National Research Ethics Service

NHS Health Research Authority

National Research Ethics Advisors' Panel

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

Date: 17 October 2012
Time: 14:00 – 17:00

Venue: 138B Skipton House
Health Research Authority
National Research Ethics Service (NRES)
Skipton House,
80 London Road,
London SE1 6LH

MINUTES

Present:
Andrew George (Chair)
Ros Levenson
Mark Sheehan
John Keen
Simon Woods

In attendance:

Hugh Davies (HRA Ethics Advisor)
Clive Collett (NREAP Manager)

1. Apologies: Peter Heasman; Søren Holm
2. Declarations of Interest

   There were none
3. Minutes of meeting held on 11 July 2012

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

4. Welcome and Introduction

Andrew George (AG) welcomed everyone to the first meeting of the newly reconstituted Panel.

4.1 NREAP Terms of Reference

AG led the panel through the revised terms of reference (ToR).

Mark Sheehan (MS) pointed out that the term "ethical training" should be replaced with "ethics training". It was agreed that this should be revised.

Ros Levenson (RL) asked whether the other NREAs would be informed if an NREA is asked to provide advice on an issue by NRES or the HRA. Would the advice and/or correspondence be circulated to the

panel? Given the fact that the NREAs would only be meeting four times a year RL felt that having this information would accelerate the NREAs learning and appreciation of each other's skills and how best to work with each other. AG explained that whether such information would be circulated or not would depend on the nature of the advice requested. On occasions, the whole panel are asked to consider providing a statement on a particular issue that would be simply minuted so that it could be referred to by NRES. On other occasions, individual NREAs are approached because of their specific experience and expertise in order to provide advice on a specific issue. In such cases, feedback has only occurred where this was seen to be useful because there were issues that came out of the situation requiring further discussion by the panel. Simon Woods (SW) agreed that having fewer meetings might necessitate more interaction by email.

AG wondered whether it would be worth logging any instances of where an NREA has been asked to provide advice or assistance outside of the formal meetings. It was agreed that this would be helpful and that Clive Collett (CC) should maintain this log.

It was noted that the current ToR included "Oversight of personal development programmes for REC chairs". Hugh Davies (HD) explained that Peter Heasman (PH) and former NREA Frank Wells had piloted this work in the past but it was not currently a live initiative. The panel felt that this was not an area that should be part of the remit of the NREAs and should be removed from the ToR.

MS commented on para 7.5 in the ToR:

> "7.5 Where the panel consider that the issue is adequately covered by existing guidance then consideration should be given to drawing the attention of RECs to this guidance by issuing an NREAP statement or other communication. Such NREAP communications should be placed on the next available agenda of all RECs for discussion."

He stated that where a large amount of guidance already exists it would be helpful if the panel analyse this to point out where there are similarities and where there are differences. SW noted that RECs generally want guidance that is practical and can be easily used to reach an opinion. John Keen (JK) agreed and felt that any guidance, or referral to guidance, issued by the panel should contain a brief three-line summary. Then members could follow any links to the guidance if they wanted to but still had an executive summary of the main points to follow. HD pointed out that in general when guidance had been produced it contained sections on background to the issue(s), links to available guidance and a table of considerations and questions a REC may wish to ask of the researchers.

MS asked HD what the difference was between his role as HRA Ethics Advisor and the role of the panel. HD explained that, in terms of provision of guidance, it was better that guidance on ethical matters came from a group rather than an individual as this helps to avoid the perception that "RECs are being told what to think". JK noted that this was possibly true but there was always a place for definitive and authoritative guidance, particularly in the case of the law or adherence to GAfREC, SOPs etc. HD agreed, but noted that such guidance was not fundamentally ethical in nature. SW felt that there could be instances when RECs might legitimately be told "how to think" on occasions in order to promote justifiable consistency. He noted that whilst there may be a valid range of views on some issues there are other issues where the latitude of opinion that should be tolerated would be quite narrow. RL felt that there was a distinction to be made between 'process' and 'outcome' i.e. all RECs should follow the same process laid down in GAfREC, SOPs and applicable law but the outcome of that process may result in different opinions.

RL commented on para 7.13 saying that she felt that in most case the consultation period should be two months and not shorter.

> "7.13 The consultation period should normally not be longer than two months, however a longer consultation period might be decided upon at the meeting where this is considered to be appropriate."

Agreed:

- Revision of the NREAP Terms of Reference:
  - The term “ethical training” should be replaced with “ethics training”.
  - Removal of “Oversight of personal development programmes for REC chairs” from the ToR
- CC to maintain log of NREA work outside of the formal meetings.
- Addition of agenda item to inform NREAs of NRES/HRA work that individual NREAs have been involved with between meetings.

Action: CC

5. MATTERS ARISING

5.1 ABPI/DH/BIA/CCRA/NRES Compensation in the event of injury in phase I Clinical Trials

Following the NREAP meeting on the 11th July, the panel's comments regarding the "ABPI/DH/BIA/CCRA/NRES Compensation in the event of injury in phase I Clinical Trials" document and its associated REC guidance (see: http://www.nres.nhs.uk/applications/guidance/phase-1-trials-guidance/?entryid62=143941) were sent to David Neal (NRES Policy Manager) for his comments.

The panel noted David Neal’s comments on the questions raised by the NREAs. CC was asked to ensure that the actions highlighted by David were taken forward.

Action: CC

6. NREAP/Chairs Network Meetings - NREA Chairs

Received for Information:

- NREAP/Chairs Network Meetings – Protocol v1.1

The NREA panel holds regional meetings with REC Chairs/Vice Chairs in each NRES region every 6 months. The Panel were asked to discuss which NREAs would Chair the regional network meetings

The following suggestions were made:

NREAP/Chairs Network Meetings:

Region	Location	Current NREA Meeting Chair	Next Meeting date
London & South East Coast	London	Andrew George	25/04/2013
North East & Yorkshire & Humber	York	Peter Heasman	TBA (April 2013)
East Midlands	Nottingham	Ros Levenson	19/04/2013
West Midlands	Birmingham	Hugh Davies	15/11/2012

North West	Manchester	Simon Woods	19/11/2012
South Central	Reading	Mark Sheehan	29/11/2012
South West	Bristol	TBA	30/11/2012
East of England	Cambridge	TBA	04/12/2012

7. Priorities/Strategies for NREAP

Received for Discussion:

- NREAP Priorities/Strategic Themes – Discussion Document

Information Sheets and the Consent Process

Participant Information sheets (PIS) are just one part of the process for ensuring that potential research participants are adequately informed about a research study prior to their taking part. However, whilst the PIS is often the only tangible element amendable to REC review it could be said to play a relatively minor role in the consent process. Might the panel usefully examine the whole of the information giving and consent process with a view to making suggestions for how this might be improved (within the limitations of the REC review process)?

SW commented that there should be greater insistence on researchers showing how they have engaged with the relevant patient population to design and validate their information sheets. In many cases, clinicians carrying out research have not engaged with their patients, whom in many cases they would know well, in order to assist in the design of the study or the information to be given to potential participants. He commented that at a recent REC meeting the investigators attended with a patient who had been involved in the production of the information sheet and this provided authority and a persuasive argument for approval of their information sheet as presented. RECs are not necessarily the arbiter of what is the best format for the provision of information; this is an issue that can be tested in the 'real world'.

He also commented that it might be important to distract RECs from a pre-conceived idea of what an information sheet should look like i.e. to move them away from an "English teacher" approach to one where they focus on the ethical challenges of presenting the required information in order to gain meaningful consent. He noted that in the case of research involving children the question of whether children were able to understand the information being presented in the information sheet was essentially an empirical question and open to testing. MS noted that a recent paper regarding a piece of mental health research which had involved patients in the design of the information sheet indicated that, despite this good example of PPI, the REC reviewing the study asked them to change the term "periods of distress" to "psychotic episodes" despite being presented with evidence that this term was actually preferred by the patients concerned.

RL noted that information sheets cover various purposes: provision of information; a way of showing that researchers have provided participants with the legally required information etc. She expressed the opinion that if NRES were able to command the necessary resources and be outward looking on this issue then it would be hugely beneficial. HD said that NRES were in fact currently doing this, involving a reference group of stakeholders including the James Lind Alliance[1], as part of their

[1] http://www.lindalliance.org/

revision of the information sheet guidance and template. HD offered to present a draft of this guidance at the next meeting. It was agreed this would be useful.

MS alerted the panel to a paper recently submitted to the Journal of Medical Ethics for publication regarding the role of lay members on RECs. The paper makes the claim that if (arguably) the main role of a lay member is to review the information sheet then patently lay members are not very good at doing this given the poor quality of information sheets that are routinely approved for use. The authors argue that the people who should be reviewing such information are the relevant patients.

AG noted that there was agreement that the content of information sheets was something that the panel wished to be involved with but he asked whether there was more radical work that could be taken forward in this area regarding the whole consent process? RL wondered if anyone had conducted a literature review in this area. HD indicated that he did have such a review available and would send it to CC for circulation to the panel.

RL noted that the process of consent involves the "what" (information sheets etc.) and the "how" (the consent taking process itself and that these both involved a range of ethical and legal issues regarding what it means to obtain informed consent. RECs may want to be assured of the "how" part of this process but it is hidden from the REC's view.

AG noted that there was general agreement that there were issues to be explored around information sheets and the consent process more generally. However, there needed to be a product at the end of this process that would be useful to RECs. He felt that the panel needed to be clear about what they can feasibly do. He suggested that the panel might be able to provide advice around the need to gather and provide evidence to RECs supporting the information sheet produced in collaboration with the relevant participant group.

Dissemination of NREAP Deliberations – 1) Communications 2) Information Resources

The panel need to be able to effectively communicate and disseminate the outcome of their discussions and formal guidance. Presently the minutes of all meetings are placed on the NREAP page of the NRES website along with formal guidance produced by the panel. However, this does not guarantee that REC members are aware of them or can easily find where the panel has discussed a particular issue.

It was felt that there should be a distinctive "brand" that differentiated the ethical advice and guidance that it disseminated from the operations and other information put out by NRES and the HRA.

It was noted that this issue was ongoing and would continue to evolve as both the panel and the HRA go forward and develop a specific comms strategy.

Risk

HD suggested the issue of "risk" as an item the panel might take forward. Specifically, how can risk be quantified and explained. In addition, he felt that we don't really know what the "risk" of conducting research is.

HD agreed to send the information sheet annexes on the 'consequences of research' to CC for circulation.

Access to Confidential Information and Patient Data

SW suggested access to confidential information and patient data as he felt there was a gap between the data protection act and the common law as it relates to accessing patient information.

There was a need to bring the statutory law and common law together in a way that was useful for RECs.

In addition SW noted that there were issues around what is known as 'big data' e.g. the linking of large datasets and issues surrounding the interconnectedness of data relating to individuals. However he noted that the Nuffield Council on Bioethics had recently announced that it has agreed to establish a new work theme to examine the ethical issues raised by sharing and linking health and biological data under the chairmanship of Professor Martin Richards, Emeritus Professor of Family Research at the Centre for Family Research, University of Cambridge.http://www.nuffieldbioethics.org/news/call-expressions-interest-new-biodata-project

Role of Lay Members on RECs/PPI

MS suggested that the panel might discuss the role of lay members on research ethics committees against the background of increasing PPI in research. If researchers begin to take the role of PPI in designing their research and information for participants more seriously then what exactly is the role of a lay member in reviewing research?

RL agreed it was an interesting area but felt that there was that lay members do play a very important part in the ethical review of research and that the role isn't just about reviewing information sheets. She felt that there was work to be done in defining what it is that potential participants would want to know about research before agreeing to take part. What would older participants like to know? Teenagers? What are the burning issues that different groups feel are important? HD commented that this was potentially a lot of work. He stated that there were several groups working in this area e.g. Jenny Newman (Consumer Liaison Officer for the Medicines for Children Research Network[2]) was carrying out work with children (see: http://www.efgcp.be/Downloads/confPresentations/PP-11-Jun-2009%20PDF%20Presentations/PP-11-Jun-2009-1215_J-Newman.pdf) and also the James Lind initiative was active in this area of engagement with patients. SW agreed that there were several organisations working in this area such as Involve[3] and explained that he is also working with patient groups to in order to help design research studies e.g. to determine appropriate control group sizes.

Agreed:

- HD would present a draft of the revised NRES information sheet guidance at the next meeting for discussion.
- HD to send literature review to CC for circulation to the panel.
- HD to send the information sheet annexes on the 'consequences of research' to CC for circulation.

- CC to draft a discussion document around the various issues raised in collaboration with appropriate NREAs. This should pose specific questions that the panel can discuss and take forward.

Action: HD; CC

8. **"Can, and should, Research Ethics Committees' ethical opinions be more consistent. If so, how might this be achieved?"**

Discussed:

[2] http://www.mcrn.org.uk/children/design/cisg
[3] http://www.invo.org.uk/

At the recent NREA interviews all candidates were asked to prepare a presentation on the question *"Can, and should, Research Ethics Committees' ethical opinions be more consistent. If so, how might this be achieved?".* The presentations produced some interesting ideas and the NREAs were invited to summarise their ideas for discussion by the panel with a view to taking them forward.

SW noted that whether or not there is 'consistency' in ethics committees' opinions is essentially an empirical question. Consistency can cover both 'intra-committee' consistency and 'inter-committee' consistency. He felt that there were issues surrounding what is the threshold for a REC to give a provisional or unfavourable opinion instead of favourable opinion. RECs might agree on the fundamental ethical issues present in the research but may weigh them differently to reach contrary opinions. He felt it was important to investigate exactly what was happening to push RECs toward one decision or another.

JK noted that in his experience RECs might give a provisional or an unfavourable opinion depending upon whether they were able to supply specific, positive suggestions for how the researchers might deal with the ethical objections raised by the REC. For example, where the committee felt that the use of a placebo arm, where proven therapy exists which would otherwise be available to participants, was unethical, they could give either an outright unfavourable opinion or a provisional/favourable opinion with conditions stipulating that the placebo arm be removed. Thus, he felt it would be useful to produce guidance on what type of opinion should be given in such cases.

SW said that he felt it was important to define exactly what we mean by "consistency" or "inconsistency". He commented that one view might be that consistency should necessarily result in more favourable opinions being given. However, his view was that it was about RECs approving studies that are consistent with applicable law and regulations and ensuring that they raise substantive ethical issues backed by sound reasoning.

RL wondered whether consistency might be a product of the work done before the application comes before the REC. In addition, consistency of opinions might be influenced by who chairs the meeting and who presents the application to the REC members. All of these would influence the committee's eventual opinion. Thus, different stages in the application process could all lead to inconsistency.

MS felt that consistency could be broken down into consistency of "process" and consistency of "content". He stated that there was no reason for inconsistency in "process" which only left the possibility of variation in "content". How much variation in opinions is to be tolerated is the main question to be addressed. Clearly, there needs to be some flexibility but there are limits that might need to be placed on that flexibility. Such limits might be amenable to empirical research regarding the public's view on how certain values might be ranked. There needs to be some way of keying in content variation and the method for calibrating the limits on that variation in the right kind of way.

AG summarised the discussion by stating that it was clear that the word "consistency" is often used without really thinking about what this means. We need to discuss exactly what we mean by "consistency" when applied to REC opinions and what limits might legitimately be placed on variation of opinions.

Agreed: the panel would address the issue of 'consistency and justifiable variation of REC opinions at the next meeting. CC was asked to produce a paper on this issue in collaboration with MS and SW

Action: CC

9. **Shared Ethical Debate (ShED) – Analysis and Feedback**

Discussed: NREAs were asked to consider how best to analyse the collated minutes of ShEDs in order to provide useful feedback to individual RECs on their review.

For Information:
Current ShED (Not yet analysed):

- ShED Exercise 10: Mental Capacity Act Study - Collated Minutes

ShED Exercise 10: Mental Capacity Act Study

Brief Summary of the study.

This is a preliminary study to investigate how effective the Hemolung System is at removing carbon dioxide and if it is possible to reduce the need for artificial ventilation. The researchers hypothesise that by partially supporting gas exchange with the Hemolung System, patients will be less dependent on noninvasive ventilation and potentially avoid invasive mechanical ventilation. Avoidance of high pressure ventilation may minimise the risk of exacerbating lung damage with artificial ventilation.

A key ethical issue is that the study may recruit patients who lack capacity to provide consent by virtue of the fact they are sedated and ventilated on the intensive care unit for their respiratory failure.

Previous ShED and Reports:

- ShED 9: Sharptalk Report - Collated Minutes for Shared Ethical Debate Cycle 9 “Sharptalk, collaborative learning on the web”
- ShED 9: Shared Ethical Debate QA Audit Report
- ShED 9: Sharptalk PowerPoint Presentation

HD explained that he was currently in the process of analysing the results of ShED 10. He noted that this process has been made easier by the use of ethical domains in the committees’ minutes.

SW commented that it would be useful to differentiate between committees that had given opinions which were out of sync with other committees, but in a reasonable and acceptable manner, and those that had given opinions which were clearly incorrect (given that this application primarily concerned adherence to the provisions and safeguards contained in the Mental Capacity Act).

AG noted that, with regards the feedback of ShED results to committees, RECs would naturally wish to judge themselves against other RECs taking part. RL felt that the main value of these exercises for RECs was to be able to reflect on the process and analyse their own decisions. In addition, it might be interesting to analyse the consistency of decisions of individual RECs over time. Such analysis might identify "risk averse" RECs and facilitate useful feedback to such committees.

JK expressed opinion that, in feeding back the results of these exercises, that someone really needed to go out to the committee's and discuss the results face-to-face and facilitate reflection upon their own opinion in the light of the results.

MS accepted that given the number of committees involved and the difficulty in an individual visiting each one individually that the circulation of the PowerPoint summary of the results may be the best that can be done. He also noted that the reflection of RECs on their decisions in these exercises would suffer from time constraints involved in committee meetings. He noted that when he first heard about the ShED exercises he thought that it involved getting RECs together to discuss real applications. He felt that this coud facilitate consistency through discussion of where different RECs might have differing opinions. AG acknowledge this networking of committee members was useful and stated that he felt it was very helpful for members to occasionally attend other RECs’ meetings. MS agreed but pointed out that this was only limited to the individual member rather than the REC as a whole. MS also asked whether results of this exercise had been shared with the original researchers who had submitted the

application. HD said that he had and that the researchers recognise that in hindsight they had "over egged the pudding" in terms of what the research could deliver and that it was really more of a fishing expedition to test the feasibility of an Internet-based approach to delivering healthcare information. MS wondered whether it would be sensible and useful to present the results to the 'e-research' community including researchers and patient groups.

10. **NREAP/Chairs Network Meetings - Minutes**

Received for Information only:

- Minutes of the London NREAP/Chairs Network Meeting held on 03 April 2012

11. **Feedback from NREAP/Chairs Network Meetings:**

Discussed:

- **Payments and incentives (including statements regarding their effect on benefit payments)**

  Following the North East/York and the Humber Chairs Meeting, held on the 3rd October 2012, one Chair in the North East emailed asking for guidance on concerns regarding the issue of rewards/incentives and expenses paid to research participants:

  For Information:

  The "Phase I Payments and Incentives Sub Group" has prepared draft guidance on this issue, which, once finalised, will be brought to the panel for comment and incorporation into NREAP guidance.

The panel addressed the issue of whether the information sheet should contain a specific statement regarding the effect payments received for research participation would have on benefits. The panel felt that, whilst there is no objection to doing so, it was not necessary for RECs to insist upon the inclusion of a statement in the information sheet regarding the impact payments made for participation in research would have on individuals in receipt of state benefits (nor the tax implications of such payments). It is the responsibility of people in receipt of state benefits to ensure that they keep to the conditions of those benefits regarding what they can do and the amount they can be paid.

Postscript: Following concern that guidance produced by Involve (discussed at the meeting) was not directly applicable to *participation* in research CC has contacted Involve for further information on this matter before any formal statement is made by the panel that refers to this guidance. The Director of Involve has replied to explain that the guidance is specifically concerned with payment for active 'involvement' in research. She passed our query on to their payment expert who has advised:

"For people receiving welfare benefits, any money (or other forms of financial reward, such as gift vouchers) received for participation in the research may be treated by the JobCentre Plus as earnings. Therefore, if the amounts received are above the disregard level[4] for an individual's benefit regulations, their benefits could be affected by receiving these payments.

The guidance in Payment for Involvement[5] is written specifically with involvement type activities in mind, but many of the systems and approaches to reduce difficulties for people receiving benefits may be potentially transferable to participation in research. However, I am not familiar enough with payment for participation (for example, the amounts offered as incentives, the regularity of payments, the number of

[4] http://www.revenuebenefits.org.uk/tax-credits/guidance/how-do-tax-credits-work/understanding-the-disregard
[5] http://www.invo.org.uk/posttypepublication/payment-for-involvement/

people receiving benefits likely to be affected, and the systems set up to pay people), to be able to judge how much of a problem this would be in practice and how transferable the guidance would be. “

- **‘Big Data’ and issues of confidentiality and data protection (including genetic frequencies/whole-exome sequencing/incidental findings**)

  This item was suggested as an item requiring guidance by a Chair at the North East/York and the Humber Chairs Network Meeting.

  N.B. At the panel meeting in July, Nalin Thakker explained that he and Hugh Davies were currently developing guidelines on the issue of genomic analysis, which would be brought to the panel in due course.

  It should also be noted that the Nuffield Council on Bioethics has recently announced that it has agreed to establish a new work theme to examine the ethical issues raised by sharing and linking health and biological data under the chairmanship of Professor Martin Richards, Emeritus Professor of Family Research at the Centre for Family Research, University of Cambridge.http://www.nuffieldbioethics.org/news/call-expressions-interest-new-biodata-project

  “…*new uses of health and biological data relating to distinguishable individuals also holds potentially far-reaching implications for privacy, interpersonal relationships and the relations between individuals and society”.*

SW noted that it was not mandatory for patient databases involving genomic information linked to patient data to be reviewed by NHS RECs and he felt this to be an oversight which should have been addressed in the current version of GAfREC. AG agreed that this seemed to be anomalous given that conceptually there appeared to be little difference between genomic *data* linked to identifiable individuals being held in a database and the holding of *tissue* within a tissue bank from which genomic data could be extracted.

SW noted that there was some good guidance in this area but there was a need to join up the disparate parts e.g. the Data Protection Act, issues around anonymisation of data, who can access patient notes, ECC approval etc. It was agreed that SW and CC should develop the specific questions that the panel might address in this area.

- **Opt-in/Opt-out Recruitment Methods**

  The issue of “When it is acceptable to have an 'opt out' approach to recruitment to studies” was raised by a London REC Chair. It was suggested at the Chairs’ meeting that there was a need for guidance to be circulated on this issue. It was noted that the following guidance, identified prior to the meeting, was useful and might be circulated to all REC members as part of the next NREAP Newsletter:

- The Research Ethics Guidebook - Opt-in Opt-Out Sampling
- Cochrane Review (Extract): Strategies to improve recruitment to RCTs – 2011
- Impact of privacy legislation on the number and characteristics of people who are recruited for research: a randomised controlled trial. L Trevena, L Irwig, A Barrat, J Med Ethics 2006;32:473–477. doi: 10.1136/jme.2004.011320

- Recruiting patients to medical research: double blind randomised trial of “opt-in” versus “opt-out” strategies. Cornelia Junghans, Gene Feder, Harry Hemingway, Adam Timmis, Melvyn Jones, BMJ, doi:10.1136/bmj.38583.625613.AE (2005)

The panel all agreed that this was an interesting area where there were conflicting opinions and guidance available. It was noted that the following paper by Jenny Hewison & Andy Haines was an interesting article that might be usefully referred to: “Overcoming barriers to recruitment in health research” BMJ 2006; 333 doi: http://dx.doi.org/10.1136/bmj.333.7562.300 (Published 3 August 2006). In the paper the authors state that:

> “Ethics committees are now insisting that researchers can approach only people who respond positively to letters from their general practitioner or hospital clinician, informing them about an opportunity to take part in research—that is, people who have opted in. However, the ethical benefits of this approach are not proved and it can lead to low response rates, wasted resources, and research of limited validity.”

The issue should be developed and framed as a specific question (by CC with assistance from MS) to be put before the panel for further discussion.

Agreed:

- SW and CC should develop the specific questions that the panel might address around the area of ‘Big Data’/confidentiality and data protection (including genetic frequencies/whole-exome sequencing/incidental findings).

- ‘Opt-in/Opt-out Recruitment Methods’ to be developed into a discussion paper by CC and MS

12. **Developing a role for the Health Research Authority: Providing a unified approval process Promoting consistent and proportionate standards for compliance and inspection for health research - A report from a multi-agency project group (September 2012)**

Received for Information:

- Developing a role for the Health Research Authority: Providing a unified approval process Promoting consistent and proportionate standards for compliance and inspection for health research - A report from a multi-agency project group (September 2012)

Background:

The HRA was charged with developing a programme of work to shape effective national roles, within its remit to provide a unified approval process and to promote consistent, proportionate standards for compliance and inspection.

This project report describes the process by which the HRA business plan was updated to include a programme of new activities alongside the activities previously agreed for the National Research Ethics Service. The report describes a range of suggestions put forward through the project, reflecting the views of the stakeholders and collaborators who were consulted. These suggestions were then reviewed and prioritised, based on feasibility and impact, to inform the HRA business plan. The business plan can be found at http://www.hra.nhs.uk/hra/hra-publications/?entryid85=141658&p=2.

A multi-agency project team was established to shape the role the HRA will play nationally. Looking at health research conducted in the NHS, the team carried out a process review of the entire research project journey, from initial idea, development, funding, approval, conduct, compliance, inspection, publication and translation. The review analysed the existing systems for individual projects, but

extended to consider how the systems related to other projects involving the same researcher or sponsor.

It was immediately clear to the group that there were a number of solutions that were already under development or that had been identified but needed multi-agency support to be implemented. There were also a number of larger scale changes that the multi-agency group was able to define more clearly, and which the group acknowledged were now achievable with the coordination and support available through the Health Research Authority

13. **Nuffield Council on Bioethics Publications**

13.1 **Novel techniques for the prevention of mitochondrial DNA disorders: an ethical review**

Received for information only:

- Summary of report: Novel techniques for the prevention of mitochondrial DNA disorders: an ethical review (Published 12 June 2012)*

Full report available at:
http://www.nuffieldbioethics.org/sites/default/files/Novel_techniques_for_the_prevention_of_mitochondrial_DNA_disorders_compressed.pdf

13.2 **Nuffield Council on Bioethics – Annual Report**

Received for information only:

- Nuffield Council on Bioethics – Annual Report 2011*

http://nuffieldbioethics.org/sites/default/files/files/Nuffield%20Council%20on%20Bioethics%20Annual%20Report%202011.pdf

13.3 **Nuffield Council on Bioethics – Strategic Plan for 2012-2016**

Received for information only:

- Nuffield Council on Bioethics Strategic Plan 2012-2016*

http://www.nuffieldbioethics.org/strategy

14. **Any Other Business**

JK asked how the panel would deliver on its promise to engage more with RECs and REC members. AG explained that the panel regularly engages directly with REC chairs and vice chairs through the NREAP/Chairs network meetings but in addition, going forward, as issues are raised which are to be developed into guidance the panel would engage and consult with REC members on these issues directly.

JK suggested that in order to facilitate such engagement each NREA should develop formal links and the relationship with, say, 10 RECs each. The panel felt that this was impractical. MS noted that general engagement for engagement sake was not always useful and that the panel needed to focus their engagement around specific issues that require such engagement. JK was invited to consult the RECs that he currently chairs on how such engagement with the panel should proceed and how the perceived "divide" between "NRES HQ" and RECs that he felt existed might be addressed.

AG noted that there was a need to address the comms strategy for the panel as part of the overall comms strategy for the HRA and NRES.

RL felt that it might be useful, given the fact that the panel would only meet four times a year, for the

NREAs to have an "away day" or similar meeting without a set agenda in order to get to know each other better and develop a stronger working relationship. It was agreed that this might be useful initiative.

15. **Date of Next Meetings:**

09 January 2013

27 March 2013

10 July 2013

09 October 2013

16. **ACTIONS**

Owner	Item	Action
CC	NREAP Terms of Reference	Revision of the NREAP Terms of Reference: • The term "ethical training" should be replaced with "ethics training". • Removal of "Oversight of personal development programmes for REC chairs" from the ToR • CC to maintain log of NREA work outside of the formal meetings. • Addition of agenda item to inform NREAs of NRES/HRA work that individual NREAs have been involved with between meetings.
	ABPI/DH/BIA/CCRA/NRES Compensation in the event of injury in phase I Clinical Trials	The panel noted David Neal's comments on the questions raised by the NREAs. CC was asked to ensure that the actions highlighted by David were taken forward.
	Priorities/Strategies for NREAP	CC to draft a discussion document around the various issues raised in collaboration with appropriate NREAs. This should pose specific questions that the panel can discuss and take forward.
	"Can, and should, Research Ethics Committees' ethical opinions be more consistent. If so, how might this be achieved?"	The panel would address the issue of 'consistency and justifiable variation of REC opinions at the next meeting. CC was asked to produce a paper on this issue in collaboration with MS and SW
	Feedback from NREAP/Chairs Network Meetings	• SW and CC should develop the specific questions that the panel might address around the area of 'Big Data'/confidentiality and data protection (including genetic frequencies/whole-exome sequencing/incidental findings). • 'Opt-in/Opt-out Recruitment Methods' to be developed into a discussion paper by CC and MS

HD	Priorities/Strategies for NREAP	• HD to present a draft of the revised NRES information sheet guidance at the next meeting for discussion. • HD to send literature review to CC for circulation to the panel. • HD to send the information sheet annexes on the 'consequences of research' to CC for circulation. • Risk: HD to draft discussion document with CC on the issue of "risk". Specifically, how can risk be quantified and explained.
MS	"Can, and should, Research Ethics Committees' ethical opinions be more consistent. If so, how might this be achieved?"	The panel to address the issue of 'consistency and justifiable variation of REC opinions at the next meeting. CC to produce a paper on this issue in collaboration with MS and SW
	Role of Lay Members on RECs/PPI	MS to produce paper with CC on the role of lay members on research ethics committees against the background of increasing PPI in research.
	Feedback from NREAP/Chairs Network Meetings	'Opt-in/Opt-out Recruitment Methods' to be developed into a discussion paper by CC and MS
SW	"Can, and should, Research Ethics Committees' ethical opinions be more consistent. If so, how might this be achieved?"	The panel to address the issue of 'consistency and justifiable variation of REC opinions at the next meeting. CC to produce a paper on this issue in collaboration with MS and SW
	Feedback from NREAP/Chairs Network Meetings: 'Big Data'/confidentiality and data protection (including genetic frequencies/whole-exome sequencing/incidental findings) Access to Confidential Information and Patient Data	SW and CC to develop the specific questions that the panel might address around the area of 'Big Data'/confidentiality and data protection (including genetic frequencies/whole-exome sequencing/incidental findings) and Access to Confidential Information and Patient Data