Health Research Authority

National Research Ethics Advisors' Panel

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

Date: **02 March 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)
Ros Levenson (RL)
John Keen (JK)

In attendance:

Clive Collett (HRA Ethics Guidance & Strategy Manager)
Hugh Davies (HRA Research Ethics Advisor)

1. Apologies: Mark Sheehan; Peter Heasman; Søren Holm; Simon Woods

2. Declarations of Interest:

3. Minutes of meeting held on 27 November 2014

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

4. MATTER ARISING

4.1. **Consistency in REC Review**

Received for Discussion:

CC gave a verbal update on how the recommendations made in the consistency statement were being taken forward by HRA.

The panel were disappointed by the lack of a formal, detailed response regarding their recommendations made as part of the panel's "consistency in REC review" paper.

HD noted that more formal plans may be made in response to the "mystery shopper" shared ethical debate exercise that had recently completed.

The panel agreed that once the report of the "mystery shopper" exercise had been received and considered by the HRA that NREAP should be provided with a clear, written plan stating how the recommendations made by the panel would be taken forward.

4.2. Research Ethics Committee (REC) Chair's And Member's Feedback Form: Phase I Cancer Trials

An email has been sent on behalf of Andrew George to Sarah Woolnough (Executive Director, Policy and Information) and Professor Peter Johnson (Chief Clinician) at Cancer Research UK to ask if there are any issues that they would like NREAP to consider about the ethics of phase I oncology trials.

They have replied to stating that they are discussing the matter internally and will come back to NREAP shortly with any comments.

At date of the meeting no response had been received.

5. NREA Activity Log

Panel members were invited to provide updates to the NREA activity log since the last meeting.

6. Action Register

Received for Review:

- NREAP Action Register

7. Information Sheets for Children Under 8 years old – Andrew George

For Information:

AG gave a verbal update on his meeting with representatives of PORT on the 9th December 2014 to discuss their concerns regarding the seeking of consent/assent from young children in research trials and the use of information sheets.

AG explained that the representatives of PORT were of the opinion that assent information should not be given to children with cancer below the age of eight and that parents are the appropriate conduit for, and best placed to judge, the appropriate information to be provided to their children.

AG noted that the provision of research information, in accordance with their ability to understand it, to children was important as it both held researchers to account and appropriately involved children in decisions regarding their care and involvement in research.

The panel agreed that there were a number of issues surrounding the involvement of children in research and noted that the Nuffield Council on Bioethics would shortly be publishing their report on "children and clinical research". It was considered appropriate for the panel to revisit these issues following the publication of that report.

AG indicated that he would send a letter to PORT in order to update them that the panel had briefly discussed the issues following his recent meeting with them to ensure that communications with the parent group are kept open.

8. Mental Capacity Act: Revision of HRA guidance

Received for Discussion/Review:

- Mental Capacity Act (MCA) Advice – Research Safeguards – DAC Beachcroft LLP
- MRC ETHICS GUIDE 2007: Medical research involving adults who cannot consent: paragraphs re loss of capacity during research
- MRC ETHICS GUIDE 2007: Medical research involving adults who cannot consent
- **HRA Guidance**: Mental Capacity Act 2005 Questions and Answers
- **HRA Guidance**: Informed consent in CTIMPs

Third party guidance linked to from HRA website:

- University of Leicester & University of Bristol:

  Adults lacking capacity – on-line toolkit

  on-line toolkit on research involving adults lacking capacity to consent for themselves. The toolkit covers the provisions of the Mental Capacity Act 2005 and the separate provisions for medicinal trials under the Medicines for Human Use (Clinical Trials) Regulations 2004. It includes a specific module on research in emergency medicine.
  https://connect.le.ac.uk/alctoolkit/

- University of Portsmouth:

  Mental Capacity Act Factsheet for Social Scientists

  http://www.hra.nhs.uk/documents/2013/07/mental-capacity-act-fact-sheet-for-social-scientists.pdf

For Background Information:

- Department of Health: "Consultation on Regulations to be made under the Mental Capacity Act 2005" June 2006

The panel were asked to review existing HRA guidance regarding the Mental Capacity Act in the light of legal advice received regarding "research safeguards" particularly in relation to the monitoring of participant capacity in long-term studies and suggest revised text.

The panel felt that as Simon Woods, the NREA with most experience regarding the provisions of the Mental Capacity Act, was not present at the meeting that it would be preferable to seek his expert advice regarding any possible revisions.

To that end the panel decided that Simon should be asked to perform the initial review of the existing HRA guidance and prepare a short paper with his suggestions in the light of the legal advice received by the HRA for review at the next panel meeting.

Action: SW

9. Guidance on presenting information about ionising radiation in Participant Information Sheets

Received for Information:

- Guidance on presenting information about ionising radiation in Participant Information Sheets

As part of the HRA Coordinated Radiation Assurance, a component of HRA Approval, guidance has been produced to assist researchers in providing a standard level of information relating to ionising radiation exposures in Patient Information Sheets.

The standard statements included in this guidance have previously been reviewed by Northern Ireland Cancer Research Consumer Forum (NICRCF), a PPI group in Belfast. This guidance has also been reviewed by the HRA Ad Hoc Working Group, composed of radiation experts and representatives of the professional bodies and regulators.

The panel welcomed the opportunity to comment on this guidance which they felt to be a positive contribution to this area. In particular they supported the approach outlined for describing risk.

The panel were unsure of the intended audience of this document, although it was assumed that it included REC members, and noted that it contained complex language and abbreviations, acronyms and jargon that would not be familiar to a non-scientific audience e.g.: "ECHO/MUGA"; "Abdo/Pelvis CT"; "...relative attributable lifetime risk based upon a relative risk of 1 at age 30"; " modality " "highly collimated targeted irradiation where dose sparing to healthy tissue is paramount" etc.

JK was of the opinion that the PIS risk statement for adults with poor life expectancy somewhat skirted around the issue that the patients only had a short time to live by using the phrase "In view of your current clinical condition" and might benefit from being revised.

The suggested sentence for nuclear medicine studies:

"This/these tests may increase you radiation exposure however it will provide your doctor with additional diagnostic information they may not obtain from other imaging procedures."

could be considered to exert an undue influence upon potential participants to take part in research.

HD noted that this guidance would need to be incorporated into the HRA's online information sheet guidance provided at www.hra-decisiontools.org.uk/consent/.

10. Nuffield Council on Bioethics: The collection, linking and use of data in biomedical research and health care: ethical issues

Received for Information:

- Full Report: The collection, linking and use of data in biomedical research and health care: ethical issues

The report and Short guide, Key recommendations and Executive summary are available from: http://nuffieldbioethics.org/project/biological-health-data/

The Council has recently published its report on '*The collection, linking and use of data in biomedical research and health care: ethical issues'.*

The HRA response to this consultation is available at: http://www.hra.nhs.uk/news/2014/01/15/hra-response-nuffield-consultation-biological-health-data/

The report sets out key ethical principles for the design and governance of data initiatives, and identifies examples of good practice relevant to anyone approaching a data initiative, such as a principal investigator in a research project, lead policy official or commissioner of services.

The panel noted the report and the recommendations addressed to the HRA. The panel asked CC to check whether the HRA were intending to respond to these recommendations.

Action: CC

11. Appeals

Discussed:

The panel were invited to more clearly focus the nature of their concern regarding which aspects of the appeal process might require further discussion and development of advice by NREAP.

RL noted that despite assurances that the appeals process was "working well" this was by no means certain given the low numbers of appeals received and allowed. She noted that theoretically a researcher could continuously appeal until they received the opinion they wanted i.e. a favourable opinion. She felt that the current process was "flat" with no hierarchy of bodies through which the appeal could move with increasing authority.

HD noted that there was a huge amount of work to be done in order to prepare for the implementation of the EU clinical trials Regulation, and once this was in place then attention would then be brought to bear on the issue of the appeal process in the light of the changes made to how RECs and the MHRA work together in providing a single Member State opinion.

AG acknowledged this and stated that it would still be useful to discuss the principles around the appeals process early on in order to inform the work necessary to implement the EU regulation.

RL and JK agreed to collaborate on a draft paper on this issue for consideration at the next meeting.

Action: RL and JK

12. Research Ethics: A guidance document for pharmacists – for NREAP review/comment?

Received for Discussion:

- Research Ethics: A guidance document for pharmacists

The Royal Pharmaceutical Society are developing develop guidance for their members on research ethics and have invited the HRA to comment on them.

The intended audience is any pharmacist, in any setting, who is involved in research, to be used as a reference source whether they are carrying out their own research or supporting research delivery. The RPS intend to widely promote the guidance once published but hope that it will have wider utility, particularly amongst the Research Ethics Committees, to support decision-making in relation to studies being undertaken in pharmacy settings, including community pharmacies.

The panel were invited to provide comments on the current draft.

The panel noted a number of minor inaccuracies and typographical errors in the draft guidance. It was felt that the document would benefit from being considerably shorter and include links to existing documents that explained the process in more detail. AG noted that he had a number of comments that he would send to CC to pass on.

13. Change in HRA status to NDPB and REC Membership

Received for Information only:

- Letter to REC Chairs from Jonathan Montgomery 05.02.2015

14. Shared Ethical Debate (ShED) 16 Report

Received for Discussion:

- ShED16 Report

The panel noted the report.

The panel agreed that once the "mystery shopper" shared ethical debate report was available then this would present a useful opportunity to consider the shared ethical debate process and its contribution to promoting consistency amongst RECs and to discuss whether any changes might need to be made.

The panel asked whether their suggestion that a piece of work looking at whether there was an "order effect" had been considered. CC explained that the suggestion along with the panel's offer to help design and assist with the conduct of the study, had been passed on to Sheila Oliver and Catherine Blewett asking for a response for this meeting, however no reply has yet been received. The panel asked CC to chase Sheila Oliver for a response.

Action CC:

15. Nuffield Report on ‘The Culture of Scientific Research In The UK’

Received for Information only:

- SUMMARY (4 pages)
- FULL REPORT: The findings of a series of engagement activities exploring THE CULTURE OF SCIENTIFIC RESEARCH IN THE UK* (N.B. 38 pages)*

The panel noted the Nuffield Council about the culture of scientific research in the UK: http://nuffieldbioethics.org/project/research-culture/.

16. NREAP/Chairs Network Meeting Minutes

Received for Discussion:

- South Central (19/11/2014)
- London and S.E. Coast (08/09/2014)

The panel noted the minutes from the NREAP/chairs network meetings.

17. Any Other Business

Received for Discussion:

The panel discussed and provided advice regarding a formal challenge to a REC opinion that had been received by the HRA.

18. Dates of Next Meetings

Monday, 18 May 2015
Thursday, 30 July 2015
Tuesday, 13 October 2015
Thursday, 26 November 2015