National Research Ethics Service

Health Research Authority

National Research Ethics Advisors' Panel

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

Date: **10 July 2013**
Time: **14:00 – 17:00**

Venue: Room 133B
Health Research Authority
Skipton House,
80 London Road,
London SE1 6LH

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:

Clive Collett (NREAP Manager)
Julie Stone (HRA Non-Executive Director)

MINUTES

1. Apologies: None
2. Declarations of Interest: None
3. Minutes of meeting held on 27 March 2013

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

4. MATTER ARISING

4.1. NREAP Terms of Reference: Conflicts of Interest

- NREAP Terms of Reference v1.8

At the last meeting it was agreed that the NREAP terms of reference should be amended to reflect the procedures detailed in the NRES SOPs with regards to dealing with members' conflicts of interest.

RL made the following suggestions

Para. 7.1: add “If in doubt about whether there is an interest to be declared, members should err on the side of caution and declare anything that may be perceived to be relevant.”

Paras. 7.2 and 7.3: The Chair, following consultation with the panel, rather than the whole panel to decide if something is a material interest (unless it was the Chair who had the potential interest). 7.4 to be reworded to also reflect this change.

The panel agreed the suggested revisions.

Action: CC to revise the terms of reference accordingly.

5. NREA Activity Log

Noted for Information:

NREA	Activity	Date(s)
NREAP	• HRA Response to the WMA Declaration of Helsinki Working Group Draft revised text for public consultation • Comment: Draft pilot for Shared Ethical Debate	June 2013
Andrew George	• London and South Coast NREAP/Chairs Network Meeting • HTA public meeting and annual review of the year. • Presentation at IAoCR conference/meeting with the IAoCR to discuss training for research • Participant in debate at Cheltenham Science festival on the ethics of research – (Not formally as NREA) • Attended Nuffield Council on Bioethics annual lecture (Prof John Harris) • Helped organise, chaired the conference on GTAC arrangements • Participated in follow up telecom on GTAC with BSGCT and Catapult	25/04/2013 09/07/2013 07/05/2013 29/04/2013 07/05/2013 29/04/2013
John Keen	• Attendance at the HFEA’s ‘Scientific and Clinical Advances Advisory Committee’ (SCAAC) meeting • HRA Website planning • HFEA Horizon Scanning • East Of England NREAP/Chairs Network Meeting • Chairs’ interviews: Newcastle, Leeds and Southampton	12/06/2013 26/04/2013 12/06/2013 18/06/2013

Peter Heasman	• HRA Assessment Strategy Group • Chaired Medical Devices Research Collaboration Group • North East and Yorkshire & The Humber NREAP Chairs Network Meeting	 May 2013 08/05/2013
Ros Levenson	East Midlands NREAP/Chairs Network Meeting	19/04/2013
Mark Sheehan	• South Central NREAP/Chairs Network Meeting • Helped organise, chaired the conference on GTAC arrangements	10/06/2013 29/04/2013
Søren Holm	West Midlands NREAP/Chairs Network Meeting	16/05/2013
Simon Woods	• North West NREAP/Chairs Network Meeting • Members Induction training	20/05/2013 04/07/2013

6. Action Register

Noted:

- NREAP Action Register

7. HFEA Research Regulation – Dr Chris O'Toole

Dr Chris O'Toole (Head of Research Regulation) attended and gave a presentation on the HFEA's work with regards research regulation and the overlap with the HRA/NRES.

Dr O'Toole noted that there were a number of stand-alone private centres involved in research that use their own research ethics committees to comply with the HFEA's requirement for ethical approval. Whilst the HFEA encouraged the use of NHS RECs for this purpose they are unable to insist upon this. AG asked whether the HFEA's guidance stipulated the need for such ethics committees to be "independent". Dr O'Toole explained that the HFEA did indeed insist upon the independence of research ethics committees but this requirement was interpreted in different ways by the research centres.

SW asked whether there were tensions between NHS RECs and the HFEA with regards to information sheets. Dr O'Toole acknowledged that there had been difficulties in the past where applications were passed backwards and forwards between the HFEA and RECs but the HFEA are now more of the view that such issues are properly within the remit of the NHS RECs to deal with provided that the specific HFEA requirements are clearly stated in the information sheet. Dr O'Toole explained that she had been in contact with Sue Bourne and would supply the HFEA's information sheet requirements to her for incorporation into the forthcoming information sheet guidance and dissemination to RECs.

Dr O'Toole asked the panel how much scrutiny RECs give to the scientific aspects of an application. AG explained that whilst RECs would supply feedback on the science where this was within the specific expertise of the chair or one of the members of the main role of the REC was to assure themselves of the scientific validity of the application. This was primarily achieved through insistence upon appropriate peer-review but RECs could also seek expert

opinion on the study. Dr O'Toole suggested that if the HFEA could speed up their own peer review of research then this was likely to be beneficial to RECs. The panel agreed that this would be extremely helpful.

8. Update on SCAAC meeting – John Keen

Received: Verbal update from John Keen on his recent attendance at the HFEA's 'Scientific and Clinical Advances Advisory Committee' (SCAAC) meeting held on 12th June.

SCAAC is a subcommittee of the HFEA which meets to consider advances in science and clinical practice which are relevant to the HFEA. The committee is appointed from members of the Authority (including a proportion of lay members) and some co-opted members.

More info can be found at: http://www.hfea.gov.uk/SCAAC.html

JK explained that he had found the meeting extremely interesting but felt it might be preferable if the NREA attending was upgraded to full attendance in order to contribute to the discussion. Dr O'Toole stated that the NREA would be more than welcome to contribute to the discussions even though they were officially attending in the capacity of an "observer".

JK also wondered whether it was necessary for an NREA to attend every SCAAC meeting as not all of the items were of direct relevance. PH suggested that the panel retain an option to attend the meeting having had sight of the proposed agenda. Dr O'Toole agreed that this was a sensible way forward.

JK indicated that he was happy to attend future meetings but it was agreed that other NREA's might attend where the items to be discussed were of particular interest to them.

9. Information Governance Review

Received for Information:

- Information Governance Review

NREAP would discuss the review and its implications in more detail once the outcome of the DH response to the recommendations made in the review has been published.

10. Consistency of REC Decisions

10.1. Consistency – Mark Sheehan

MS apologised for not having had time to produce a revised version of this paper in time for the meeting. He explained that he had reviewed the existing literature and noted that there was currently very little published on the subject[1] and what had been published tended to focus on complaints around REC consistency.

His paper currently focused on procedural consistency and, the more novel aspect of his work, the "calibration argument". He explained that whilst he was currently using the term "calibration" to describe how RECs might ensure that their decisions are taken within the appropriate context, i.e. "calibrated" against the appropriate medical context and the views of the relevant medical community along with the general public, this was likely to change once

[1] E.g. Edwards, S. J.L., Ashcroft, R. and Kirchin, S. (2004), Research Ethics Committees: Differences and Moral Judgement. Bioethics, 18: 408–427. doi: 10.1111/j.1467-8519.2004.00407.x

he had considered the appropriate term more thoroughly. He stated that RECs must have a clear appreciation of the weightings and values used in the medical context within which the research would take place. His work on this area is likely to result in two papers: one of which would be suitable for publication as an academic paper by himself and his team; and the other which would be more suitable as an NREAP document to for dissemination to both the REC community and external stakeholders.

RL wondered whether the position taken by the paper intended for endorsement by the panel might be in tension with her own views and/or those of other panel members with regards to PPI. MS replied that whilst the academic paper would present his opinions and arguments the NREAP document would be placed before the panel for full discussion and agreement before publication. He acknowledged that there might be differences in these two papers with regards the calibration and weightings to be used.

MS would finalise the document for the next panel meeting in October.

Action: MS

11. Process for Handling of Queries/Issues Requiring New Ethics Guidance

Received for Information:

- Process for Handling of Queries/Issues Requiring New Ethics Guidance

The purpose of this paper is to describe how the HRA formulates new ethics guidance. It has been reviewed by AG and HD and will be reviewed at the HRA Board Meeting on the 23rd July.

RL made a number of suggestions for changes:

- It should be made clearer in the following paragraph that consultation on ethical documents would normally be with the full panel and not individual NREAs.

> *"Such items, including discussion documents or frameworks for ethical decision making (where they contain a significant ethics component), should always involve consideration by the National Research Ethics Advisors' Panel (NREAP) or individual NREAs, in conjunction with the HRA Ethics Advisor and others as appropriate unless there are justifiable reasons for not doing so."*

- There should be a minimum frequency for review of guidance stated on page 2. This should be in line with the existing NREAP terms of reference i.e.:

> *"8.19 After one year the published guidance is sent again to RECs and stakeholders for review and feedback on whether it has been considered to be helpful. The panel will then give consideration to revising the guidance in light of the feedback received.*
> *8.20 NREAP guidance may be reviewed at any time but will be reviewed at a formal meeting of the panel at least every five years. Where necessary a period of further consultation may be embarked upon in order to inform any update to the guidance.*

Julie Stone stated that she would like stakeholders to *always* be involved in the development

of new ethical guidance. AG noted that there might be minor pieces of guidance or advice which did not warrant full stakeholder engagement but acknowledged that important *substantive* guidance should always involve relevant stakeholders. AG suggested that the term "substantive" should be used i.e:

> *"Where appropriate, relevant stakeholders should be involved in the development of new substantive guidance".*

The panel agreed to all of the suggested changes.

Action: CC to revise the proposal in accordance with the agreed changes.

12. NREAP Membership

Discussed:

The panel were asked to reflect on whether additional members are required.

RL stated that, whilst she acknowledged the excellent clinical and academic expertise of the current members, she thought there was a need for more lay representation on the panel. She noted that it is rare for any committee to only have one female member. She felt that the HRA's reputation was at stake and noted that she had been approached by individuals outside the organisation who had noted that the panel had no visible ethnic diversity and only one woman.

MS stated that he felt there needed to be a focus on what the justification for the panel was and what it did. The membership would flow from the answer to this. Any new members would need to clearly add to the ability of the panel to carry out its remit.

PH sounded a note of caution. As a member of the previous panel he noted that a lot of thought had gone into reducing the numbers on the panel to the current seven members which he felt were working well together. SH agreed noting that he did not think the panel should be much larger as larger committees tended to be less efficient.

The panel agreed that at least one extra panel member should be sought and possibly two, but no more than this was required. It was agreed that any recruitment materials should explicitly encourage individuals from ethnic minorities and women to apply.

Action: AG and CC would discuss how to take forward the recruitment of new panel members.

13. Novel Neurotechnologies: intervening in the brain

Received for Information/Discussion:

- Novel Neurotechnologies: intervening in the brain
- Extract from 'RCP Guidelines on the practice of ethics committees in medical research with human participants - Fourth edition (2007)' – 'Research in practical procedures: surgery and other modalities'

The Nuffield Council on Bioethics (NCOB) has recently published a report that considers the ethical, legal and social issues raised by the development and use of a range of neurotechnologies that intervene in or interact with the brain.

Two recommendations are made in the report directly relate to the HRA. The panel were asked to consider both of these but are asked to particularly focus on the recommendation regarding the production of guidance related to the use of sham surgery.

1) **We recommend that the GMC, the HRA and the MRC work together to produce guidance for clinicians pursuing experimental therapies. This would address lacunae between the regulation of research and treatment, with the aim of ensuring that experimental interventions are pursued in a responsible way that protects patients' interests, while supporting inventiveness thorough the generation of new knowledge in the public interest**. The recommended guidance would adopt the best features of each of the treatment and research governance paradigms, while seeking to eliminate the worst. What this might mean in practice is that:

   ■ The primacy of patient interests is imported from the treatment paradigm, entailing a duty of care that persists beyond the period of experimentation.
   ■ Unlike clinical trials, experimental treatments taking place in this middle-ground cannot be expected to meet the requirements for large numbers of participants, control groups, or double blinding of participants and investigators.
   ■ They can, however, be expected to be grounded in an evidence base that is appropriate to the (necessarily) exploratory context.
   ■ The pursuit of an intervention solely because it putatively represents a patient's 'last best hope' is likely to be too cavalier to justify an experimental intervention.
   ■ A responsible approach imported from the clinical research paradigm would, therefore, recommend adopting clear investigatory protocols, including means of assessing efficacy and risk, as well as methods of recording and sharing findings.
   ■ Humility recommends independent ethical oversight of these protocols and practices. We suggest that this guidance might usefully build on the MRC's *Experimental medicine toolkit*.

2) Recommendations have been made as to how the risk-benefit ratio of sham surgery may be improved, including permitting it to be used only when a trial has a sufficiently strong scientific rationale; when the sham procedure is the least invasive possible while maintaining uncertainty; where information provision is thorough; and when participants will have opportunities (all being well) to receive active interventions after the trial. It is notable that no professional bodies in the UK have issued guidance on the consideration and weighing of criteria such as these. We suggest that this represents a significant gap and that the production of such guidance ought to be prepared in time to inform the progression of UK clinical trials of neural stem cell therapies to Phase II in which efficacy is assessed.
   We recommend that – to support decision-making by clinical investigators, sponsors and Research Ethics Committees – the Health Research Authority (HRA) should develop guidance on the kinds of circumstances in which sham neurosurgery may, or may not, be an appropriate part of clinical investigations, and what post-trial obligations should hold in respect of participants assigned to the sham arm of trials.

AG noted that whilst the first recommendation was sensible it was not within the panel's remit to take this forward although the panel would be happy to assist if required.

The second recommendation, regarding guidance for sham neurosurgery trials, was clearly a suitable matter for consideration by the panel.

SH noted that there had been much debate over many years on this issue. SW noted that many of the issues surrounding the use of sham surgery were the same issues involved in the use of placebos e.g. how much does the placebo need to mimic the intervention, scientific validity, prior engagement with the patient population etc. He noted the current RCP guidance and agreed that it was correct to state that an outright ban on the use of sham surgery would be wrong.

MS thought that this was an important issue for surgery which tended to lack robust evidence to support many of the techniques used. He felt there was a clear need to encourage proper research into surgical techniques and the use of sham surgery, where appropriate, was to be encouraged.

SH volunteered to produce a short briefing paper on this issue for consideration by the panel at the next meeting.

Action: SH to write briefing paper on sham surgery for consideration by the panel

14. RCP Guidance

Received for Discussion:

Prof John Saunders of the Royal College of Physicians asked NREAP to review the following two paragraphs from the current 'RCP Guidelines on the practice of ethics committees in medical research with human participants - Fourth edition (2007)'.

He wished to seek the panel's comments on whether they are reasonable and correct statements regarding the distinction between ''medical research and innovative medical practice":

> 3.4 The distinction between medical research and innovative medical practice derives from the intent. In medical practice the sole intention is to benefit the individual patient consulting the clinician, not to gain knowledge of general benefit, though such knowledge may emerge from the clinical experience gained. For example, a randomised and blinded multiple crossover trial of one or two treatments for a single patient ('n of one trial') may appear initially to be research but is in fact medical practice.[76–80] In medical research the primary intention is to advance knowledge so that patients in general may benefit: the individual patient may or may not benefit directly.
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> 3.5 When a clinician departs in a significant way from standard or accepted practice entirely for the benefit of a particular individual patient, and with the patient's consent, the innovation need not constitute research, though it may be described as an experiment in the sense that it is novel and unvalidated. (In this context, an 'experiment' is a procedure adopted on the chance of its succeeding. 'Research' is a systematic experiment or series of observations to establish facts or principle and generalisable knowledge.) Clinicians should be prepared to justify their innovative therapy both ethically and scientifically if challenged.
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> 76 Guyatt G, Sackett D, Taylor DW *et al*. Determining optimal therapy – randomised trials in individual patients. *N Engl J Med* 1986;314:889–92.
> 77 Mahon J, Laupacis A, Donner A,Wood T. Randomised study of n-of-1 trials versus standard practice. *Brit Med J* 1996;312:1069–74.
> 78 McLeod RS, Taylor DW, Cohen Z, Cullen JB. Single-patient randomised clinical trial. Use in determining optimum treatment for patient with inflammation of Kock continent ileostomy reservoir. *Lancet* 1986;i:726–8.
> 79 Irwig L, Glasziou P, March L. Ethics of n-of-1 trials. *Lancet* 1995;345:469.
> 80 Porta M. The search for more clinically meaningful research designs: single-patient randomized clinical trials. *J Gen Intern Med* 1986;1:418–9.

MS did not agree with the statements in the RCP guidance that *"In medical practice the sole intention is to benefit the individual patient consulting the clinician, not to gain knowledge of general benefit"* and "*In medical research the primary intention is to advance knowledge so that patients in general may benefit: the individual patient may or may not benefit directly".* He noted that it was incorrect to state that the "*sole"* intention of medical practice was to benefit the patient. Whilst this might be true of an idealised notion of medical practice it was simply not the case in the real-world context within which medicine is practised. Both statements should refer to the "*primary*" intention as this reflected the complexity of both medical practice in research and the difficulty of restricting intention to only one possible outcome. Furthermore, MS disagreed that *"a randomised and blinded multiple crossover trial of one or two treatments for a single patient ('n of one trial') may appear initially to be research but is in fact medical practice"* particularly as it was difficult to explain why an intervention should be "randomised" or be "blinded" for the benefit of the patient.

PH agreed and felt that the RCP should be advised not to use *research* terminology in an example which is being used to clarify the difference between medical practice and research.

SH agreed that the example given was problematic as it was by no means clear that this was medical practice, it could also be research. He noted that there are occasions when doctors might do something along the lines of the example given if the patient preferred one treatment and their doctor preferred another. In this case the treatments might be randomised and blinded and the patient report their symptoms whilst receiving each treatment. The code could then be broken and the data analysed to ascertain which treatment had resulted in a reduction in the patient's symptoms. This would then inform the patient's future treatment. He noted that both medical practice and research were undertaken to provide "knowledge" but in the medical case the knowledge obtained was about an individual.

MS noted that there was a presumption that all research was about obtaining generalisable knowledge. This is not always the case. He felt that in all cases, where it was not clearly treatment or research, it was preferable to call the activity "research" with the results then being made publicly available.

RL noted that the guidance appear to be written solely from the physicians point of view. She felt that "intent" was not the issue. The issue was more gaining information to base treatment decisions upon and this was an issue of number of patients receiving the intervention. She felt that the words *"if challenged"* should be removed from the statement *"Clinicians should be prepared to justify their innovative therapy both ethically and scientifically if challenged"*.

AG stated that he felt that the intention of the RCP guidance in this area was to define when an activity needs to come to an NHS research ethics committee. He noted that physicians might conduct "n=1" type studies as a form of medical practice and that these would not be required to be submitted to a REC but this did not mean that this type of approach should not be done within an ethical framework. The distinction between what is 'medical practice' and what is 'research', and thus needs to come before an NHS REC, is a grey area and difficult to clearly define in a manner which addresses all possible scenarios.

Currently the NRES document "Is my project research "Defining Research: NRES guidance to help you decide if your project requires review by a Research Ethics Committee" defines research as "The attempt to derive generalizable new knowledge including studies that aim to generate hypotheses as well as studies that aim to test them."[2]

[2] http://www.nres.nhs.uk/applications/is-your-project-research/

15. Tissue Banks - Re-consent Once Child Becomes an Adult

Received for Discussion:

- Email correspondence between a REC and the HTA regarding whether a child should be re-consented for the continued storage and use of their tissue for research when they reach adulthood.

The panel were asked to consider endorsing the following statement:

> "In line with the consent requirements of the Human Tissue Act 2004 and the HTA code of practice the panel do not consider it necessary for individuals, whose tissue was placed in a research tissue bank (RTB) with appropriate consent whilst they were children, to be contacted to seek their further consent for the continued storage and use of their tissue once they have reached adulthood[3]. If a child consents to a procedure, then this consent carries over into adulthood unless they withdraw their consent. Notwithstanding this any request from an adult or competent child to remove their tissue from an RTB should always be respected."

SH noted that the suggested statement did not differentiate between the use of extensive clinical data and permission to trace etc. These two examples involved very different degrees of involvement. He felt that the HTA response that "consent carries over into adulthood unless they withdraw their consent" is problematic as no child can give valid consent. The statement would need to make it clear that legal, valid consent had been given by an adult on their behalf. Whilst we know that adults who take part in trials can often forget the details of those trials or even that they had taken part, it remained true to say that at some point they were aware of being involved in a research study. However, in the case of children many will not know at the time that they were being involved in a research study or were having tissue taken and stored. Thus, there is a presumption that all of us would need to keep checking whether tissue had been taken whilst we were children and was currently being stored. Thus an argument could be made that such children should be informed upon reaching adulthood that they have had tissue taken and stored as part of a research project.

Dr O'Toole noted that until recently children would have had to be deemed Gillick competent in order to have their gametes taken and stored for future clinical use. Since 2008 this has changed and parents can now consent for the storage of their child's gametes. In addition, if tissue has been taken to produce stem cells and those cells are still in storage at the time the child becomes competent, or reaches the age of 18, then those stem cells cannot be used without their explicit consent.

SW noted that whilst there was an argument that tissue taken from an individual when they were a child should not be used for research without their explicit consent once they had become an adult, there was a concern that we should not place too many barriers in the way of conducting research.

MS agreed that he was in favour of not creating extra barriers to the conduct of research. He noted that, as SH indicated, that it would be quite likely that the child involved would not know that they had been involved in a research project and had tissue taken and also would

[3] Under the HT Act, a child is defined as being under 18 years old www.opsi.gov.uk/acts/acts2004/ukpga_20040030_en_5#pt3-pb2-l1g54.
Under the HT (Scotland) Act, a child is defined as being under 16 years old www.opsi.gov.uk/legislation/scotland/acts2006/asp_20060004_en_8#pt7-l1g60.

not have been involved in any way in the original decision allowing them to participate. This would mean that child would not be able to exercise their right to withdraw their tissue once an adult.

AG agreed that the issue was problematic. The draft statement above would need to be revised to acknowledge the current legal position also take account of the fact that the child may not have been involved in the original consent decision nor be aware that they had in fact been enrolled into a research study. He acknowledged that it would be difficult to set hard ethical guidelines on this issue but felt that RECs might need to be assured that the child was aware that tissue had been taken and stored. Clearly, the involvement of a child aged 15 would be less problematic as they would be aware of their involvement, whilst in contrast the involvement of a two-year-old would be more difficult as they would not be aware that their tissue would be stored for future use at a time when they were an adult and thus be able to request its withdrawal from the tissue bank.

SH stated that whatever obligation might exist with regards seeking the further consent of the child once an adult the *weight* accorded to that obligation would depend upon what is going to happen to the tissue once the child becomes an adult. If the tissue is stored with no ethical implication for the individual this would be very different to a situation where the researchers were still collecting data on that individual.

Agreed: The panel did not endorse the suggested statement. The statement would need to be redrafted for further review by the panel.

Action: CC to re-draft statement

16. CO-ENROLMENT TO CRITICAL CARE STUDIES AND TRIALS IN THE UNITED KINGDOM - A guidance document

Received for Information/Discussion:

- CO-ENROLMENT TO CRITICAL CARE STUDIES AND TRIALS IN THE UNITED KINGDOM - A guidance document*
- Editorial: Journal of the Intensive Care Society (Volume 14 Number 2 April 2013)*

The attention of the panel was drawn to the attached guidance produced by the Intensive Care Society who state that their key aim is for RECs to be aware of this guidance, developed with very widespread consultation (listed in the guidance). It is the ICU community's view, that this be used as the primary guidance document for co-enrolment to critical care studies and it is hoped that reference to this document will promote consistency amongst RECs in this area.

The Panel recently made the following statement which was primarily in relation to research in are or orphan diseases but is also related to the issue of co-enrolment:

- 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

The panel were asked to consider the compatibility of this statement with the ICU guidance.

The panel agreed that their previous statement was entirely compatible with the ICU guidance and thus did not require revision.

The panel welcomed the guidance and felt it should be disseminated to all RECs. It was noted that Appendix IV "Summary of issues to consider in relation to co-enrolment to multiple critical care studies" would be of use to RECs in considering the issue of co-enrolment and the attention of RECs should be explicitly drawn to this when disseminating the guidance.

It was noted during discussions that the panel did not entirely agree with the ABPI's position on suitable washout period between participation in CTIMPs referred to in the guidance. The panel did not feel that four months was always necessary and preferred that the washout period should be clinically informed and thus might vary between different trials.

Agreed: The panel agreed that the guidance document should be endorsed by the panel and disseminated to all RECs with a cover note pointing out that appendix IV was a useful tool for RECs to use in considering this issue. The cover note should explain that the panel do not agree with the ABPI position with regards a four-month washout period between participation in CTIMPs and preferred that the washout period might vary depending on the trials involved but should always be clinically informed and justified.

Action: CC to draft a cover note to accompany dissemination of the guidance document "Co-Enrolment to Critical Care Studies and Trials in the United Kingdom"

17. NREAP/Chairs Network Meeting Minutes

Received for Information:

- East Midlands (19/04/2013)
- West Midlands (16/05/2013)
- London (25/04/2013)
- North West (20/05/2013)

JK noted that some meetings had been relatively poorly attended. The panel asked that data on attendance be provided at the next meeting as well as statistics regarding RECs opinions.

The panel noted that the minutes of the East Midlands meeting raised the issue of seeking consent to inform participants' GPs and asked that this be brought to the panel. CC would produce a draft statement for consideration of the panel at the next meeting on this issue.

Action: CC to draft statement for the panel to consider regarding seeking consent to inform participants' GPs.

17.1. NREAP/Chairs Network Meetings - Engagement with Academic Arguments: Reflections and Suggestions for Future Topics

Discussed:

The panel were invited to:

i) Provide feedback on the discussion of the academic papers related to "inducements" at NREAP/Chairs network Meetings and
ii) Suggest other topics/academic papers for discussion at future NREAP/Chairs network meetings

SH noted that the West Midlands meeting exhibited a fruitful tension between people seeing the argument contained in the academic papers and also seeing the opposite arguments.

PH also felt that the item worked well as it got people thinking about the issues.

RL felt that the discussion was only conducted at a moderate level whilst MS noted that from his experience REC attitudes on this issue had not moved on.

CC noted that on one or two occasions it appeared that individuals had enthusiastically engaged with the arguments and had in fact changed their minds on the issue having been persuaded by the arguments presented in the papers. However, in general he felt that the level of engagement by the majority of attendees had been relatively low.

It was agreed that the presentation of academic papers at these meetings was useful and had resulted in some interesting discussion and had prompted individuals to evaluate their own position on payments.

AG asked the members to provide suggestions for future topics:

JK suggested "sham surgery". This could be based upon the briefing paper shortly to prepared by SH.

18. Any Other Business

19. Date of Next Meetings

09 October 2013

20. ACTIONS

Owner	Item	Action	Due Date
CC	4.1. NREAP Terms of Reference: Conflicts of Interest	CC to revise the terms of reference accordingly.	09/10/2013
	11.0 Process for Handling of Queries/Issues Requiring New Ethics Guidance	CC to revise the proposal in accordance with the agreed changes.	17/07/2013
	12.0 NREAP Membership	AG and CC to discuss how to take forward the recruitment of new panel members.	09/10/2013

	15.0 Tissue Banks - Re-consent Once Child Becomes an Adult	CC to re-draft statement	09/10/2013
	16.0 “Co-Enrolment to Critical Care Studies and Trials in the United Kingdom”	CC to draft cover note to accompany dissemination of the guidance document “Co-Enrolment to Critical Care Studies and Trials in the United Kingdom”	09/10/2013
	17.0 NREAP/Chairs Network Meeting Minutes “Seeking consent to inform participants’ GPs.”	CC to draft statement for the panel to consider regarding seeking consent to inform participants’ GPs.	09/10/2013
MS	10.1 Consistency of REC Decisions	MS to finalise the consistency document for the next panel meeting in October.	09/10/2013
AG	12.0 NREAP Membership	AG and CC to discuss how to take forward the recruitment of new panel members.	09/10/2013
SH	13.0 Novel Neurotechnologies: intervening in the brain	SH to write briefing paper on sham surgery for consideration by the panel	09/10/2013