NHS
Health Research Authority

National Research Ethics Advisors' Panel

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

Date: **09 October 2013**
Time: **14:00 – 17:00**

Venue: Room 140B
Skipton House
Health Research Authority
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:

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

Observers:

Shaun Griffin (Executive Director of Communications, Engagement and Partnerships)
Sue Bourne (Head of Partnerships & Guidance)
Aimi Yusof (PhD Student, Oxford University)

1. Apologies: None

2. Declarations of Interest:

2.1 Agenda item 17.0 GMC Consent Guidance.

Ros Levenson informed the panel that she was a former GMC member who had sat on the panel responsible for this guidance. The chair noted the competing interest and decided that she remain in the meeting room but take no part in the discussion.

2.2 Agenda item 7.0 Nuffield Council on Bioethics Consultation on Children and Clinical Research

MS declared that he is a member of the Nuffield Council on Bioethics working party for this consultation and thus might be seen to have a competing interest. The chair noted the competing interest and decided, with the agreement of the panel, that MS may remain in the meeting room and take a full part in the discussion.

3. Minutes of meeting held on 10 July 2013

The minutes were approved subject to a minor amendment:

RL requested that the word "representative" be changed to "member" in the sentence "She noted that it is rare for any committee to only have one female representative."

4. MATTER ARISING

4.1. **Revised National Research Ethics Advisors' Panel Terms of Reference v2.0**

Received:

- National Research Ethics Advisors' Panel Terms of Reference v2.0

  The panel were asked to approve the revised terms of reference which have been updated in line with the comments made at the last meeting with respect to conflict of interests. Minor changes have also been made to clarify the role of the HRA ethics advisor with respect to the panel, reflect the establishment of the Health Research Authority and Clive Collett's new job title.

  RL was of the opinion that the current document was a mixture of both 'terms of reference' and 'operating procedures'. She suggested that the sections related to operating procedures be moved to an appendix.

Action: CC to re-draft terms of reference accordingly.

4.2. **Deputy Chair**

The panel were asked to consider the appointment of a deputy chair in line with the requirement in the panel's terms of reference: "3.4 The Deputy chair is appointed from among the panel members".

Background: At the meeting held on 10 November 2010 the panel discussed the appointment of an *'interim NREAP Deputy Chair'* pending the outcome of the Academy of Medical Sciences' review. At that time it was agreed that Hugh Davies (HRA Ethics Advisor) would chair the meetings in the Chair's absence. It was also agreed that a Deputy Chair should be formally appointed following the announcement of the outcome of the AMS review when the future of NRES and the role of the panel would be clearer.

The panel felt that due to the very few occasions that a Deputy chair was required that it was not necessary to formally appoint a member of the panel to fulfil this role.

The panel preferred that the terms of reference be revised to indicate that, where absence of the chair required that the meeting be chaired by another member of the panel, this be decided on an ad hoc basis.

Action: CC to re-draft terms of reference accordingly.

4.3. **NREAP Membership: Recruitment**

CC informed the panel that advertisements had been widely distributed calling for applications from individuals with senior experience in the pharmaceutical industry but that, whilst he had received some expressions of interest and requests for application forms, to date there had been no applications submitted.

It was noted that there may be a need to re-advertise and in addition extend the deadline for receipt of completed applications (31st October) and that CC and AG would discuss.

RL requested that if it was necessary to re-advertise that any recruitment materials should more explicitly encourage individuals from ethnic minorities and women to apply.

4.4. **Meeting Frequency**

AG invited discussion regarding whether the current meeting frequency was adequate for the role of the panel. He noted that it was implicit in the use of the term "panel" that its members should ideally meet in person to conduct its business.

Each agreed that the panel's view was not always best sought through other means of communication such as e-mails which did not afford the panel the opportunity of thorough discussion. SW said that he felt that the model used for past consultations, where one NREA takes the lead role in bringing together the initial discussion document for the panel might be useful. However, he noted that this would require volunteers to put themselves forward. AG felt this might be useful as the panel would have the opportunity to have an initial discussion followed by e-mail follow-up culminating in a final panel discussion to close the issue.

RL felt that unless the panel meet every month there would always be a problem with frequency of meetings. She noted that better decisions resulted from face-to-face discussion and that e-mail discussion was far from satisfactory. AG agreed and noted that monthly meetings tended to leave little time in between to advance the items under discussion.

SH noted that whilst he had no major issue with a small increase in meeting frequency there would still be some consultations where the deadlines provided a very tight time constraints which would not always be conducive to discussion and meetings. AG agreed and felt that where the panel was asked to discuss such items that we need to be clear that they should be brought to the panel's attention with as much advance warning as possible.

RL suggested the possibility of a timed agenda. It was agreed that this should be explored.

PH noted that it would be helpful if items were placed on the agenda "for information only" were not extensively discussed during the meeting.

5. NREA Activity Log

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

Action: All NREAs to forward details of their activity to CC

6. Action Register

Noted:

- NREAP Action Register

7. Nuffield Council on Bioethics (NCoB) Consultation on Children and Clinical Research

Received for Discussion:

- Children and clinical research: ethical issues - Call for evidence. August 2013
- Draft response to Nuffield Council on Bioethics Consultation on Children and Clinical Research (combined NREA Chair/NREA comments)
- REC Chairs' Responses

The panel were invited to comment upon the draft response to this consultation along with the responses received from chairs of RECs flagged for paediatric research. The resulting document will inform the HRA response to this consultation (N.B. closing date: 31 October 2013).

SW noted that he had already provided evidence to the working party.

AG started by saying that he felt it was important to set out in any response what is *unique* with respect to children's research. SH felt that we should be wary of using the term "unique" as the issues affecting children would also apply to other groups e.g. incompetent adults. He felt the term "specific" was preferable. He felt it would be important to set out how proxy decision-making works in real life and how RECs take into account the restrictions regarding research.

SW noted that reference should be made to the role of RECs in facilitating research in children e.g. by ensuring that appropriate information is provided to children. He felt there should be some interrogation of the questions put forward by the NCoB. For example, in Q 10:

> "Are there any circumstances where it would be right for a research ethics committee to approve research involving risks they would usually regard as too high, if parents and young people had clearly expressed their willingness to accept these?"

It is not clear where the benchmark of degree of risk is. He noted that there was currently a legal inconsistency between the threshold of risk that applied to research involving children and incompetent adults where children are allowed to take on a higher degree of risk in taking part in research which is not in their direct benefit. Such questions of risk become meaningless unless we unpack them. He noted that with regards Q10 that the fact that parents are "willing" and in favour of their child participating in research should not necessarily influence RECs decision on whether such research should go ahead. He noted that consent does not validate the "rightness" of a decision and that the REC has a role in such decisions. MS explained that the question was trying to explore the trade-off between acceptable risks and benefits and whether considerations that might apply to adults also applied in conducting relatively high risk research with children. He noted that the standard position was that whatever the risk allowable for adults and research that for children that level of risk would be lower.

SW reiterated that a "willingness" to participate should not carry any weight.

MS wondered whether in cases where a REC has decided that the risks involved in the proposed research were of a level that they would "usually regard as too high", what the

response of the REC should be where the researchers come back to the committee with evidence that the patients and parents themselves are more than willing to take part in this "too high risk" research? PH felt that in such circumstances it would be right for the REC to reconsider its opinion. SW had difficulty in accepting that the REC should review its opinion in such circumstances if "willingness to participate" was the only evidence being provided noting that there was often some zealotry involved in patients' willingness to take part in research. RL agreed that "no" was the most appropriate answer to Q10 stating that strength of feeling would not normally outweigh other factors and that the REC needed to take a high level rounded view. SH stated that the REC would need "evidence" not "willingness. The onus will be on the applicant to provide evidence that the REC has misunderstood the nature of the disease or the burdens that would be imposed by the research which has resulted in an error regarding the weighing of the risks and possible benefits. Willingness of patients in and of itself will not be persuasive in reaching such decisions, the REC would still need to be convinced that it had erred in its assessment of the acceptability of the risks/burdens and the likely benefits that might accrue from the research.

AG wondered whether there was a difference between 'burden' and 'risk' that could be usefully explored by RECs. SH answered that there might be occasions where the REC misunderstands how risk is seen and understood by the patient group.

With regards Q.12 "With limited resources, how would you decide which childhood conditions should be the priorities for research? Who should be involved in making these decisions?" AG noted that the reality of research was that, whilst the input of stakeholders was important, research is also the "art of the possible". He wished to move away from the idea that researchers are not focusing on trivial diseases and noted that the public and patients might not fully understand why scientists are working on the areas that they do. SW also noted that as patient organisations grow they can often become the funding resource and thus participate directly in the funding of and discussion of priorities for research. He also noted that it was unclear what the phrase "limited resources" meant.

The panel noted that with regards Q.14 the HRA had already produced guidance relating to the issue of the provision of care after research setting out the issues involved and providing a framework of questions to help NHS RECs and their applicants address this issue. See http://www.hra.nhs.uk/resources/during-and-after-your-study/care-after-research/. In addition the HRA have also published "The HRA interest in good research conduct - Transparent research (May 2013)"[1] which acknowledges that there is work for the HRA to do in encouraging researchers to inform participants of the results of the research they have participated in.

SW felt that the comments in the draft response document related to Q.3 "How useful is the concept of assent? Is it helpful to distinguish between consent and assent for young people?" were too sparse for such an important question. He felt that the HRA should give an account of what they expect RECs to do in regard to such issues. What is the status and role of assent in legitimising research? He noted that 'assent' would not be as powerful as 'consent' but that a well-thought-out review of what assent was would be helpful. He felt that the principle of involving children in decisions made about them was an important one but RECs needed to be mindful of certain safeguards surrounding such involvement and ask sensible questions around the recruitment procedures, experience of the researcher(s), involvement of parents and children and patient groups in the design of the research. RECs also needed to be assured that the researchers had thought through these issues for themselves.

AG noted that there was a difference between *disinclination* on behalf the child to taking part versus an active dissent. HD cautioned that we needed to be aware of what autonomy

[1] http://www.hra.nhs.uk/documents/2013/08/transparent-research-report.pdf

children normally have in everyday life i.e. they would defer to their parents. SH noted that we do not normally dissect the reasons for objection by competent adults to taking part in research.

In terms of information sheets SW felt that there needed to be a well thought out approach which involved children in the production and testing information sheets. JK felt that a stratified approach based on age was reasonable. RL agreed that children needed to be involved in the production of information sheets. HD noted that children's groups had been involved in the recent update to the HRA information sheet guidance.

Action: CC to draft revised version of the response document for circulation to the panel by e-mail for comments to be returned by 20th October. This draft would then be sent for comments to both EMT and the HRA board before submission as an HRA response.

8. Shared Ethical Debate (SHED)

8.1. **Shared Ethical Debate Reports**

Received for Discussion:

- ShED 12 Report: Development of Decision Support for Hyperacute Stroke
- ShED 13 Report: Clinical Trial of Investigational Medicinal Product “Is Liceko ® more effective than Lyclear against head lice?”

PH welcomed the revised format of the reports but felt that the ShED exercises needed to strive to be as genuine as possible, preferably carried out in a manner that did not allow the REC to know that they were reviewing a ShED application. He noted that there was reasonable support for this "secret" ShED approach from REC chairs.

MS explains that recognising ethical domains is nontrivial and that a large part of the work of ethical review by RECs is determining which parts of their discussion fall under the relevant ethical domains. RECs need to determine what their view is on each of the domains.

PH wondered whether there was now an opportunity to marry up the 'consistency' work being led on by MS with the ShED exercise. MS thought there might be the possibility to work on using ethics officers to develop links to appropriate guidance.

RL felt that there needed to be more work looking at why RECs are taking the decisions they are. JK believed that the chair was often the most important factor in how REC operates and reaches its decision. HD asked if it might be possible to produce an objective criteria are reviewing the ethical decision-making RECs. SH noted that there were at least generic criteria for good/bad chairing the could be used to assess this aspect of the decision-making process.

During the discussion the issue of publication of ShED reports was raised. The panel asked Shaun Griffin to discuss this with the HRA

8.2. **Shared Ethical Debate pilot process**

The main changes to the shared ethical debate process were discussed

The main changes are:

- RECs will be expected to complete one exercise every 2 years as opposed to every year – this will mean 6 exercises over the 2 years with 15 approx. RECs participating per exercise.
- A group of Chairs/REC members and/or NREAs where deemed necessary (identified by the HRA Operational team) will be asked to rank the themes identified in the analysis, in order to suggest those that a competent REC should have identified and addressed – this provides a benchmark against which an individual REC can be compared
- The inclusion of a standard report format to be used when producing the report in order to provide a corporate identity for the report for possible wider dissemination in the future

The panel were invited to consider whether one or more panel members would like to be involved in this pilot procedure as one of the group who would rank the themes that emerged from the initial analysis of REC responses.

Agreed: SH and AG agreed to assist in the ranking of themes

9. Consistency of REC Decisions

9.1. **Consistency – Mark Sheehan**

Received for Discussion:

- Should the decisions of Research Ethics Committees be more consistent? Mark Sheehan and Aimi Yusof - The Ethox Centre
- Draft NREAP Statement: Can and should the decisions of Research Ethics Committees be more consistent?

MS explained that since the last version of the academic paper was presented to the panel he had thought more about the issue of what was previously called "calibration" and had decided that "contextualisation" was a more appropriate term. This referred to the process of contextualisation of the research as it would apply in the clinical setting. MS noted that both papers still require some work particularly the practicalities that were proposed for RECs.

RL welcomed the papers but made a number of minor comments:

- She questioned whether the statement "Insofar as the law does not allow for interpretation or judgement, knowledge of (or access to knowledge of) the law will be an important aspect of procedural consistency" was correct given that the law does indeed allow and require interpretation/judgement.
- There needed to be more emphasis on the involvement of patients and the public (PPI) as a factor always to be considered by RECs.
- The statement that "As a rule of thumb, committees should consider each of the ethical categories as though there was a member of the committee who thought that category was the overriding ethical category for the given piece of research" is over prescriptive. RL preferred the term "significant" to "overriding".
- "Emergency medicine research is a good example here. We can very easily get used to the crucial importance of consent to participate in research and, where it cannot be obtained, being very careful about the level of risk to which the unconsented subject is exposed" was felt to be a little "glib". RL felt this section needed to be developed more. She preferred reference to reasons not to obtain consent rather than referred to RECs "getting used to" not obtaining consent

- RL cautioned that the proposal that "co-development of a research proposal between members of a committee and the researchers" might cross the line between being helpful and being directly involved and are setting up competing interests.
- The final paragraph regarding public involvement was felt to be to narrow in scope. Public involvement goes beyond focusing on scrutiny and publication.
- Whilst RL acknowledged the need for a degree of consistency over time she noted that ethical values and weightings change. Linear consistency (i.e. over a period of time) may not be what is needed if values change. She gave the example of the organ retention scandal involving Alder Hey and other hospitals who were retaining patients' organs without family consent which resulted in the Human Tissue Act being enacted.

SH stated that he liked the proposed "NREAP" paper but felt there might be some minor changes made. He felt that the heading “Can and should the decisions of Research Ethics Committees be more procedurally consistent?" should be revised as it currently inferred that current decisions were not procedurally consistent. He suggested that this be revised to include the concept of "striving towards procedural consistency". On page 4 the paragraph "(b) Limits on content" used both "unacceptable" and "beyond the pale". SH felt that the term "unacceptable" should be used on both occasions. SH said he agreed with RL's comments regarding the use of the term "overriding ethical category". He could see that this made some sense in principle but in practice it might look a little strange particularly with reference to projects where there is minimal burden and no risk. In such cases it would be odd to encourage lengthy discussions on such issues where there were more important ethical issues at stake. SH also made the general point that it is risky to take the procedures used for one kind of research and apply them to other kinds of research e.g. the model developed in clinical research (involving competent adults) does not quite fit other kinds of research.

SW noted that whilst the concerns voiced by RL regarding "crossing the line" between helping researchers and direct involvement in the research were valid there were opportunities for joint training/workshops involving both REC members and researchers. AG also noted that the presence of researchers on RECs themselves was an important mechanism for introducing contextualisation into REC deliberation.

PH liked the idea of "institutional memory" which should result in test/retest reliability. He noted that currently a single REC may have different members attending over different meetings resulting in different responses from the same committee. AG noted that institutional memory could sometimes become a form of laziness arising from a familiarity with the research which could lead the REC to become complacent. Such institutional memory might need to be regularly revalidated and noted that in his experience this could happen through the introduction of new members questioning that institutional memory. MS noted that past decisions needed to be engaged with not necessarily adhered to.

JK noted that the recent introduction of ethics officers, currently being piloted, would play an important part in the promotion of consistency and that this should be included in these papers.

MS noted that whilst there was work to be done on the academic paper the "NREAP" paper should shortly be handed over to NREAP and the HRA to develop separately.

Action:

All panel members to send comments on the shorter 'NREAP' consistency paper to MS cc'ing in CC. MS and CC to need to discuss the paper and taking it forward.

MS to revise “shorter” consistency paper in line with NREA comments

10. Sham Surgery – Søren Holm

Received for Information/Discussion:

- Sham Surgery: discussion paper

At their meeting in July the panel considered the Nuffield Council on Bioethics (NCOB) recently published report on 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.

This report recommended that

> **"… 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**."

SH considered that, in principle, sham surgical techniques were no different from the taking of extra blood samples from controls.

He noted that guidelines in the literature were produced by professional bodies with a fairly narrow scope and are biased towards those who would wish to carry out sham surgery.

SH explained that there were three main scenarios involving sham surgery:

1. Blinding + placebo effect
2. Single intervention: Blinding + placebo + non-specific effect
3. Implanted device: Blinding + placebo + non-specific effect

1. Blinding + placebo effect

Example: Sham surgical incision

Considerations:

1. Sham intervention chosen to be the least invasive and/or least risky intervention that can achieve effective blinding + placebo effect (in relation to the planned outcome measures)?
2. Risk – Benefit analysis of a fairly standard type

Conclusion: Probably no need for specific guidance

2. Single intervention – Blinding + placebo + non-specific effect

Example: Stem cell treatment where the mechanical means by which the cells are injected in the tissue, or the fluid in which the cells are suspended may have non-specific effects.

Considerations:

1. Is there an alternative research design that does not involve sham surgery and which is (nearly) as good?
2. Is there good justification for the potential existence of a non-specific effect?
3. Sham intervention chosen to be the least invasive and/or least risky intervention that can achieve effective blinding + placebo effect + non-specific effect?
4. Risk – Benefit analysis of a fairly standard type

Conclusion: Probably no need for specific guidance

3. Implanted device – Blinding + placebo + non-specific effect

Example: Implantation of electrode assembly etc. for deep brain stimulation

Considerations:

1. Is there an alternative research design that does not involve sham surgery and which is (nearly) as good?
2. Is there good justification for the potential existence of a non-specific effect?
3. Sham intervention chosen to be the least invasive and/or least risky intervention that can achieve effective blinding + placebo effect + non-specific effect?
4. Risk – Benefit analysis of a fairly standard type (but more complex than in relation to the two previous scenarios)
5. Specific problem in relation to how the usual promise, that if the intervention is effective, the people in the control group will get it later, will be interpreted. Considerable risk that it will be interpreted not as "if – then", but "not now, but later". Need to make sure that potential participants are fully aware that there is a considerable risk that the intervention will be found to be ineffective and that those in the control group will not be treated later. May be one of the cases where researchers need to check that potential participants actually know this before they consent.

Conclusion: Possibly need for specific guidance

SH noted that the panel whilst he considered it unnecessary for the panel to issue guidance covering the first two scenarios they could develop guidance on the area of implanted devices but wondered if it was really necessary.

HD asked if this third scenario was relatively common. JK stated that in his experience this type of intervention was not very common. SH agreed this was a relatively small area of research, most of which was taking place in the USA and Singapore.

Agreed: The panel agreed that, following the analysis prepared by SH, that there was no overriding need for the panel to produce guidance on the issue of sham surgery.

The panel felt that the following statement captured the panel's position on this issue and this and the minutes of this item could be referred to by RECs as necessary:

NREAP consider that, in principle, the ethical considerations relating to sham surgical techniques are no different from those related to the taking of extra blood samples from controls.

Action:

- CC to inform HRA of the outcome of the panel's discussion

- CC to contact Nuffield Council on Bioethics to inform them of the outcome of the panel's discussion

11. 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 considered this item at the last meeting and did not endorse the original proposed statement.

The panel were asked to consider endorsing a revised statement.

Agreed: the panel endorsed the revised statement subject to a minor change. SH requested that the word "still" should be added to the phrase "where the researchers are also actively collecting data on the individual".

The final agreed statement is as follows:

> "The panel note that the consent requirements of the Human Tissue Act 2004 and the HTA code of practice do not require 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[2]. **If valid consent has been given for a child's tissue to be taken and stored for future use (either from an adult with parental responsibility or a Gillick competent child), then this consent still applies, once the child reaches adulthood, unless that consent is withdrawn**. Any explicit request from an adult or competent child to remove their tissue from an RTB should always be respected.
>
> Notwithstanding the *legal* position it can be argued that a *moral* obligation to seek the further consent of the child exists once that child becomes an adult. However, the weight accorded to that obligation will depend upon what will happen to the tissue once the child becomes an adult. For example, where tissue is stored with no ethical implications for the individual the weight given to the obligation above is less than in circumstances where the researchers are still actively collecting data on the individual."

12. Seeking consent to inform participants' GPs.

Discussed:

[2] 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.

At their meeting in July the panel noted that the minutes of the East Midlands NREAP/Chairs Network meeting included the issue of seeking consent to inform participants' GPs which they asked to be brought before the panel for their view:

> "**7.1 Drug Trials Seeking Consent to Inform GP**
>
> The group agreed that it should be clear in the participant information sheet if the participant's GP needs to be notified of their participation, and seek consent for this. It was also agreed that it was not always necessary for low risk trials.
>
> MH [Dr Martin Hewitt] felt this point did not accurately reflect the discussion; he wanted to make clear the point was if a participant is involved in a clinical trial the GP MUST be informed and if the participant does not wish this to happen they must be excluded from the trial. MH wanted this to be raised at the next NREAP meeting, CC confirmed he would look into this further as he felt this topic had already been discussed at NREAP."

CC was asked to produce a draft statement for consideration of the panel at the next meeting on this issue. Following the meeting CC noted that the panel had made a previous statement on this issue (June 2012):

> Informing GPs and other healthcare professionals (HCPs) of their patient's participation in research is not a universal requirement. It should only be mandatory in the following circumstances:
>
> i. Where the GP or HCP may have information about the patient that might influence the consideration as to whether it is safe for the patient to join the study;
> ii. Where participation in the study would impinge on the provision of health care to that patient by the GP or other HCP."

The panel were invited to discuss whether this statement is sufficient or whether it needs to be revised.

RL requested confirmation that the statement meant that the consent of the participant would be required before the GP was contacted. CC responded that this was indeed the case but agreed that this could be made more explicit.

JK noted that there were often benefits to informing GPs that patients were taking part in research. For example, on occasions the GP is able to flag up the fact that the participant was a serial research subject and should not be taking part in the research.

The panel agreed that the statement should be revised to indicate that:

- the consent of the participant would be required before the GP was contacted
- that the participants GP should always be informed of their participation in a CTIMP

Agreed: The following revised statement was agreed by the panel

Informing GPs and other healthcare professionals (HCPs) of their patient's participation in research is not a universal requirement. It should only be mandatory in the following circumstances and always undertaken with the knowledge and consent of the patient concerned:

i. Where the GP or HCP may have information about the patient that might influence the consideration as to whether it is safe for the patient to join the study;
ii. Where participation in the study would impinge on the provision of health care to that patient by the GP or other HCP.
iii. Where the patient is enrolled in a Clinical trial of an Investigational Medicinal Product (CTIMP)

13. NREAP Guidance: Payments & Incentives

Received for Discussion:

- Discussion paper on "Payments & Incentives"

NREAP have previously discussed the issue of payments and incentives at a number of meetings. This topic was initially raised at the panel meeting held April 2011 in response to request from a REC in the North West regarding the issue of the inclusion of payment amounts on advertising materials. This issue was taken forward via the Phase 1 Advisory Group who produced guidance on 'payments and incentives in phase I studies' which the panel endorsed at their meeting held on 27 March 2012 and has now been published and disseminated to RECs.

The panel were asked to consider the issue of providing more general guidance on 'payments and incentives' that goes beyond phase 1 studies and encompasses the issue of payments to patients and healthy volunteers in both therapeutic and non-therapeutic research.

SH queried how the term "reasonable individual" should be understood. The decisions taken by a "reasonable" self-interested individual would be different form a "reasonable" altruistic individual. He asked that more thought be given to this section of the proposed guidance.

RL felt that the term "mantra" should not be used in the final text.

With regards the use of luxury items as incentives SH held the view that these should not be used in any generic or specific advertising as this could lead to the possibility of circumventing the current £100 a day limit stipulated in the Phase 1 Advisory Group guidance.

CC was asked to redraft the guidance for consideration at the next meeting

Action: CC to redraft discussion paper on "Payments & Incentives" for discussion at the next meeting

14. Medics and Eligibility

Received for Discussion:

- Medical Doctors and Eligibility Meeting Minutes 7th August 2013, BPR, London

Joan Kirkbride (HRA Director of Operations) wished to seek the panel's view on the discussion detailed in the minutes of the 'Medical Doctors and Eligibility Meeting' regarding whether it would be acceptable, under certain circumstances, for non-medics to make the *eligibility decision* under a risk-adapted approach for the inclusion of a patient in a clinical trial (assuming it has been delegated to an appropriately trained person, and that it is documented in the protocol and in the IRAS application form).

SH noted that provided that the individual was "suitably qualified" then he saw no reason why that individual would have to be a medical doctor. He could not see any ethical reasons why any *registered* healthcare professional (HCP) could not take this decision.

AG agreed noting that there needed to be accountability in the system. RECs should be assured that there was appropriate accountability for the decision and in most cases this would be exhibited by the individual being professionally registered.

PH agreed and felt that at this early stage the decision should only be made by a registered healthcare professional.

Agreed: The panel agreed that they saw no ethical objection to eligibility decisions being undertaken by appropriately trained and professionally registered healthcare professionals.

15. Information Governance Review

Received for Information:

- Information: To Share or not to Share - Government Response to the Caldicott Review (published 12 September)

- HRA press release: "The HRA welcomes the publication of Dame Fiona Caldicott's Information Governance Review"

16. House of Commons Science and Technology Committee: Clinical trials - Third Report of Session 2013–14

Received for information only:

- House of Commons Science and Technology Committee: Clinical trials - Third Report of Session 2013–14. Published 9 September 2013
- House of Commons Science and Technology Committee: Conclusions and Recommendations
- HRA press release: "HRA responds to House of Commons Science and Technology Committee report into Clinical Trials"

17. GMC Consent Guidance

Received for discussion:

- GMC: Good practice in research and Consent to research

The HRA have been invited by the GMC to review their current "good practice in research and consent research" guidance for any major inaccuracies.

Ros Levenson informed the panel that she was a former GMC number who had sat on the panel responsible for this guidance. The chair noted the competing interest and accepted RL's decision that she remain in the meeting room but take no part in the discussion.

The panel made the following comments on the guidance:

- Page 3, principle 9: the requirement that the "anticipated benefits to participants outweigh the foreseeable risks, or the foreseeable risks to participants are minimal if the research only has the potential to benefit others more generally." Was open to misinterpretation and somewhat problematic when applied to the use of placebos.
- Page 4, principle 19: RECs are not the appropriate body to inform regarding a belief that participants are at risk of significant harm.
- Page 4, principles 15 & 17: both principles directly address individual doctors. However, these principles failed to take account of the reality of the conduct of research and the distribution of responsibility which will involve many individuals, including several doctors.
- Page 5, principle 28: the requirement for "consent from participants before involving them in any research project" is not true of all research. For example, consent would not be required for:

    - Research involving previously collected, non-identifiable information
    - Research involving previously collected, non-identifiable tissue samples
    - access to confidential patient information without consent provided this has Confidentiality Advisory Group (CAG) approval under Section 251 of the NHS Act 2006.

- Page 9: the title "Consent Research" should be "Consent to Research".
- Page 11, principle 12: it should be noted that NREAP have stated that the requirement to "inform their GP and other clinicians responsible for their care about their involvement in a research project" is not mandatory and should occur only in the following circumstances with the knowledge and consent of the patient concerned:

    - **Where the GP or HCP may have information about the patient that might influence the consideration as to whether it is safe for the patient to join the study;**
    - **Where participation in the study would impinge on the provision of health care to that patient by the GP or other HCP.**
    - **Where the patient is enrolled in a Clinical trial of an Investigational Medicinal Product (CTIMP)**

18. NREAP/Chairs Network Meeting Minutes

Received for Information:

- London (02/09/2013)
- N.E. & Yorkshire and the Humber (08/05/2013)

19. Any Other Business

There was none

20. Dates of Next Meetings

15th January 2014

2nd April 2014
2nd July 2014
8th October 2014

21. ACTIONS

Owner	Item	Action	Due Date
ALL NREAs	9. Consistency of REC Decisions	All panel members to send comments on the shorter 'NREAP' consistency paper to MS cc'ing in CC. MS and CC to need to discuss the paper and taking it forward.	31/12/2013
CC	3.0 Minutes	CC to revise the minutes accordingly in line with RL comment: the word "representative" should be changed to "member" in the sentence "She noted that it is rare for any committee to only have one female representative."	15/01/2014
	4.1. NREAP Terms of Reference: Conflicts of Interest 4.2. Deputy Chair	CC to revise the terms of reference accordingly.	15/01/2014
	7. Nuffield Council on Bioethics (NCoB) Consultation on Children and Clinical Research	CC to draft revised version of the response document for circulation to the panel by e-mail for comments to be returned by 20th October. This draft would then be sent for comments to both EMT and the HRA board before submission as an HRA response.	11/10/2013
	10.Sham Surgery	CC to inform HRA of the outcome of the panel's discussion CC to contact Nuffield Council on Bioethics to inform them of the outcome of the panel's discussion	30/11/2013
	13. NREAP Guidance: Payments & Incentives	CC to redraft discussion paper on "payments & Incentives"	15/01/2014
MS	9. Consistency of REC Decisions	MS to revise "shorter" consistency paper in line with NREA comments	31/12/2013