Health Research Authority

National Research Ethics Advisors' Panel

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

Date: **18 May 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)
Simon Woods (SW)

In attendance:

Clive Collett (HRA Ethics Guidance & Strategy Manager)
Observer: Dr Martin Stevens (Social Care REC Chair) (MS)

1. Apologies: Søren Holm, Mark Sheehan
2. Declarations of Interest: None declared
3. Minutes of meeting held on 02 March 2015

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

4. MATTER ARISING

4.1 Order Effect Study

At the March 2015 meeting the panel asked whether their suggestion that a piece of work looking at whether there was an "order effect" had been considered.

The panel noted that HRA Operations have considered this and have responded that whilst such a piece of work might be interesting it would not be taken forward as it was not clear what action could be taken to remedy such an effect should it be shown to exist. This and other matters related to consistency of REC opinions would be returned to following review of the recent "mystery shopper" exercise.

The panel noted this and also commented that on reflection the undertaking of any "order effect" study would be extremely complex given the large number of variables

involved. The panel were content that this would not be taken forward and noted that there must be existing academic work in this area that might provide useful information.

5. CAG and NREAP Membership Extension Proposals – HRA Board Approval

Received for Information:

On 15th April 2015 the HRA Board approved a request for Andrew George, Peter Heasman and Simon Woods' terms to be extended until end September 2016 to allow continuity business during the challenging year ahead and to allow sufficient time for review of membership and terms of reference and subsequent recruitment and appointment of new NREAs including a Chair via a public recruitment process (summer 2016).

The Board further approved the request that all three NREAs would be eligible to reapply to join the panel (and (re)apply for the Chair) at such time as new members/Chair are sought and, if successful, would be appointed to a term adjusted to bring their total time as an NREA to 10 years.

Revised NREA Terms of Office:

NREA	Term End Date	Appointment date
Andrew George (Chair)	**30th September 2016**	September 2009
Peter Heasman	**30th September 2016**	September 2009
Simon Woods	**30th September 2016**	September 2009
Søren Holm	**23rd September 2017**	September 2012
Ros Levenson	**23rd September 2017**	September 2012
Mark Sheehan	**23rd September 2017**	September 2012
John Keen	**23rd September 2017**	September 2012
Malcolm Boyce	**31st December 2018**	December 2013

6. NREA Activity Log

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

7. Action Register

Received for Review:

- NREAP Action Register

7.1 Nuffield Council on Bioethics: The collection, linking and use of data in biomedical research and health care: ethical issues - Recommendation 2

The panel agreed that this item could be closed following confirmation from Steve Tebbutt and Sheila Oliver that no action is currently being taken by the HRA to respond to this recommendation.

7.2 Payments & Incentives: research participation as employment

The panel agreed that this item required further work and that CC should produce a short briefing paper on the issues for consideration at the next meeting.

ACTION: CC

8. Dr Martin Stevens (Social Care REC (SCREC) Chair)

Dr Martin Stevens attended the meeting to informally discuss the work of the Social Care REC which was hosted by the Social Care Institute for Excellence (SCIE) for the past six years.

When the HRA became a Non Departmental Public Body on 1 January 2015 it took formal responsibility for research in adult social care. The Social Care REC and its secretariat transferred to the HRA 1 April 2015.

(see: http://www.hra.nhs.uk/resources/before-you-apply/non-nhs-recs/national-social-care-research-ethics-committee/ for more information and remit)

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

To Receive 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 were also asked to consider the provisions regarding loss of capacity set out in the Clinical Trials Regulations (consent previously given when capable remains legally valid) and those contained in the Mental Capacity Act and discuss whether the MCA provisions are considered unduly restrictive.

Simon Woods provided the following summary:

1. There are differences between domains of research involving adults who lack the capacity to consent (ALC).

    - All **Clinical trials need to be conducted in accordance with the UK Clinical Trials Regulations** (Medicines for Human Use (Clinical Trials) Regulations 2004). These regulations make specific provision for the inclusion of adults who lack capacity (ALC).

    - The regulations allow for the inclusion of ALC provided that the patient (P) or their legal representative have provided consent (or in emergency circumstances under conditions agreed by the REC in accordance with The Medicines for Human Use (Clinical Trials) Amendment (No.2) Regulations 2006).

    - However the study must have REC approval and meet the criteria for inclusion of ALC (which has a higher threshold than under the MCA).

    - The provisions for giving consent in the Regulations are at odds with the approach taken in English Common Law where there has never been provision for proxy consent for adults.

2. **The MCA covers all other instances of intrusive research that might include ALC**. *Intrusive* means research for which it would be normal to obtain informed consent. There are some instances of research where consent exemptions are permitted and this also permits exemption from the MCA

3. All research that *intends* to include ALC must have REC approval and meet the criteria and safeguards as set out in sections 30-33 of the MCA – this includes a requirement to consult an appropriate person in relation to an ALC.

    If a study has REC approval then it may include participants who initially have, but subsequently lose, the capacity to consent. To retain their full involvement in *intrusive* research requires that consultee procedures are in place.

    The MCA can be regarded as a development of the English Common Law approach and the consultee procedures (and other safeguards) offer a level of protection to P but do not change the position on proxy consent. Any such decisions for P must be in their best interests (or arguably not *against* their interests) and the consultees provide advice on this matter rather than legally valid consent.

4. The legal opinion obtained by the HRA clarifies the fact that the MCA is consistent with English Common Law and points to the fact that the MCA is a statement of principles rather than providing detailed guidance for every eventuality.

    - The legal opinion points to the main reference made to loss of capacity in the MCA which is in relation to the transitional arrangements (s 34) made for longitudinal studies.
    - However, the MCA is clear that conducting intrusive research on ALC is unlawful unless it fulfils the conditions set out in ss 30-33. This includes those who lose capacity after research has commenced. A study that *intends* to recruit ALC must have REC approval from the outset, comply with the criteria in s 32 and have consultee procedures/ emergency provisions in place. A participant may enter such a study with capacity but if they subsequently lose capacity they can only be retained as a full participant in intrusive research if consultee procedures are then brought into effect. Where an individual loses capacity in a study that does not have MCA approval then that participant must either be removed from the study or the study must seek REC approval for the inclusion of ALC.

5. What is the obligation on the researcher (R) to check capacity?

    R can presume capacity but must take reasonable steps to ensure that P has capacity initially (i.e. normal consent procedures) and retains capacity on subsequent contact for research purposes.

    In a longitudinal study where R has infrequent contact with P it is lawful to presume capacity unless they are made aware that capacity has been lost. Therefore a REC ought to discuss with the researcher what, within the constraints of the study, are the reasonable measures they ought to take to ensure that P's capacity has not changed or to be made aware of such changes?

SW felt that the current guidance from the HRA is not overly restrictive because it doesn't actually stipulate measures that are restrictive beyond the requirements of the MCA – e.g. that consent does not endure loss of capacity and that conducting research without compliance with the MCA is unlawful.) In addition, the less restrictive position taken in the clinical trials regulations is not compatible with either English common law or the MCA.

SW stated that in his opinion the legal advice received by the HRA also reinforces the existing HRA guidance.

SW indicated that he was not aware of any RECs imposing restrictive practices nor of any appeals where this has been an issue. However, the panel could advise that some further detail is given regarding monitoring capacity in a longitudinal study, perhaps with suitable vignettes. For example, the HRA's Mental Capacity Act 2005 Questions and Answers could include an additional question such as "Do I have to monitor capacity? SW suggested that the answer to this question might be "*Although capacity can be presumed there are circumstances in which a change in capacity is possible. For example in a longitudinal study where you expect that a proportion of participants are likely to lose capacity then you should*

take reasonable steps to ensure that P retains capacity, either by re-consent on next contact or by having means to be informed by those in close contact with P….".

In terms of monitoring capacity AG wondered whether a "Chinese wall" approach might be taken whereby any discovery of a participant's lack of capacity by a clinician need not be communicated to the researcher. SW said that this would be a matter of the "reasonableness" of such an approach and suggested that it would be very unlikely that such an arrangement could ever be said to be reasonable.

SW also explained that should a participant lose capacity during a longitudinal study *for reasons that are not related to the impairing condition* then that participant would need to be withdrawn from the study as their continued participation would not satisfy the MCA criteria.

The panel agreed that the current HRA guidance was compatible with existing legislation.

However, it was felt that the HRA's existing 'Mental Capacity Act 2005: Questions and Answers' might be revised to provide further guidance on monitoring capacity in longitudinal studies. SW agreed to provide suitable text and vignettes for further discussion by the panel.

Action: SW

10. Review of Ethical Opinion

Received for Discussion:

- DRAFT revised SOPs regarding review of ethical opinion (Concerns/Challenges)
- Review of Ethical Opinion - Ros Levenson Comments

The panel discussed the comments provided by RL regarding the current procedures for the review of existing ethical opinions and agreed that, given that these procedures are likely to require change in the light of the forthcoming EU Clinical Trials Regulation, it would be premature for the panel to engage in formulating advice regarding changes to the current system.

The panel agreed that NREAP should be formally updated on, and invited to review, any proposed revisions to the SOPs regarding appeals or challenges to REC opinions, particularly those made to accommodate the requirements of the forthcoming EU clinical trials regulation.

The panel also considered the draft SOPs regarding review of ethical opinion (Concerns/Challenges).

RL noted that as currently written it would be possible for the Appointing Authority Lead, following consideration of the advice given by NREAP, to take a decision that contradicted or ignored that advice. She felt that it would be advisable to add an additional step whereby the final decision is taken by the HRA Board rather than the appointing authority lead so that the final decision regarding a challenge would be taken by a body with sufficient authority and accountability. In addition RL questioned whether the proposed procedures would be compliant with Article 6 (Right to a fair trial) of the Human Rights Act.

The panel recommended that the HRA seek professional legal advice on whether the existing appeals procedures and the proposed procedures for concerns and challenges were compatible with existing law.

11. NREAP Objectives/Workstreams for 2015/16

Received for Discussion:

- HRA Business Plan 2015/16

The panel were invited to discuss possible NREAP items to take forward this year (in line with the HRA business plan) and in agreement with the HRA.

Suggested items:

- Information Sheets

AG felt that this was an area in which the panel might make bold suggestions that go beyond simple tweaking of existing patient information sheet templates to examine how new media and technology might be incorporated into information provision and consent seeking procedures in a way that empowered and supported potential participants in reaching a truly informed decision regarding research participation. SW noted that whilst documents such as the Declaration of Helsinki included principles regarding the informed consent process the problem remains that these were too often mediated through the provision of a single paper document i.e. the PIS.

The panel agreed that this would be an interesting and fruitful area for the panel to examine but acknowledged that this would constitute a very large piece of work to undertake and that expertise beyond the panel would need to be included including academics and the public and that this is likely to require additional resources.

- Information needed for REC review

AG explained that this second item related to consideration of the amount and format of information that would need to be provided to a research ethics committee to enable them to undertake robust ethical review in a manner proportionate to the research in question. This work could, for example, include consideration of *class approval* for specific types of research methodology and *protocol only review*.

The panel agreed that this was also an area worth considering.

AG and CC would prepare short papers on both these areas for consideration by the panel at the next meeting.

Action: AG & CC

12. Protocol Guidance and Template for Use In a Clinical Trial of an Investigational Medicinal Product (CTIMP) – For Consultation

Received for Discussion:

- CTIMP Protocol Guidance and Template (for consultation in use (Active))
- Qualitative Protocol Guidance and Template (N.B. internal use only - not currently out for comment)

MB considered that these templates were presumably aimed at academics rather than industry given that the protocols put together by industry were generally extremely comprehensive.

AG commented that the documents need to be clear about what is prescriptive and what is merely a suggestion as it was currently unclear. PH agreed noting that the success or otherwise of these templates will be dependent upon how they are perceived and interpreted by researchers and RECs.

AG wondered whether the documents might usefully indicate where the information entered into the protocol template could also be be used to populate specific sections of the IRAS form (either manually or by linking the form into IRAS directly).

13. Guidance on Identifying Potential Applicants For Health Research – Mark Taylor/Amanda Hunn

Received for Discussion:

- Background Note: Guidance on Consent to Approach and other ways to identify Potential Research Participants

Mark Taylor (CAG Chair) and Amanda Hunn (Engagement and Policy Manager) attended the meeting to present the paper and seek the panel's comments.

Mark Taylor explained that revisions to the NHS Constitution in 2013 have committed the health service to recognise and promote the value of research, and the Health and Social Care Act 2012 placed obligations on NHS organisations to support this. The NHS Constitution commits the NHS to informing patients of research studies in which they may be eligible to participate.

in December 2013 the HRA launched a call for evidence to identify good practice in identifying potential participants in health research and seek examples of different models for making information about research available and for identifying potential participants to health research studies. It was anticipated that the request for information on current practice would inform the development of advice for researchers and provide good practice examples to inform future guidance. This guidance, currently being drafted by Mark and Amanda, will address concerns around the identification and recruitment of potential participants and spell out some of the ways in which approaches to patients can be both lawfully and ethically be made, building on the examples of good practice in identifying patients sent in response to the call for evidence.

SW asked whether the provision for the sharing of data for research purposes under the Data Protection Act might be relied upon to facilitate the identification of research participants. Mark Taylor replied that whilst it was true that such provision does exist within the Data Protection Act the act was not the only legal instrument to be considered as the common law duty of confidentiality was also in play and this meant that implied consent cannot be relied upon for research purposes as it only had traction in the context of treatment and provision of direct care.

The panel agreed that they would be very happy to review an early draft of the guidance when available. In addition, individual NREAs would also be happy to be involved in this work as necessary.

14. Nuffield Council on Bioethics: Children and Clinical Research: Ethical Issues

Received for Discussion:

- NCoB report: Children and Clinical Research: Ethical Issues*
- Involving children and young people in health research – getting it right (Magazine)*
- Animation*
- Report Summary*
- Recommendations for HRA and RECs*

The full report is available at: **http://nuffieldbioethics.org/project/children-research/**

The panel welcomed the report and commented that it was one of the best reports produced by the Nuffield Council on Bioethics.

The recommendations made in the report directed towards the HRA and RECs were noted and deemed to be reasonable. As these were directed at the HRA the panel did not address them directly but would be happy to provide further advice if asked to do so by the HRA.

15. NREAP/Chairs Network Meetings

The panel were invited to discuss whether the current arrangements/hosts needed to be revised.

The panel agreed that the current assignment of NREAs to regional chairs meetings was satisfactory.

16. NREAP and Devolved Administrations (DA)

Received for Information/Discussion:

The panel were invited to consider whether more could be done to:

- highlight DA's opportunity to access the panel (e.g. hosting chairs network meetings)
- highlight areas of value for the DAs in the current work of NREAP

The panel suggested that chairs from RECs in the devolved administrations could be invited to existing chairs network meetings taking place in England.

Consideration could be given to whether NREAs might attend similar regional chairs' meetings organised by the devolved administrations. However, it was unclear whether such meetings were currently taking place and also the number of REC Chairs involved.

DA's should also be made aware of the work the panel have already done e.g. current NREAP guidance, the provision of the panel's minutes on the HRA website and also future work under consideration and how the DA's and their RECs might be usefully involved.

17. MRC Ethics Series - Human Tissue and Biological Samples for Use in Research: Operational and Ethical Guidelines

Received for Information:

- The MRC Ethics Series Human Tissue and Biological Samples for Use in Research: Operational and Ethical Guidelines (November 2014)*

The MRC's '*Human Tissue and Biological Samples for Use in Research: Operational and Ethical Guidelines'* have been updated to reflect the MRC and cross-funder commitment to maximising the use of biosamples, and a shift in public attitudes towards this kind of research.

The guidance focuses on the ethical principles of using human samples in research and provides advice on how to achieve these principles in practice. The guidance is contained in the MRC blog article by Prof. James Ironside: Getting the best out of biological samples. (http://www.insight.mrc.ac.uk/2015/02/12/getting-the-best-out-of-biological-samples/)

18. Removal of NRES Branding

Received for Information:

"As you are aware, the HRA was established on 1 December 2011. DH branding procedures requires that an NHS organisation has a single brand and as a result of this we have been gradually moving from using the term NRES, for example we now refer to "HRA Standard Operating Procedures" and "HRA RECs".

We will now be making a positive effort to remove all reference to NRES in job titles, correspondence etc and replacing this with the terminology "Research Ethics Service".

I would like to take this opportunity to thank your for your continued commitment and support to the service.

Kind regards.

Joan Kirkbride, Director of Operations and Approval
Health Research Authority"

19. Assessing Professional and Public Opinion of the HRA

Received for Information:

- **Assessing Professional and Public Opinion of the HRA**

The Health Research Authority recently commissioned a survey that shows 97% of the public think health research is important and 74% of people think every patient should be offered the opportunity to participate in research. The findings were gathered from over 1000 members of the public.

The panel noted the content of the report and asked CC to enquire what the intention was behind the commissioning of this survey and whether it is likely to be repeated to monitor changes in public opinion.

The panel particularly noted the recommendation made in the report that:

"The HRA should also consider how it can improve the perceptions of lower SEG groups, minority ethnic members of the public, and younger people who may be less likely to participate"

and also asked for feedback on how the HRA intended to address this.

Action: CC

20. New Rules of Consent: The Patient Decides

Received for Information:

- **New Rules of Consent: The Patient Decides.** Fiona Godlee. BMJ 2015;350:h1534 (Published 19 March 2015)*
- **The Death of Sidaway: Values, Judgments and Informed Consent** Kirsty Keywood*

(The full judgment is available at http://www.bailii.org/uk/cases/UKSC/2015/11.html)

21. Any Other Business

The panel discussed with Martin Stevens (MS) how the provision of guidance might need to be adapted for a social care audience.

MS pointed out that whilst the ethical principles involved were similar in both health and social care research there was a need for the language used to be responsive to and accommodate the social care audience. It was noted that whilst there were large number of RECs involved in looking at health care research there was only one SCREC and thought would need to be given to the production of future guidance so as to ensure that SCREC were not excluded by the use of language not appropriate to their needs. It was suggested that a glossary could be added to future guidance as a way of ensuring that any language not familiar in the social care context was adequately explained.

It was further acknowledged that approaches and practices used within the social care context could also be usefully applied in the health care context, one example being the concept of "safeguarding" i.e. "protecting people's health, wellbeing and human rights, and enabling them to live free from harm, abuse and neglect".

22. Date of Next Meetings

Thursday, 30 July 2015
Tuesday, 13 October 2015
Thursday, 26 November 2015