

National Research Ethics Advisors' Panel

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

Date: 27 March 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)

John Keen (JK)

Ros Levenson (RL)

Mark Sheehan (MS)

Simon Woods (SW)

In attendance:

Richard Tiner (Chair, Phase I Advisory Group)

Sue Bourne (Head of Partnerships & Guidance, HRA)

Hugh Davies (HRA Ethics Advisor)

Clive Collett (NREAP Manager)

1. Apologies: Søren Holm
2. Declarations of Interest
3. Minutes of meeting held on 09 January 2013

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

4. MATTER ARISING

5. NREA Activity Log

For Information:

NREA	Activity	Date(s)
Peter Heasman	Teleconference: Beyond Compliance - Consent Issues	18/01/2013

Simon Woods	<p>Advice on three separate MCA related applications to NRES</p> <ol style="list-style-type: none"> 1. Regarding REC approval for market research and the MCA 2. Regarding whether research is related to an impairing condition, 3. Regarding MCA and research registers. 4. Advice to a research applicant on the MCA and presumption of capacity for a questionnaire survey. 5. Advice to an academic researcher on GAFREC and the requirements for NRES REC approval. 5. Advice to Channel 4 programme researcher on the ethics of research (regarding a series of 'trials' on everyday products). 6. Advice to NRES on ALC training. 7. Advice to Joan Kirkbride re query related to MCA consultee role and "consents" 	2012/2013
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6. HRA Update: Janet Wisely

Received for Information:

- Draft paper “The HRA interest in good research conduct – transparency” (Feb 2013)

HRA Business Plan: The HRA business plan has now been approved. The first phase of the HRA assessment for approval of research in the NHS is now underway. The HRA assessment task groups’ findings will be considered at the first HRA assessment project Board on 4th April. Following this the HRA would move to the pilot and testing phase focussing on the assessment of the validation component to ensure that poor quality applications do not pass further through the system. The HRA Board will decide at the end of June 2013 whether it is feasible to move on to the implementation phase.

Transparency: The HRA’s draft paper “The HRA interest in good research conduct – transparency” was currently out for consultation and JW informed the panel that the HRA Transparency in Research Workshop would be held on the 25th of April, 2013. The workshop will consider issues for the HRA in developing a HRA policy framework for transparent research, looking at registration, publication, dissemination, access to data, access to tissue and providing information on study results to participants.

In addition, the HRA has begun an audit of final reports to check compliance with their stated plans to publish and disseminate study results. Also RECs have been asked for their views (as part of a Single Issue Debate) on their role to review plans as part of the initial REC review and opinion.

MS welcomed the HRA’s work on transparency but noted that this had been an issue for over 20 years with very little progress being made. He felt that this suggested there were important cultural issues at work here such as negative results being felt to represent “failure” and that this was coupled with a general lack of will by journals to publish such results.

HD commented that there was a difference between “publication” and research being in the “public domain”. JW agreed and said that this is something that the HRA intended to explore. AG felt that we do need to think about what “publication” actually means. Given that it is almost impossible to publish *everything* we need to consider what research *must* be published (e.g. clinical trials) and where there might not be any benefit from publishing negative results. SB felt that we should not lose sight of why research results should be in the public domain. She stated that it is very important to ensure that results aren’t just published but are “findable”.

7. Research Summaries/Summary of Opinion

- Update on publication of Research Summaries/Summary of Opinion

The update had not been submitted at the time of meeting and would be postponed until the next meeting.

8. Revised Shared Ethical Debate (ShED) procedures and NREAP involvement

Received for Information/Discussion:

- Revised Shared Ethical Debate (ShED) procedures (to be circulated separately prior to the meeting)

The panel noted that the revised ShED procedures included a role for the panel in identifying key ethical principles in ShED applications. MS wondered how this proposal fitted with the existing ethical domains as he felt that the domains already provided the “key ethical principles”. He worried that the proposal might be seen as “telling RECs how to think” – the ShED process should be used to find consensus and an alignment on ethical views.

Whilst SW felt there was a need to “close the loop” in the ShED exercises he did not agree with the proposal as he felt it was against the spirit of the ethical debate. He preferred that any analysis of the responses should be done in a safe learning environment and not be part of a “top down” exercise. He thought that one of the main reasons for conducting the ShED was to investigate how well RECs could articulate their reasons, although it was not clear how the panel could best contribute to this aspect.

RL agreed stating that she felt the procedure should be “iterative”. The current proposal implies that the panel “knows better”.

HD felt that an alternative method would be to analyse the results afterwards, take these back to the RECs involved for their comments and then bring these to the panel for a summing up and conclusion.

PH noted that originally ShED was a *training* exercise and he had never been convinced that it was a useful management tool to investigate consistency of REC decision making as it was too vague and inappropriate. Furthermore, some RECs would spend much longer than others on this type of exercise and he felt that a level playing field needed to be created. He suggested that the ShED application might be sent to RECs with the direction that they only look at a handful of specific issues or parts of the application. The RECs would then document their views along with the reasons for them. He felt that this directed exercise would allow NRES to more clearly investigate how RECs think and remove the pressure that RECs might feel to identify every possible ethical issue.

AG stated that we needed to be clearer about what the learning and training objectives of the ShED exercise are. He felt that the time seemed right to pause and reflect upon the objectives of the ShED exercise in order to define more clearly the panel's role.

The panel agreed that this would be appropriate and ask CC to feedback the panel's views to the QA team in order to inform the next steps.

Action: CC

9. Consistency of REC Decisions

9.1. ShED – Putting ‘Consistency’ Into Context – Hugh Davies

9.1.1 Shared Ethical Debate (ShED) Reports

Received for Information/Discussion:

- ShED 10 MCA – PowerPoint presentation
- ShED 10 MCA - Good practice minutes
- ShED 11 Proportionate Review - PowerPoint presentation

HD noted that in ShED 10 committees that had expert members who were familiar with the use of the ‘Hemolung’ equipment were swayed by their views. However, there appeared to be a disconnect between the tone of the comments made by the committee and the final decision given. HD believed that this was because RECs would rather say “maybe” than “yes”. AG wondered whether the use of a “provisional opinion” was still the default option amongst RECs. SW felt that the use of favourable opinion with conditions were still under used. RL agreed and wondered whether the panel could offer some leadership on this issue.

9.2. Decision Making – Trend Data by REC 2009-2012

Received for Information:

- Decision making – Trend Data by REC (2009 - 2012)

PH commented that it somewhat bewildering that some committees gave around 90% of applications a favourable opinion whilst other committees gave such opinions only on 10%. AG agreed that such diversity was difficult to defend and thought that it was REC chairs who were most likely to be able to influence opinion rates. He felt that such trend data should be the starting point for a discussion with outlying committees and that NREAs and regional Chairs might have a role in this discussion under the direction of the Operations team.

HD felt that this data should be taken to RECs to comment on and could possibly be sent out as a single issue debate. MS thought this might be useful but only if it was directed towards the outliers themselves. Such RECs needed to be asked for their views on how they could address their opinion rate.

9.3. Ethical Domains – Hugh Davies

This item was not discussed as the content of the domains was currently under revision.

9.4. Consistency – Mark Sheehan

MS gave a verbal update on his work on “consistency” focussing on possible practical solutions.

MS noted that some of the issues discussed at today’s meeting focused on “procedural consistency”. He noted that REC Chairs have a role to play in such consistency and wondered whether the use of a “revolving chairs” might play a role to play.

In terms of “ethical consistency” MS had started to tease out what this amounted to and how the process of “contextualisation” (i.e. ensuring that the RECs do not reach their decisions in “rarefied air” but take into account accepted clinical practice) might be addressed.

He also noted there was a question of how we could capture progress in the system. He suggested that we could build in alerts to protocols that had been approved and could state that similar protocols would also be accepted within specified limits of contents variation.

MS stated that he should have both an academic paper and practical suggestions for implementation ready for the next panel meeting in July. Following this, the suggestions would be taken to the REC community for consultation.

10. NREAP Guidance: Payments and Incentives

The Panel were invited to discuss the recommendations made by the Phase I Advisory Group regarding payments and incentives in phase I research and discuss the incorporation of these into wider NREAP guidance on this issue for all types of research.

The panel were invited to endorse immediate publication of the phase I group recommendations.

Received for Discussion:

- Phase I Advisory Group Minutes (08/02/2013) – Incorporating recommendations for payments and incentives in Phase I research
- Phase I payments and incentives working group minutes (13/12/2013)

MS questioned the use of the word “never” in the initial statement “Payments made to participants in phase I trials must never be related to risk” as this was difficult to justify in every case. Furthermore, he wondered why we might think that people should never be paid for risk in phase I, or indeed any, studies. What difference would payment make in the case of a study that was considered risky? Indeed, if the study was too risky than it should not have been approved by an ethics committee. We might think that payment might undermine an individual’s freedom of choice, but we live in a world geared around monetary reward and there are many instances where individuals are remunerated highly precisely because of the risk involved in their occupation. RT commented that higher risk phase I studies would often involve a high level of discomfort that might require a higher payment.

MS noted that there was an interesting trend in some countries to protect participants in phase I studies through employment laws i.e. it was explicitly accepted that participation in phase I trials, for monetary reward, constituted a ‘job’ and participants were ‘workers’.

AG wondered whether the issue of compensation for risk was something that might be taken forward by the panel. RL agreed and noted that we need to define exactly what risks we are

talking about in the context of participation in research. HD stated that he had been to two public engagement meetings and found that there were still factual errors in understanding shown by the attendees. He noted that much discussion around risk was based on erroneous information and that there was a real need for a solid evidence base to properly inform such discussions. He noted that the TOPS system provided an excellent opportunity to look at the numbers involved in phase I research and its attendant risks. He believed that the risks involved in participation in such research were “tiny”.

AG asked the panel whether there was also an issue around the payment to patients to take part in research. He wondered whether there was a ‘mantra’ amongst RECs that patients should never be paid for their participation beyond reimbursement of expenses. He noted that the panel had previously taken the position that where a patient was recruited to a study for reasons other than their disease that had no therapeutic benefit for them then there was no reason why they should not be treated effectively as a healthy volunteer and be paid for taking part. JK agreed that payment of patients for taking part in research was anathema to most RECs but agreed that this was an area that might benefit from some discussion and further guidance.

AG noted that the minutes of the phase one advisory group stated that the use of “luxury items” in generic advertisements should be discussed. RT confirmed that this was an issue for the CROs involved in the phase I advisory group and noted that the use of such items was not entirely in accordance with the ABPI code of practice. MS asked whether there was any difference between the offer of money and the offer of a “thing” such as an iPad, handbag etc. stating that he believed there wasn’t. RL stated that the use of such items to entice people onto phase I volunteer panels “felt wrong” stating that she preferred an honest explanation of why someone may wish to join such a panel.

MS noted that since the 1990s the academic literature has mostly gone against the unacceptability of inducements for participation in research with most academics agreeing that there is only a problem at the extreme limits¹. He noted that this viewpoint appeared to be at odds with the position adopted by most RECs and wondered how this “mismatch” might be addressed so that RECs engage with the academic arguments for the acceptability of inducements. JW wondered whether the key to such debates was to talk directly to the recipients of payments to establish their view on the issue and to make these available to RECs. RL felt that it would be difficult for the panel to weigh up the academic argument, the views of participants and the views of RECs and say who had “won” the argument but the panel could set out the arguments for and against the use of inducements along with the risks and benefits.

AG agreed and felt that the issues of payment for risk and payment to patients might be worked up into a paper by the panel which could then be used as a basis of engagement with stakeholders. MS pointed out that there any consultation on this issue was quite different from other consultations in that we would like stakeholders to engage with the academic *arguments* involved rather than seek *opinions*.

HD agreed to send the Annex on ‘payment’ from the forthcoming Information and Consent guidance to CC in order to inform an initial discussion paper.

AGREED:

¹ Wilkinson, M. and Moore, A. (1997), Inducement in Research. *Bioethics*, 11: 373–389. doi: 10.1111/1467-8519.00078

- 1) The panel endorsed the following guidance regarding payments and incentives in phase I studies which could be published immediately:

Generic advertisements:

Payments made to participants in phase I trials must never be related to risk.

Payment amounts can be detailed in generic advertisements in the form of a daily rate (in this context the term "daily" refers to a 24-hour period). A minimum daily rate should be used in all generic advertisements and stated as being "from £X". The group recommends that the minimum amount to be stated is £100. Therefore, generic advertisements should not normally give a range but instead solely state that the payment amount would be "from £100". (This minimum amount would need to be regularly reviewed to ensure its continuing relevance).

Study specific advertisements:

The group agreed that specific payment amounts could be used in the context of study specific advertising. Such specific amounts should be backed up with clear reasons in any submission to an ethics committee clearly explaining how the amount had been calculated.

Payment amount should be discreet and not prominent within the advertisement i.e. it should not be the headline or very first line of the advert.

Terminology:

The terminology proposed by the Nuffield Council on Bioethics in their report "Donation - Human bodies: donation for medicine and research (October 2011)²" should be used in any advertising materials. i.e.:

- **Payment:** a generic term covering all kinds of transactions involving money, and goods with monetary value, whether those transactions are understood as recompense, reward or purchases.
- **Recompense:** payment to a person in recognition of losses they have incurred, material or otherwise. This may take the form of the reimbursement of direct financial expenses incurred in donating bodily material (such as train fares and lost earnings); or compensation for non-financial losses (such as inconvenience, discomfort and time).
- **Reward:** material advantage gained by a person as a result of donating bodily material, that goes beyond 'recompensing' the person for the losses they incurred in donating. If reward is calculated as a wage or equivalent it becomes remuneration.
- **Purchase:** payment in direct exchange for a 'thing' (e.g. a certain amount for a kidney, or per egg)³.

- 2) CC & AG would discuss how best to take forward the issues of "payment for risk" and "payment to patients" for discussion at the next meeting.

11. Avoidance of Arbitrary Upper Age Limits in Clinical Research

² <http://www.nuffieldbioethics.org/donation>

³ Donation - Human bodies: donation for medicine and research (October 2011), p. 2 para. 7

Following an email received by the NRES Regional Manager (South) regarding the use of arbitrary upper age limits in research the panel are invited to endorse the NIHR statement “Equity in Clinical Research: Inclusion of Older Participants”

Received for Discussion

- Email: “Avoidance of Arbitrary Upper Age Limits in Clinical Research”
- NIHR: “Equity in Clinical Research: Inclusion of Older Participants”

Received for Information:

- [“No more arbitrary upper age limits for clinical research”](#). Marion E T McMurdo - BMJ 2012;344:e4040 doi: 10.1136/bmj.e4040 (Published 12 June 2012)
- [“Why the exclusion of older people from clinical research must stop”](#). Geoff Watts - BMJ 2012;344:e3445 doi: 10.1136/bmj.e3445 (Published 21 May 2012)

RT explained to the panel that this issue had been discussed in meetings arranged by the RCP who had made the following statement:

“A cut-off age for participation in clinical trials is arbitrary and unfounded in good science”

PH agreed that you cannot exclude anyone from research simply because of their age. However, researchers might be able to justify the use of a cut-off age if, on the balance of probabilities those over the proposed age would be very likely to have physical or psychological attributes that would make them unsuitable for inclusion in the study. RL agreed noting that age is a poor proxy for physical/psychological attributes. She felt that it wouldn't be ethical to routinely exclude older people from participating in research and it is incumbent upon researchers and RECs to deal with this issue. JK agreed that felt it was worth pointing out that on occasions the cost of including certain groups could be a justifiable factor for their exclusion in the face of a limited research budget.

AGREED: the panel agreed and endorsed the RCP statement on this issue:

“A cut-off age for participation in clinical trials is arbitrary and unfounded in good science”

The panel also supported the NIHR statement on “Equity in Clinical Research: Inclusion of Older Participants”⁴

12. Third Party Locators

The panel were invited to discuss the use of ‘third party locators’ to trace participants in CTIMPs who are lost to follow up. The panel were asked to consider whether they might wish to advise the HRA on the use of such third party location services (possibly in collaboration with the Confidentiality Advisory Group to advise on data protection issues) in the light of alleged inconsistency by RECs on this issue.

Received for Information/Discussion:

- Extract from applicant's email to NRES Queries Line

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http://www.crncc.nihr.ac.uk/Resources/NIHR%20CRN%20CC/Documents/equity_in_clinical_research_22June2010.pdf

SW felt that this was a straightforward data protection issue. The acceptability of such procedures would depend upon the terms of the original consent. However, he suspected that in many cases the consent would not have encompassed the possibility of the use of such services.

The panel did not feel that they had sufficient information to comment upon the use of third party locators beyond the requirement that they act within applicable data protection laws. It was suggested that the NIGB may have more expertise in this area and may wish to comment upon the acceptability of the use of these.

13. Draft European Data Regulation

Received for Information:

- Joint statement on the draft European Data Protection Regulation
- ICO Timeline – EU data protection reform

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation):

http://ec.europa.eu/justice/data-protection/document/review2012/com_2012_11_en.pdf

Background:

Press Release: Brussels, 25 January 2012 – The European Commission has today proposed a comprehensive reform of the EU's 1995 data protection rules to strengthen online privacy rights and boost Europe's digital economy. Technological progress and globalisation have profoundly changed the way our data is collected, accessed and used. In addition, the 27 EU Member States have implemented the 1995 rules differently, resulting in divergences in enforcement. A single law will do away with the current fragmentation and costly administrative burdens, leading to savings for businesses of around €2.3 billion a year. The initiative will help reinforce consumer confidence in online services, providing a much needed boost to growth, jobs and innovation in Europe.

"17 years ago less than 1% of Europeans used the internet. Today, vast amounts of personal data are transferred and exchanged, across continents and around the globe in fractions of seconds," said EU Justice Commissioner Viviane Reding, the Commission's Vice-President. *"The protection of personal data is a fundamental right for all Europeans, but citizens do not always feel in full control of their personal data. My proposals will help build trust in online services because people will be better informed about their rights and in more control of their information. The reform will accomplish this while making life easier and less costly for businesses. A strong, clear and uniform legal framework at EU level will help to unleash the potential of the Digital Single Market and foster economic growth, innovation and job creation."*

The Commission's proposals update and modernise the principles enshrined in the 1995 Data Protection Directive to guarantee privacy rights in the future. They include a policy Communication setting out the Commission's objectives and two legislative proposals: a **Regulation** setting out a general EU framework for data protection and a **Directive** on protecting personal data processed for the purposes of prevention, detection, investigation or prosecution of criminal offences and related judicial activities.

Key changes in the reform include:

- A **single set of rules** on data protection, valid across the EU. Unnecessary **administrative requirements**, such as notification requirements for companies, will be removed. This will save businesses around €2.3 billion a year.
- Instead of the current obligation of all companies to notify all data protection activities to data protection supervisors – a requirement that has led to unnecessary paperwork and costs businesses €130 million per year, the Regulation provides for increased **responsibility and accountability** for those processing personal data.
- For example, companies and organisations must notify the national supervisory authority of serious **data breaches** as soon as possible (if feasible within 24 hours).
- Organisations will only have to deal with a **single national data protection authority** in the EU country where they have their main establishment. Likewise, people can refer to the **data protection authority** in their country, even when their data is processed by a company based outside the EU. Wherever **consent** is required for data to be processed, it is clarified that it has to be given explicitly, rather than assumed.
- People will have easier **access to their own data** and be able to **transfer personal data** from one service provider to another more easily (right to data portability). This will improve competition among services.
- A '**right to be forgotten**' will help people better manage data protection risks online: people will be able to delete their data if there are no legitimate grounds for retaining it.
- EU rules must apply if personal data is **handled abroad** by companies that are active in the EU market and offer their services to EU citizens.
- **Independent national data protection authorities** will be strengthened so they can better enforce the EU rules at home. They will be empowered to fine companies that violate EU data protection rules. This can lead to penalties of up to €1 million or up to 2% of the global annual turnover of a company.
- A new **Directive** will apply general data protection principles and rules for **police and judicial cooperation** in criminal matters. The rules will apply to both domestic and cross-border transfers of data.

The Commission's proposals will now be passed on to the European Parliament and EU Member States (meeting in the Council of Ministers) for discussion. They will take effect two years after they have been adopted.

The panel noted that the draft European Data regulation and advised that the HRA should be involved in the negotiations within the EU

14. Draft Conflict of Interest Policy for the Confidentiality Advisory Group (CAG)

The panel were asked to consider whether they need to adopt a specific policy regarding conflicts of interest similar to the CAG policy.

- Draft CAG policy

Received for Information:

Extract from current NREAP Terms & Conditions:

"6. Declaration of interests

You are required, within four weeks of this appointment, to declare any personal or professional interests that have potential to conflict with the purpose, role or remit of an NREA. The purpose of this declaration is to ensure that the functions of the

NREAP can be exercised free of bias that could affect its independence and to ensure public confidence in the independence of the panel.

You agree to inform the NREAP Manager in writing of any changes to your declaration arising throughout the term of the appointment within a period of four weeks from their occurrence.”

The panel discussed whether it was necessary to adopt a specific policy regarding declaration of interests. Whilst they felt that the CAG policy was very thorough it was not felt necessary to adopt their specific policy. It was acknowledged that the panel’s current terms of reference and terms and conditions do not explicitly state how declared conflicts of interests should be dealt with. CC noted that the NRES SOPs include the following section regarding declarations of interest and suggested that the panel’s terms of reference be amended to reflect these provisions:

“Declarations of interest

2.59 Members and deputy members should declare to the Committee any material interests they may have in relation to an application for ethical review or any other matter for consideration at that meeting. Such a declaration may be made orally at the meeting, prior to the matter being considered, or in writing to the Chair prior to the meeting. A material interest is any personal or business interest that may, or may be perceived to, unduly influence the member’s or the Committee’s judgement about the matter concerned.

Applications for ethical review

2.60 Subject to paragraph 2.64, where the member concerned is the Chief Investigator or another key investigator/collaborator named on the application form, the REC should not proceed with the review, and arrangements should be made urgently for the application to be transferred to another REC.

2.61 In the case of any other declared interest, the Committee should collectively consider whether it is a material interest and, if so, whether it is appropriate for the member concerned to take any part in the review of the application. Account should be taken of the closeness of the member’s interest in the application and the potential for a conflict of interest. In some cases, the declaration of the interest may in itself be sufficient to ensure that the decision of the Committee is not unduly influenced.

2.62 The Committee has the following options:

- (i) The member should leave the meeting room and take no part in the discussion or the vote on the application.
- (ii) The member may remain in the meeting room in order to provide any relevant information requested by other members, but may not vote.
- (iii) The member may remain in the meeting room and take a full part in the review.

2.63 The minutes should record any declaration of interest the Committee considers to be material, and its decision on the procedure to be followed. If the Committee is in any doubt, it is recommended that the member should leave the meeting room as in paragraph 2.61(i) above.”

AGREED: the panel agreed that the NREAP terms of reference be amended to reflect the procedures detailed in the NRES SOPs with regards to dealing with members’ conflicts of interest.

Action: CC

15. Any Other Business

15.1. Care and Support Bill: The HRA and Transparency in Research: A matter for NREAP/HRA Board

The panel received an email from Christopher Roy-Toole regarding “transparency in research”. The panel were aware that a response had been sent by Jonathan Montgomery (Chair, HRA) to Mr Roy-Toole regarding this issue and had nothing further to add.

15.2. Publication of summaries of research/REC approved documents

JW informed the panel that she had been made aware of a perception amongst researchers and sponsors that summaries of research results could not be published on a website without prior REC approval. In addition, there had been an instance of a researcher thinking that a research participant could not be shown the study protocol as this had not been explicitly approved by a REC. She asked the panel for their views on this.

The panel agreed that there was a difference between simply placing documents in the public domain (which did not require REC approval) and sending research-related documents directly to participants as part of a specific study (which did require REC approval).

The panel agreed that the publishing of a research summary on a website did not require ethical review. The panel also noted that the HRA had recently become a signatory to the www.alltrials.net campaign and recommended that all research protocols should be placed in the public domain. Research-related documents not in the public domain sent directly to research participants, or potential research participants, would require REC approval.

15.3. NREAP Membership

RL asked that the panel address the issue of membership and particularly the issue of appropriate gender/ethnic representation.

The panel agreed that membership should be an issue for the next agenda and that the panel should reflect on whether additional members are required.

16. Date of Next Meetings

10 July 2013

09 October 2013

17. ACTIONS

Owner	Item	Action
AG	10. NREAP Guidance: Payments and Incentives	To discuss how best to take forward the issues of “payment for risk” and “payment to patients” for discussion at the next meeting.
CC	10. NREAP Guidance:	To discuss how best to take forward the issues of

	Payments and Incentives	“payment for risk” and “payment to patients” for discussion at the next meeting.
	14.Draft Conflict of Interest Policy for the Confidentiality Advisory Group (CAG)	Revise a NREAP terms and conditions to reflect NRES SOPs regarding conflict of interests.