discuss the issues involved and the panel's view with PORT.

Action: CC to contact PORT to offer further discussion with AG on this issue and to provide the HRA response to the Nuffield consultation and the minutes from this meeting.

13. NREAP/Chairs Network Meeting Minutes

Received for Information:

- South Central (10/06/2013)
- East of England (03/12/2013)
- North East and Yorkshire & The Humber (16/10/2013)

PH noted that the level of attendance at the North East and Yorkshire & The Humber meeting was very low. CC confirmed that in the absence of the chair either the vice-chair, alternate vice-chair or another member of the committee were invited to attend.

The Panel wished to know how HRA Operations endeavoured to ensure the attendance of at least one REC member at these meetings and the ramifications for any REC not doing so.

The issue of expert recruitment was raised at more than one of the chairs meetings. NREAP shared the concerns expressed that it was becoming increasingly hard to recruit expert members due to the difficulty in securing session time for attendance from their NHS employer. It was noted that the letter entitled "Joint Government/GMC letter regarding requests from doctors for absence to undertake national work of benefit to healthcare systems across the UK" had been previously circulated to NHS employers and that this also applied to REC membership.

The panel asked SB to raise these concerns (attendance at chairs network meetings and expert recruitment) to the next Operational Management Group (OMG) meeting.

14. Any Other Business

15. Date of Next Meetings

2nd April 2014
2nd July 2014
8th October 2014

16. ACTIONS

Owner	Item	Action	Due Date
CC	4.1 NREAP Terms of Reference	CC to revise the terms of reference accordingly.	02/04/2014
	9.0 Consistency of REC Decisions?	CC to revise consistency paper to include summary of issues, work already done/in progress to promote consistency and list of proposals for further consideration by the HRA.	02/04/2014
	11.0 NREAP Guidance: Payments & Incentives	CC to revise paper and email to panel for further comment.	02/04/2014
	12.0 NREAP Guidance/Statement: Information Sheets for Children Under 8 years old	CC to contact PORT to offer further discussion with AG on this issue and to provide the HRA response to the Nuffield consultation and the minutes from this meeting.	02/04/2014