Health Research Authority
National Research Ethics Service

National Research Ethics Advisors' Panel

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

Date: **09 January 2012**
Time: **14:00 – 17:00**

Venue: HRA 1, Skipton House
Health Research Authority
National Research Ethics Service (NRES)
Skipton House,
80 London Road,
London SE1 6LH

MINUTES

Present:
Andrew George (AG) (Chair)
Peter Heasman (PH)
Søren Holm (SH)
John Keen (JK)
Ros Levenson (RL)
Mark Sheehan (MS)
Simon Woods (SW)

In attendance:

Jonathan Montgomery (Chair, HRA)
Sue Bourne (Head of Partnerships & Guidance, HRA)
Hugh Davies (HRA Ethics Advisor)
Clive Collett (NREAP Manager)

1. Apologies: None
2. Declarations of Interest
3. Minutes of meeting held on 17 October 2012

Approved subject to minor revisions. Comments were received from Joan Kirkbride requesting minor revisions to the minutes. These were accepted and approved by the panel.

4. MATTER ARISING

4.1. NREAP Terms of Reference

Endorsed:

- Revised NREAP Terms of Reference

These were revised in response to comments made at the last NREAP meeting.

- The term “ethical training” has been replaced with “ethics training”.
- “Oversight of personal development programmes for REC chairs” has been removed

Agreed: The changes were endorsed by the panel

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

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

Following concern that guidance produced by Involve was not directly applicable to *participation* in research CC contacted Involve for further information on this matter.

A response was received form Involve:

- Response from Lucy Simons (Public Involvement Advisor, Involve)

The Panel noted that the Involve guidance “Payment for involvement”[1] was not intended to apply directly to participation in research. The term ‘involvement in research’, as used by Involve, means “*an active partnership between members of the public and researchers in the research process, rather than the participation of people as the ‘subjects’ of research*”[2]. It noted that Lucy Simons observed that much of the advice contained in this document might be potentially transferable to participation in research. SW also noted that the Involve guidance was useful and covered many of the issues surrounding payment encountered in research participation.

The panel did not wish to revise its previous statement made in response to this issue in the light of the email from Lucy Simons.

5. **NREA Activity Log**

For Information:

NREA	Activity	Date(s)
NREAP	Wellcome Trust / MRC - Health related findings consultation	10/12/2012
Søren Holm	Member of interview panel for MODREC Chair interviews	23/10/2012
John Keen	Participation in Chairs National Training Day	05/12/2012
Ros Levenson	Health Research Authority ‘S251’ Stakeholder Event - London	16/01/2013
Mark Sheehan	Presentation on behalf of Janet Wisely at DIA GCP Forum 2012. “New Clinical Trial Legislation and Changes in the Good Clinical Practice Framework on the Horizon”. Hilton London Docklands Riverside Hotel, London	14/11/2012

[1] Involve: Payment for involvement (http://www.invo.org.uk/resource-centre/publications-by-involve/?keywords=Freetext&after=&before=&cat%5B%5D=payments) 2010 (updated 2012)
[2] Involve: What you need to know about payment (http://www.invo.org.uk/wp-content/uploads/2011/06/INVOLVEpaymentdocument2011.pdf) March 2011

	Participation in Chairs National Training Day	05/12/2012
Simon Woods	1. Request from Joan Kirkbride for guidance on an issue related to data protection and confidentiality arising in a research application. 2. Request from Social Care REC on issues related to confidentiality and the deceased in research. 3. Request from Ann Tunley regarding best practice for recruitment of adults lacking capacity - related to a research application. 4. Steering committee member for pilot of Ethics Officer and PR documentation pilot. 4. Member of the project advisory group to a research project from the Cicely Saunders Institute at Kings College London. (The Mental capacity and processes of informed consent on end-of-life care: development of best practice guidance (MORECare Capacity) seeks to produce guidance on the inclusion of people who are terminally ill in research related to end of life care. It is envisaged that any recommendations from this project will be quickly adopted into NRES guidance through liaison via Simon and the NREAP.)	Various dates Nov 2012 – Jan 2013

6. Discussion with Prof. Jonathan Montgomery

The meeting was attended by Prof. Jonathan Montgomery (JM) (Chair of the HRA).

A useful discussion was had on a broad range of items including the working relationship between the HRA Board and the panel and the future role of the NREAs.

7. Information Sheet Guidance: Hugh Davies

HD provided a verbal update on the ongoing work to revise the existing information sheet guidance. He hoped to release the guidance in Spring 2013.

8. Consistency of REC Opinions – Mark Sheehan

Received for Discussion:

- 'Consistency' Discussion Paper – Mark Sheehan
- Opinion Rates for all RECs in the past year – John Keen

MS presented his paper on his initial thoughts regarding the consistency of ethical opinions. He posed the question "What does it mean for the decisions to be consistent?" and noted that there is a range of things that we might mean by consistency and it is important to be clear about what kind of consistency is at issue. We might for example simply mean by consistency that two RECs would give the same decision for the same research proposal. Alternatively, we might think that consistency requires that RECs give the same decision for at least roughly the same reason. In both cases, we might think it is important that these decisions are not 'one-off' and that consistency requires that two RECs would give the same

decision (or the same decision for roughly the same reason) in a series of cases (perhaps that differed in a range of relevant respects).

We might think that these two accounts, particularly over a series of cases, will need to be connected. It looks as though one of the best explanations for why two RECs might continually make the same decision is related to the kinds of reasoning process that they use in coming to a judgement. On this account, having a common or similar reasoning process would ground the resulting decision. This suggests that it is useful to consider more than simply the resulting decision when focussing on consistency.

He noted that a distinction might be drawn between two types of 'consistency': *procedural* and *content* consistency. When we require consistency of content in decisions, we require that the RECs do or would reach the same judgement about a particular research study, for broadly the same reasons. It does not make much practical sense to require consistency of content without also requiring procedural consistency since, by design, having a consistent procedure is partly designed to reduce certain kinds of potential causes of variation. For this reason, requiring procedural consistency is prior to any requirement of content consistency.

Why is it ethically important for RECs to be procedurally consistent? MS felt that this question could be primarily answered through an appeal to justice or fairness, where such an appeal involves claims about the equal or unequal treatment of those involved in the process. That is, the basic claim against a system in which REC decisions are inconsistent is that it is unfair: one researcher's work is permitted and another's is not when they are both working on a presumptively similar project. For purportedly ethically equal projects, one is being treated unequally in comparison with the other. One important way of treating people equally is by giving them a chance to a fair hearing or a decision procedure that enables the full and equal consideration of the range of reasons that each stakeholder might see as relevant. This approach takes justice to rest on the idea of a fair process.

MS argued for the position that, in general, there should *not* be an expectation of consistency in terms of content. Individuals, and so individual committees, will value (weigh or judge) different ethical elements differently and can do so reasonably. The direct consequence of this is that two committees (that are procedurally consistent) may legitimately come to a different decision about the same research proposal.

However, this overarching claim is heavily qualified by the recognition that there are limits to the range of valuings that are acceptable. These limits (and so the values of RECs) should be *calibrated* against relevant, reflective research and clinical practice. We would not countenance all possible combinations of weightings of research ethics considerations: someone who rated a high risk of substantial harm as a relatively minor consideration in the face of largely speculative research might be an example that is unacceptable. The consequence of these limits is that there needs to be some way of ensuring that while the decisions that REC make can vary (so long as they are procedurally consistent) *they do so within limits*.

Why should REC weightings be calibrated within limits of variation? The danger, without appropriate calibration, is that RECs (and the ethics review system) become isolated and removed from the practical context in which research is conducted, medicine is practiced and patients are successfully or unsuccessfully treated, and about which they must judge.

MS suggested a number of areas for practical development that follow from his argument:

- The first involves the articulation of the ethical categories that are to be explicitly considered in making decisions about specific research proposals. One possibility would be to develop a research ethics equivalent of the resource allocation 'Ethical

Framework' (see for example: http://www.oxfordshirepct.nhs.uk/professional-resources/priority-setting/documents/south-central-ethical-framework.pdf).

- The second and third areas for practical development both involve the suggestion that the values of RECs might be calibrated with the appropriate clinical and research contexts. This calibration would require broader engagement with researchers about their research but more particularly with the values, standards and practicalities of current clinical and research practice in specific parts of medicine. This might include (i) extended discussions about broad programmes of research and the ethical issues that might arise in particular contexts between groups of researchers and committee members and (ii) co-development of a research proposal between members of a committee and the researchers.

- The final area for practical development would be to incorporate the broader public into the discussion about standards. The publication of the decisions made by RECs alongside the rationale for those decisions[3] could function to promote understanding of research as well as helping to ensure accountability and potentially providing another source of calibration.

Discussion:

SW welcomed Mark's discussion paper and felt that the concept of 'calibration' was an interesting one and agreed that it was important to understand the context in setting within which research takes place and the values that were accepted within that context. However, he asked how the normal standard would be established against which REC opinions could be calibrated? JM noted that it would be important to look at *who* carries out this calibration. Historically, it might be said that ethics committees have protected some groups more than others without consulting them over whether they wished to be protected in that way. Such groups could be consulted over acceptable levels of risk. Such public consultation could inform what a REC's working assumptions should be.

It was asked whether it would be possible to make a judgement on whether RECs are in fact consistent or not. How do you judge? We do not currently have robust evidence regarding the consistency or quality of reasons put forward by REC for their opinions. Indeed, Mary Dixon-Woods has carried out work on REC opinions as detailed in opinion letters and has noted that such letters often do not explicitly state the reasons for their decisions:

> "Threats to legitimacy (in the sociological sense) are reinforced by the lack of formal ethical reasoning in the letters; there are few examples of ethical arguments being rehearsed. When issues such as informed consent are raised, it is usually as a procedural norm embedded in institutional logic rather than as a (contestable) ethical principle. A good example of this is the reference by an REC to a requirement for informed consent to data processing under the *Data Protection Act*, where there is no acknowledgement in the REC letter that the interpretation and indeed ethical justification of this requirement are widely contested (Manson and O'Neill 2007). Thus, by promoting judgements as 'facts', and asserting their (administratively conferred) privilege to make rulings based on these judgements, RECs may risk appearing as though they are indulging in an illegitimate exercise of power."[4]

[3] N.B. this work is currently being undertaken by NRES as part of the research summary and summary of opinion projects

[4] O'Reilly, M., Dixon-Woods, M., Angell, E., Ashcroft, R. and Bryman, A. (2009), Doing accountability: a discourse analysis of research ethics committee letters. Sociology of Health & Illness, 31: 246–261. doi: 10.1111/j.1467-9566.2008.01132.x http://onlinelibrary.wiley.com/doi/10.1111/j.1467-9566.2008.01132.x/full

RL noted that Mark's appeal to justice and fairness as part of his justification for consistency in ethical decision-making should also include reference to research participants i.e. participants would also have a legitimate interest in research being treated equally and fairly with regards the review process. MS agreed.

RL asked how it would be possible to establish a calibration method that wasn't simply mechanistic and a "tick box" exercise and she suggested that it was important to do so. She also felt that there was a danger that lay members could sometimes become removed from the values and views of the wider public as a result of training and long exposure to the views of professional colleagues[5], and while training was essential, it was important to ensure that lay opinion was valued for its distinctive contribution. MS stated that training lay members does not necessarily make them less "lay. Encouraging lay members not to have a "yuck factor" response to certain types research (for example on children), where such research is deemed to be broadly acceptable, is a good thing stating that lay members should bring a "perspective" not a "response".

SH stated that it was important to distinguish between consistency over the short-term and historical consistency. Researchers and patients may have a stronger claim for consistency tomorrow than consistency between decisions that were widely separated in time. In the case of emergency research, he stated that we have seen the pendulum swing back and forth with regards to consent, perhaps, being overvalued in the past and possibly underrated in the future.

It was noted occasionally, for some types or classes of research where a broad consensus on its acceptability has been reached and where researchers might legitimately expect a favourable opinion, a REC can occasionally raise issues that result in an unfavourable opinion being given. In such cases, where the prevailing view is that such research is acceptable then RECs should adhere to this agreed view. MS agreed and said that this fits with the concept that there can be general values that are agreed. He noted that, in the Oxford University system, research that is based on standard protocols where the issues have been already discussed and the levels of risk deemed to be well-defined and minimal would be subjected to proportionate review (for example by subcommittee). In this scenario the main question to be answered is does the research fit the standard protocol[6].

PH welcomed the paper and commented that the main benefit would be that it would make everyone think about what the term 'consistency' actually means. In his view, the fundamental requirement of consistency was "reliability". We do not know to what extent any particular ethics committee is reliable particularly given that the REC members who meet in any particular month are not the same individuals who meet the following month and yet the decisions made are all attributed to the same "research ethics committee". PH felt that whilst the shared ethical debate (ShED) process was informative it did not necessarily provide insight into how the committee weighs the values in question. He noted that some years ago he was involved in a project that involved individuals sitting in on ethics committee meetings and looking at their weighted judgements to see if there was some consistency. This work did in fact find that there was a high level of consistency involved. He also noted that the limited range of final decisions available to committee (i.e. unfavourable opinion, provisional

[5] See: 'PPI, paradoxes and Plato: who's sailing the ship?' J Med Ethics doi:10.1136/medethics-2011-100150 http://jme.bmj.com/content/early/2012/01/20/medethics-2011-100150.short and response: 'There is no paradox with PPI in research'. J Med Ethics doi:10.1136/medethics-2012-100512 http://jme.bmj.com/content/early/2013/01/02/medethics-2012-100512.extract

[6] N.B. The Ministry of Defence REC (MODREC) employs a similar system of Standard Approved Procedures (SAPs) (see http://www.science.mod.uk/engagement/documents/modrec_saps.pdf). If the proposed research procedures fall within the (SAPs) then ethical approval can be given on behalf of MODREC by its chairman or vice-chairman following scrutiny by the appropriate scientific advisory committee.

opinion, favourable opinion, favourable opinion with conditions) does not reflect the complexity of the discussion which has arrived at that judgement and does not make it easy to dissect the weighting and value judgements being made.

JM noted that there are analogies to be drawn with legal thinking. Judges need to grapple with the application of the law even if they don't think the law is right. When can a REC legitimately say they don't agree with the existing accepted values? There may be times where what was deemed acceptable in the past might be called into question in the present and there would be a question of how we find mechanisms to get broader discussions on these issues to inform ethical decision-making. He noted that NREAP might be involved in such discussions. JM also drew a parallel with judicial review i.e. in reviewing any REC decision it would be important to assess whether that REC had taken into account all relevant considerations and whether their opinion was within the bounds of *reasonable* disagreement.

HD noted that currently a set of ethical "domains" are used by many committees and are used for the ShED process. He noted that it would be useful if the panel could reach agreement around these domains and endorse their use. SW noted that currently there is additional guidance for RECs regarding the formulation of minutes in relation to duties of RECs under the Mental Capacity Act. Thus, he wondered if it would be possible to apply this model to the use of ethical domains for other types of ethical review. HD agreed but noted that currently the domains do not lead to RECs giving explicit "reasons" for their decisions only that they have considered a particular area. SH noted that it might be considered a "bizarre" account of what it is to be independent if ethical review is expected to be based upon specific domains. MS wondered whether the term "ethical framework" for these domains would be more useful. HD did not think so as the term "domain" was understood by RECs and to change the terminology might be potentially confusing

- The panel also considered and discussed the summary paper ‘Opinion Rates for all RECs in the past year’ compiled by JK.

JK noted that it could not be right that in the same regional area one committee had a 25% unfavourable opinion rate whilst another had a rate of 2.8%. He felt that many RECs did not see themselves as providing a service. He noted that within the NHS if a GP appeared to be a significant outlier in their behaviour then they would be subject to review. He felt that NRES should visit such ‘outliers’ in a process of what he termed "non-threatening direct contact” to ascertain the reasons for their opinions seemingly being at odds with other RECs. HD pointed out that this does happen with members of the operations team visiting such RECs. JK acknowledged this but felt that such visits was somewhat limited and that committees might benefit from a greater level of engagement.

HD asked whether the panel would support the use of this paper setting out the opinion rates as a shared ethical debate exercises. The panel agreed that they would be happy to endorse this. PH felt that it would be enlightening to discuss with RECs the reasons for their opinion rates in a workshop situation but agreed that initially the use of the shared ethical debate process would be most useful. MS agreed that the use of the paper as the basis for a shared ethical debate would be helpful but that it would be more useful if it involved a number of specific questions with some qualifying text that would help RECs reflect upon the ways they tend to reach their judgements.

Agreed:

- The panel agreed that the document produced by MS was extremely useful and the panel broadly agreed with the arguments made within it. MS would revise the document taking into account the comments made by the panel. The revised version would be considered at the next meeting.
- The current domains used by NRES should be circulated for information.
- The panel supported the use of the paper 'Opinion Rates for all RECs in the past year' to form the basis of a shared ethical debate with appropriate questions and supporting text.

Actions:

- **MS to revise the discussion paper on consistency**

- **CC to circulate NRES ethical domains.**

9. How to manage staged funding and applications for approval

Discussed:

The Panel were invited to discuss the following issue

1. How to manage staged funding and applications for approval e.g. when a pilot study does not need REC approval but a later stage does. How best to plan and manage such studies
2. How should studies that are partly within the remit of NRES (e.g. a study involving both NHS staff and patients) be managed. Studies ONLY involving NHS staff do not require NHS REC review. Should NRES accept the full application incorporating both aspects of the research? If so, should RECs review all aspects of the study or restrict their comments and opinion to the patient-related aspects?

It was noted that operational advice on the issue of studies involving both NHS staff and patients had been issued in OMEA 56:

> **"Mixed staff/patient research**
>
> A further question submitted to the Queries Line related to research projects involving NHS staff. Proposed projects involving only staff are excluded from NHS REC review by GAfREC 2.3.13. However, RECs may need to review projects which involve NHS patients and staff. Best practice would be for the REC to receive a complete protocol and an application form which covers both elements and which it can then review – it can be very difficult to review half a story. The formal opinion expressed by the REC should relate only to the patient participants. The REC may make comments or recommendations in respect of the staff involvement but these do not form part of the formal opinion."

PH had always taken the view that projects involving both NHS staff and patients should be presented as a whole study and that the REC could not give a different view on different parts of the study but instead gave an opinion of the whole research.

SH noted that any such policy with regards opinion letters would need to be clearly communicated to the outside world. He explained that a University REC would not expect to review research if it had already undergone NHS REC review. He wondered if this might be communicated through AREC.

SW noted that even if there is no requirement for an NHS REC to review a study it could still undertake an ethical review.

MS felt that this needed to be looked at in terms of "trigger" criteria. In research involving both NHS staff and NHS patients the involvement of NHS patients *triggered* the review of the study and that review should focus on the study in its entirety and provide an opinion on it as a whole. SH agreed stating that much research involving staff and patients would be impossible and illogical to dissect e.g. where researchers wished to interview both patients and the doctors treating them.

With regards staged funding the panel felt that it was important for the researchers to put their project in context of the programme of development, but make it clear what aspects REC opinion was being asked for. If approval was being asked for several stages in a research project then the researchers would need to make that clear, including the criteria for proceeding.

Action: AG, CC and HD would pass on the comments of the panel to the operations team to discuss whether the existing advice needed to be altered.

10. **Public Engagement - Topics for discussion by NREAP – Amanda Hunn**

Received for Discussion:

- Public Engagement - Topics for discussion by NREAP

Amanda Hunn (AH), Engagement Project Lead, attended the meeting to seek the Panel's feedback on the HRA's proposed patient and public involvement (PPI) work.

PH explained that the HRA have secured funding from Sciencewise[7] to undertake engagement work involving both an externally commissioned survey of the general public plus a number of workshops with stakeholders around the UK. The national survey would look at levels of awareness of the work of the HRA as well as systems and levels of perception of protection.

AG wondered whether these workshops might possibly test public acceptability of information sheets with concise, stripped down information. In addition he felt it would be interesting to explore the acceptability of class approvals of research and whether the public would feel that they were adequately protected by them. RL agreed that this would be interesting but felt that such issues were better explored in a discursive setting.

MS wondered whether it would be possible to explore the public's understanding of the distinction between research and treatment as more evidence on this would be useful.

SB felt it would be interesting to link the results to the time at which they were taken e.g. in the light of advertising by groups such as CRUK which would raise awareness of health research. Also the results needed to be judged in the context of any negative press regarding health research such as the TGN1412 phase 1 study.

RL thought it would be interesting to explore what would make people participate or decline to participate in research.

Both RL and MS offered to meet with AH to assist in this work. CC would provide AH with their contact details.

[7] http://www.sciencewise-erc.org.uk/cms/

11. Enquiries sent to the Panel

11.1. Should a clinician in charge of patient care who is also involved in the research take consent?

Received for Discussion:

- Email correspondence regarding whether a clinician in charge of patient care, who is also an investigator, can take consent?.

The Panel made the following statement regarding general principles:

- The panel do not consider it to be inappropriate for an investigator who is also the HCP responsible for the patient's clinical care to take consent for research.
- Anyone taking consent must have full knowledge of the study in question in order that they are able to answer any questions the potential participant may have.
- Any individual taking consent must have undergone appropriate training.

- The panel support research into the issues around the taking of consent where the investigator is also the treating physician

11.2. Research in Rare/Orphan Diseases

Received for Discussion:

- Email correspondence regarding whether such research involves special ethical considerations.

The Panel made the following statement:

- Researchers should not place blanket restrictions on patients' freedom of action without justifiable reasons for doing so agreed with the REC.
- RECs should look closely at any project that stipulates that participants should not take part in any other studies to assure themselves that any such restriction was necessary, primarily for participants' safety. This applies especially to studies involving long-term follow-up of participants.
- RECs should reassure themselves that data from the study will be publically available or available through professional and public bodies that are involved in the care of the patient group

12. Community-based participatory research: A guide to ethical principles and practice

Received for Information:

The panel contributed recently to a consultation on ethical guidelines for 'community-based participatory research', which has now been published:

- Community-based participatory research: A guide to ethical principles and practice

- Ethics in community-based participatory research: case studies, case examples and commentaries

The authors have also organised a conference on this issue:

'Tackling ethical challenges in community-based participatory research'

Thursday 28th February 2013, 10.30-16.00 - Holgate Conference Centre, Grey College, Durham University, South Road, DH1 3LG

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

Received for Information:

- Minutes of the London NREAP/Chairs Network Meeting held on 24 September 2012 (NREA Chair: AG)
- Minutes of the North West NREAP/Chairs Network Meeting held on 19 November 2012 (NREA Chair: SW for PH)
- Minutes of the East of England NREAP/Chairs Network Meeting held on 04 December 2012 (NREA Chair: JK)

14. **Any Other Business**

14.1 HRA Meeting - Health Research Authority - Year 1 Stakeholder Forum

NREAs were invited to attend the 'Health Research Authority - Year 1 Stakeholder Forum' to be held on 6 and 7 February 2013 in central London.

The aims of the meeting are:

- To understand the HRA ambition to make it easier to do good quality research in the NHS
- To hear about work the HRA has delivered in its first year
- To learn about the set of projects within the remit of the HRA Collaboration and Development Steering Group
- To be involved as the HRA takes this ambitious programme of work forward

14.2 HMRC visit to HRA

For information: CC informed the panel that the HRA had decided, following a visit by the HMRC triggered by its establishment as a Special Health Authority on the 1st December 2011, to end 'off-payroll' payments e.g. for chairs' honoraria as it had been identified that there was a risk that these payments were not then subsequently declared by the recipient as taxable earnings. In future all such payments would need to be made through either the recipient's own employer's payroll or through the HRA payroll. As a consequence of receiving payments through the HRA certain business travelling expenses incurred whilst on HRA business may be eligible for tax relief.

The HRA considered that the declaration of tax was a personal issue and where an individual was identified as having not declared taxable income from the HRA it would not prejudice their position as a chair or member of a REC or other HRA committee.

15. **Date of Next Meetings:**

27 March 2013

10 July 2013

09 October 2013

16. **ACTIONS**

Owner	Item	Action
CC	Consistency of REC Opinions	CC to circulate NRES ethical domains.
MS	Consistency of REC Opinions	MS to revise the discussion paper on ‘consistency’
AG, CC and HD	How to manage staged funding and applications for approval	To discuss with operations whether the existing advice (OMEA 56) regarding mixed research needs to be altered.