|  |  |
| --- | --- |
| **Agenda item:** | **7** |
| **Attachment:** | **B** |

**HRA BOARD COVER SHEET**

|  |  |
| --- | --- |
| **Date of Meeting:** | 22 July 2015 |

|  |  |
| --- | --- |
| **Title of Paper:** | NREAP update for Board |
| **Purpose of Paper:** | To provide the Board with an update regarding the work conducted by NREAP over the last year. |
| **Reason for Submission:** | For information |
| **Details:** | Andrew George, NREAP Chair and Clive Collett, HRA Ethics Guidance and Strategy Manager to attend. |
| **Time required for item:** | **25** |

|  |  |  |  |
| --- | --- | --- | --- |
| **Recommendation / Proposed Actions:** | **To Approve** | |  |
| **To Note** | | **x** |
| **For Discussion** | | **x** |
| **Comments** |  | |

|  |  |
| --- | --- |
| **Name:** | Clive Collett |
| **Job Title:** | HRA Ethics Guidance and Strategy Manager |
| **Date:** | 15/07/2015 |

**National Research Ethics Advisors’ Panel**

**HRA Board Update 2014/15**

**Contents:**

**1.** [Introduction](#Intro)

**2.** [Work Highlights 2014/15](#Highlights)

**3.** [Guidance](#Guidance)

**4.** [NREAP Statements](#Statements)

**5.** [HRA Responses to External Consultations](#Consultations)

**6.** [Future Work Under Consideration](#Consideration)

[Annex 1: National Research Ethics Advisory Panel Members](#Annex1)

[Annex 2: Additional Work Undertaken on Behalf of the HRA](#Annex2)

[Annex 3: NREAP/Chairs Network Meetings Held in 2014/15](#Annex3)

[Annex 4: NREAP Terms of Reference](#Annex4)

1. Introduction

**Over the past year the National Research Ethics Advisors have continued to discuss ethical issues faced by research ethics committees, issue guidance and statements and provide the basis of HRA responses to important external consultations.**

**An important strand of the panel’s work is hosting the regional ‘Chairs’ Network meetings’ which are now established and continues to develop as an important forum for dialogue between the Chairs/Vice-Chairs, their committees and the panel thus keeping the panel informed of issues that affect RECs at the ‘sharp end’ of ethical review. Each meeting includes at least one item engaging attendees with academic thought on a relevant ethical issue facing RECs as well as opportunities to debate and comment upon early drafts of NREAP ethical guidance. Attendance at the National Research Ethics Advisors’ Panel (NREAP) hosted meetings can be recorded as 2 hours of self-directed learning and count towards a REC member’s annual training requirement. See** [Annex 3](#Annex3) **for Chairs’ meetings held during 2014/15**

**Meetings**

**In 2014/15 NREAP meetings were held on:**

**15th January 2014**

**2nd April 2014**

**2nd July 2014**

**8th October 2014**

**2nd March 2015**

**5th March 2015 (‘Away Day’)**

**18th May 2015**

**The minutes of all NREAP meetings are available at:** <http://www.hra.nhs.uk/about-the-hra/our-committees/panels-and-advisory-groups/nreap-meetings/>

**NREAP Away Day**

**On the 5th March the panel held an “Away Day” meeting at the Indian YMCA in London to discuss**

* **NREAP role, composition and remit in context of changes to HRA remit and status brought about by Care Act (change from Special Health Authority to Non Departmental Public Body (NDPB)).**
* **Better Ways of Working Together**

[Professor Jeremy Wyatt](http://medhealth.leeds.ac.uk/profile/600/239/jeremy_wyatt) **also attended to present on “E-Health – Future Possibilities and Ethical Challenges”**

**This first NREAP “Away Day” was considered a great success, providing the panel with an opportunity to meet and discuss broad issues related to the panel and its future direction in a neutral environment. Going forward the panel will hold an “Away Day” each year to facilitate teambuilding, enable broader discussion of the panel’s work and agenda setting for the coming year.**

**Membership**

**See** [Annex 1](#Annex1) **for NREAP membership.**

**On 15th April 2015 the HRA Board approved a request for Andrew George (NREAP Chair), Peter Heasman and Simon Woods’ terms to be extended until end September 2016** to allow continuity of business during the challenging year ahead and to allow sufficient time for review of membership and terms of reference and subsequent recruitment and appointment of new NREAs including a Chair via a public recruitment process (summer 2016).

**The Board further approved the request that all three NREAs would be eligible to reapply to join the panel** (and (re)apply for the Chair) at such time as new members/Chair are sought and, if successful, would be appointed to a term adjusted to bring their total time as an NREA to 10 years.

**Revised NREA Terms of Office:**

|  |  |  |
| --- | --- | --- |
| **NREA** | **Appointment date** | **Term End Date** |
| **Andrew George (Chair)** | September 2009 | **30th September 2016** |
| **Peter Heasman** | September 2009 | **30th September 2016** |
| **Simon Woods** | September 2009 | **30th September 2016** |
| **Søren Holm** | September 2012 | **23rd September 2017** |
| **Ros Levenson** | September 2012 | **23rd September 2017** |
| **Mark Sheehan** | September 2012 | **23rd September 2017** |
| **John Keen** | September 2012 | **23rd September 2017** |
| **Malcolm Boyce** | December 2013 | **31st December 2018** |

1. Work Highlights 2014/15

**Consistency of REC Decisions**

**Mark Sheehan led on this important piece of work resulting in an NREAP paper “**[Consistency in REC review](http://www.hra.nhs.uk/documents/2014/10/consistency-rec-review-2-may-2014.pdf)” (**published** 2 May 2014) and **an academic paper which has been submitted for publication (under Mark Sheehan’s and Aimi Yusof’s authorship acknowledging the involvement of NREAP and the HRA)**.  **Both documents set out what is meant by “consistency” in the context of REC decision making and proposes a number of practical suggestions for building upon the improvements already made by NRES in this area.**

**HRA Operations have recently responded to these suggestions. The panel will review and discuss this response at the 30th July 2015 NREAP meeting.**

**Nuffield Council on Bioethics (NCoB) - Novel Neurotechnologies: intervening in the brain – Sham Surgery Workshop (May 2015)**

**In July 2013 the panel considered of the recommendation made by The Nuffield Council on Bioethics in their report “Novel Neurotechnologies: intervening in the brain” published in June 2013** and considered 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.*”

**On 27 February 2014 Andrew George, Søren Holm and Clive Collett met with Emily Postan (Leader of NCoB Novel Neurotechnologies Project) and Hugh Whittall (Director of NCoB), to discuss the reasons behind the panel’s conclusion and examine useful ways of moving forward. This resulted in a joint NCoB/HRA workshop held on the 1st May 2015. The outcome of this meeting was:**

**a. Statement of the importance of research in surgery, explaining that placebo-controlled surgical trials are a part of this.**

It was suggested that a statement from the Royal College of Surgeons (in consultation with their Patient Group), the Academy of Medical Sciences and Health Research Authority should be developed to clearly communicate this message to researchers, surgeons, anaesthetists and patients.

**b. Supportive material with ‘questions to consider’ to help surgeons think about how to tackle the issue of placebo controlled surgical trials.**

It was suggested that the HRA, Academy of Medical Sciences and Royal College should work together to develop a series of questions. The GMC and other professional bodies could help promote through their networks.

This could take the format of an A4 page to help researchers/surgeons develop high quality placebo controlled surgical trials, and provide a useful framework before presenting the proposal to a REC.

This might include:

• What are the types of placebo controlled surgery?

• What is good practice in this field?

• When is a placebo-controlled surgical trial not appropriate?

• When is it necessary?

**Draft Guidance ‘Proportionate Consent for Simple and Efficient Trials in the NHS**

The Panel advised on draft guidance regarding proportionate approaches to consent which was subsequently put out for [consultation](http://www.hra.nhs.uk/about-the-hra/consultations-calls/consent-simple-trials/) in October 2014. The report summarising the responses received and next steps will be published shortly.

**Mental Capacity Act: Revision of HRA guidance**

The panel were asked to review existing HRA guidance regarding the Mental Capacity Act in the light of legal advice received regarding “research safeguards” particularly in relation to the monitoring of participant capacity in long-term studies and suggest revised text.

The panel agreed that the current HRA guidance was compatible with existing legislation. However, it was felt that the HRA's existing 'Mental Capacity Act 2005: Questions and Answers' might be revised to provide further guidance on monitoring capacity in longitudinal studies. This work is ongoing.

**Links with Social Care REC**

When the HRA became a Non Departmental Public Body (NDPB) on 1 January 2015 it took formal responsibility for research in adult social care. The Social Care REC and its secretariat transferred to the HRA 1 April 2015. Dr Martin Stevens attended the May 2015 NREAP meeting to informally discuss the work of the Social Care REC. Clive Collett attended the June SCREC meeting and Andrew George will also attend a future SCREC meeting.

**Third party challenge to the study “Evaluating the net effects of extending the age range for breast screening in the NHS Breast Screening Programme in England from 50-70 years to 47-73 years”.**

In March 2015 the panel considered a challenge to a REC opinion and the Operations response to that challenge under new SOPs which involve the panel providing advice to the HRA to inform their response to the challenger.

Following their review of the above challenge, and contemplation of lessons learnt, the panel subsequently commented on revised SOPs regarding review of ethical opinion (Concerns/Challenges).

1. NREAP Guidance:

**Payments & Incentives Guidance**

**In May 2014 the panel published guidance** on “[Payments and Incentives in Research](http://www.hra.nhs.uk/documents/2014/05/hra-guidance-payments-incentives-research-v1-0-final-2014-05-21.pdf)”. This document incorporates the guidance developed by the Phase 1 Advisory Group on 'payments and incentives in phase I studies' but now provides 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.

1. NREAP Statements:

**The panel have made a number of statements that should be taken into account by RECs, where applicable, in reaching an opinion:**

**Patient Information Leaflet (PIL) and Information Sheets**

Sheila Oliver (Head of NRES) asked the panel to provide guidance or a position statement on the the issue of whether when a study involves the use of a licenced drug the information provided in the PIS should be a complete transcript of the Patient Information Leaflet (PIL) that would be provided with the medication had it been prescribed for normal care and treatment.

The panel endorsed the following statement:

"Potential participants in a clinical trial involving licensed medicines should be provided with information equivalent to that they would have received had they been prescribed those medicines as part of their standard care (i.e. the information contained in the Patient Information Leaflet (PIL)).

This information may be provided separately to the Participant Information Sheet (PIS)"

**Payments & Incentives: Impact on Benefits and PIS**

The panel revised a previous statement made in October 2012 regarding the provision of information to research participants on the effect of payment for research participation on benefit payments in order to highlight when it would be more appropriate to inform participants that acceptance of payment for taking part in research may affect their benefit payments:

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

The panel addressed the issue of whether the information sheet should contain a specific statement regarding the effect payments received for research participation would have on benefits. The panel felt that, whilst there is no objection to doing so, it was not necessary for RECs to insist upon the inclusion of a statement in the information sheet regarding the impact payments made for participation in research would have on individuals in receipt of state benefits (nor the tax implications of such payments).

However, there may be situations where it would be appropriate for researchers to explicitly alert participants to the effect research payments may have on their benefits (e.g. where the study specifically targets, or would be very likely to include, participants in receipt of benefits).

It is the responsibility of people in receipt of state benefits to ensure that they keep to the conditions of those benefits regarding what they can do and the amount they can be paid.

1. HRA Responses to External Consultations:

**Formal Responses:**

**2014/2015 saw a substantial number of consultations that NREAP discussed and contributed to formal HRA responses to:**

* [Department of Health Consultation ‘Protecting Health and Care Information’](https://www.gov.uk/government/consultations/protecting-personal-health-and-care-data) **(July 2014)**
* [Health & Social Care Information Centre (HSCIC) Code of Practice on Confidential Information](http://systems.hscic.gov.uk/infogov/codes/cop) **(July 2014)**

**Informal Responses:**

**Research Ethics: A guidance document for pharmacists**

The Royal Pharmaceutical Society is developing guidance for their members on research ethics. The panel provided comments on behalf of the HRA.

1. Future Work Under Consideration:

**Participant Information**

The panel are interested in exploring how new media and technology might be incorporated into information provision and consent seeking procedures in a way that empowers and supports potential participants in reaching a more truly informed decision regarding research participation. NREAP acknowledge that this would constitute a very large piece of work to undertake and that expertise beyond the panel would need to be included including academics, industry and patients and the public and that this is likely to require additional resources.

**Information Needed for REC review**

The panel are considering undertaking work looking at the amount and format of information needed to enable a research ethics committee to undertake robust ethical review in a manner proportionate to the research in question. This work could, for example, include consideration of ‘*class* *approval’* for specific types of research methodology and ‘*protocol only review’*.

The panel will discuss these issues further at their meeting on the 30th July.

**Annex 1**

**National Research Ethics Advisory Panel Members:**

|  |  |
| --- | --- |
| **[Andrew-George-photo](http://www.hra.nhs.uk/wp-content/uploads/2013/07/Andrew-George-photo.jpg)** | **Professor Andrew George** (Chair)  Andrew is Vice Principal (Education & International) at Brunel University. He was formerly Professor of Molecular Immunology in the Faculty of Medicine, Imperial College, and the Director of Imperial College’s Graduate School and School of Professional Development.  Andrew is the Alternate Vice-Chair of the West London & GTAC research ethics committee and a member of the MHRA’s Clinical Trials Expert Advisory Group of the Commission of Human Medicine. He is also a trustee of Action Medical Research, a governor of Richmond Adult Community College, and is on the Training Advisory Group of NERC. |
| **[P-Heasman-photo](http://www.hra.nhs.uk/wp-content/uploads/2013/07/P-Heasman-photo.jpg)** | **Professor Peter Heasman**  Peter Heasman is Professor of Periodontology and Honorary Consultant in Restorative Dentistry at the School of Dental Sciences, Newcastle University. He is the Chair of the North East – Northern and Yorkshire Research Ethics Committee and has been a member of NREAP since its inception in 2009. |

|  |  |
| --- | --- |
| **[Soren Holm](http://www.hra.nhs.uk/wp-content/uploads/2013/07/soren_holm.jpg)** | **Professor Søren Holm**  **Søren Holm is a medical doctor and philosopher. He is professor of bioethics at Manchester University and professor of medical ethics (part-time) at the University of Oslo.**  **He is currently the Editor In Chief of the journal Clinical Ethics and the former Editor in Chief of the Journal of Medical Ethics. He is a member of the UK Biobank Ethics and Governance Council and the UK Stem Cell Bank Steering Committee. He is also the Chair of the University of Manchester Committee on the Ethics of Research on Human Beings.** |
| **[John Keen](http://www.hra.nhs.uk/wp-content/uploads/2013/07/john-keen.jpg)** | **Dr. John Keen**  John Keen has been a GP in Chiswick since 1988. He is the chair of the London – Brent Research Ethics Committees and is a member of the Home Office UKBA Family Returns Panel.  He is a Director of NowMedical Ltd, a company that provides medical and psychiatric advice to the housing departments of local authorities, housing associations and trusts, on matters such as medical priority for allocations and transfers, vulnerability for priority need, and special housing needs. |
| **[Ros Levenson](http://www.hra.nhs.uk/wp-content/uploads/2013/07/ros-levenson.jpg)** | **Ms Ros Levenson**  Ros Levenson is an independent researcher, writer, evaluator and policy consultant, with a particular interest in health and social care, including medical ethics.  Ros is currently a non-executive director of the NHS Litigation Authority. She is also a member of the Architects Registration Board.  Ros was a lay member of the General Medical Council (GMC) and Chair of the GMC Standards and Ethics committee from 2009 to 2012. She served for 5 years on the Ethics and Confidentiality Committee of the National Information Governance Board until September 2010, and for 3 years as a lay member of the National Commissioning Group until October 2010.  She was also a non-executive director of an NHS Trust for 10 years and deputy Chair of the Trust for 6 years until she completed her term of appointment in November 2007. |

|  |  |
| --- | --- |
| **[Mark Sheehan](http://www.hra.nhs.uk/wp-content/uploads/2013/07/mark-sheehan.jpg)** | **Dr Mark Sheehan**  **Mark Sheehan is Oxford NIHR Biomedical Research Centre Ethics Fellow at the Ethox Centre, a Research Fellow at the Uehiro Centre for Practical Ethics and a Senior Research Fellow in Philosophy at St. Benet’s Hall, University of Oxford.**  **He is a member of the Advisory Group for National Specialised Services (AGNSS), vice-chair of the Thames Valley Priorities Forum (MOBBB) for the South Central Strategic Health Authority and is an Associate Editor of the Journal of Medical Ethics.** |

|  |  |
| --- | --- |
| **[Simon Woods](http://www.hra.nhs.uk/wp-content/uploads/2013/07/S-Woods-photo.jpg)** | **Dr Simon Woods**  **Simon Woods is a senior lecturer and Co- Director of the Policy, Ethics and Life Sciences Research Centre, an ethics ‘think tank’ at Newcastle University involved in research teaching and public engagement on the ethical and social implications of the life sciences. He was one of the original NREAs appointed in 2009.**  **He spent 10 years as a clinical cancer nurse and Macmillan lecturer and he holds bachelor and doctoral degrees in philosophy.**  **He has conducted empirical and conceptual research in bioethics and has taught and published widely in the field.** |
| **[Photo_MalcolmBoyce](http://www.hra.nhs.uk/wp-content/uploads/2014/01/Photo_MalcolmBoyce-e1389190102201.jpg)** | **Dr. Malcolm Boyce**  **Malcolm is the Managing Director of Hammersmith Medicines Research, London, a contract research organisation.**  **He has held various posts in clinical and academic medicine, and has worked for several of the major pharmaceutical companies. He is also an Honorary Senior Lecturer in Clinical Pharmacology at St Bartholomew’s Hospital Medical College.**  **He is the chairman of the Faculty of Pharmaceutical Medicine Advisory Committee for the Diploma/Certificate in Human Pharmacology, and a member of the MHRA GCP Consultative Committee, NRES Phase 1 Advisory Group, and the Founding Council of the Faculty of Medical Leadership and Management. He was a member and alternate chair of the London Research Ethics Committee 1997–2007.** |

**Secretariat**

|  |  |
| --- | --- |
| **[CJ Collett](http://www.hra.nhs.uk/wp-content/uploads/2013/07/mr-mephisto.jpg)** | **Clive Collett**  **Clive Collett is the HRA Ethics Guidance & Strategy Manager and is responsible for the provision of the secretariat for the panel. He has been involved in the work of research ethics committees since 1996 when he became the Assistant R&D Manager at Hammersmith Hospital with responsibility for the local REC (now the ‘West London & GTAC’ REC) for which he was the coordinator until April 2012.**  **He is a lay member of the Ministry of Defence Research Ethics Committee (MoDREC) and has a PgDip in Healthcare Ethics and MA in Medical Ethics & Law, both from King’s College, London.** |

**Annex 2**

**Additional Work Undertaken on Behalf of the HRA**

|  |  |  |
| --- | --- | --- |
| **NREA** | **Activity** | **Date(s)** |
| **Andrew George** | GTAC committee training  Nuffield Council on Bioethics: Ethical issues around genome editing – ‘think tank’  Nuffield Council on Bioethics/HRA: Sham Surgery Workshop  MISG R&D workstream – contribution to HRA Response | 18/02/2014  22/04/2015  01/05/2015  06/05/2014 |
| **Søren Holm** | Provision of comments to HRA response to: “COMMITTEE ON BIOETHICS (DH-BIO) Draft Recommendation on research on biological materials of human origin”  Nuffield Council on Bioethics/HRA: Sham Surgery Workshop | 27/04/2015  01/05/2015 |
| **Simon Woods** | Evidence to Nuffield Council on Bioethics consultation on children in Research: This included being asked to act as a reviewer which gave me the opportunity to correct comments about the HRA and NRES.  Oral evidence given to EMA regarding placebo design for rare disease research.  Written evidence to EMA regarding clinical trials for children with rare disease.  Ethics advisory group Genomics England re 100,000 Genomes project Further Advice Re: Genomics England REC application (esp. regarding MCA aspects) NRES consultation on MCA application.  NRES consultation on 23andMe.  Chaired workshop on children's participation on genetic disease research (which included EMA PPI lead) Consultation on: Re-examination of Recommendation (2006) 4 on research on biological materials of human origin.  Appointment to IRDiRC (International Rare Disease Consortium) working group on ethics and governance.  Invitation to provide expert review for the Confidentiality Advisory Group (adults who lack capacity). Review of (non-research) application being reviewed by the CAG.  Provision of comments to HRA response to: “COMMITTEE ON BIOETHICS (DH-BIO) Draft Recommendation on research on biological materials of human origin” | Jan. 2015 - May 2015  15/01/2014  27/04/2015 |
| **Malcolm Boyce** | MISG R&D workstream – contribution to HRA Response | 06/05/2014 |

**Annex 3**

**NREAP/Chairs Network Meetings Held in 2014/15**

|  |  |  |  |
| --- | --- | --- | --- |
| **Region** | **Location** | **NREA Meeting Chair** | **Meeting dates** |
| **London & South East Coast** | London | Andrew George | 10/03/2014  08/09/2014 |
| **North East & Yorkshire & Humber** | York | Peter Heasman | 09/04/2014  15/10/2014 |
| **East Midlands** | Nottingham | Ros Levenson | 09/05/2014  14/11/2014 |
| **West Midlands** | Birmingham | Søren Holm | 15/05/2014  06/11/2014 |
| **North West** | Manchester | Simon Woods | 19/05/2014  10/11/2014 |
| **South Central** | Reading | Mark Sheehan | 14/05/2014  19/11/2014 |
| **South West** | Bristol | Hugh Davies | 29/05/2014  20/11/2014 |
| **East of England** | Cambridge | John Keen | 10/06/2014  09/12/2014 |

**Annex 4**

(N.B. These Terms of Reference will need to be revised next year following consideration of social care aspect, NREAP role etc. The revised ToR will be sent to a future Board meeting for approval)

**National Research Ethics Advisors’ Panel (NREAP)**

**Terms of Reference**

* 1. The panel is independent but hosted within HRA and is a resource available to all RECs, funded by the UK Health Departments, within England and the devolved nations[[1]](#footnote-1).

1. **Terms of Reference of the National Research Ethics Advisors' Panel**
   1. The overall objective of the panel is to help RECs deliver robust, consistent and fair decisions through:

* Facilitation of RECs’ knowledge and use of currently available guidance and the development of new guidance where it is identified that appropriate guidance is not available;
* Consultation with REC members and other stakeholders to inform and develop guidance. Each NREA will be expected to consult with appropriate stakeholders as required.
* Facilitation and provision of ethics training to RECs;
* Seeking and inviting appropriate expertise, as necessary, to advise the panel and contribute to guidance;
* NREAP hosted Chairs’ Network Meetings;
* Support for the HRA in dealing with disagreements arising from appeals and/or challenges to REC decisions;
* Oversight of the ‘shared ethical debate’ external quality assessment programme for RECs;
* Advice to the HRA or RECs regarding alleged fraud or misconduct in research;
* Support for HRA with relationships with other regulators and stakeholders including research funders, universities, patient groups, professional bodies and industry including AREC;
* Support for the HRA with patient and public involvement in research;
* Support for the HRA with media enquiries and response to news items or journal articles about HRA;
* Representing the HRA at events conferences and meetings;
* Facilitating the HRA events;
* Chairing ad hoc advisory groups and working parties as appropriate.

1. **Membership**
   1. The membership of the panel should include:

* Chair
* Legal expert
* Experienced REC Chair
* Experienced academic clinical researcher
* Individual with senior pharmaceutical industry experience
* Individual with Patient and Public Involvement (PPI)/NHS experience
* Individual with academic expertise in the ethics of research
  1. The HRA Chief Executive (or their nominated representative) may attend meetings by invitation of the panel.
  2. The Chair is appointed by the HRA, on behalf of the Department of Health and the devolved nations. It is expected that the Chair will fulfil at least one of the membership categories listed above (other than “Chair”) however; this is not a mandatory requirement for appointment to the position.
  3. The Deputy chair is appointed from among the panel members.
  4. All NREAs are appointed by the HRA, on behalf of the Department of Health and the devolved nations on a yearly reviewed basis up to a maximum period of five years initially. Appointments may be renewable at the end of the first period of office; however, NREAs should not normally serve more than two consecutive terms of five years.
  5. Members may resign from the panel at any time by giving three months notice in writing to the Chair and Chief Executive of HRA.

1. **Secretariat**
   1. The secretariat will be provided by the HRA Ethics Guidance & Strategy Manager.
   2. The HRA Ethics Guidance & Strategy Manager will facilitate use of guidance by RECs and support REC training. They will also attend REC and HRA centre meetings (including NREAP hosted Chairs’ Network Meetings), as necessary, to present guidance and other panel documents and to seek feedback from RECs on existing guidance and suggestions for items to be the subject of future consultation and guidance.
2. **Meetings**
   1. Meetings will normally be held quarterly (every 3 months).
   2. Ad-hoc meetings may be held by agreement of the Chair as and when required.
   3. Meetings may, exceptionally, be cancelled by agreement of the Chair.
   4. Meetings will normally be held in London but may be held elsewhere in the UK as appropriate
   5. Meeting dates will be set and communicated to all panel members prior to the beginning of each calendar year.
   6. Panel members are required to attend in full at least three quarters of all scheduled NREAP meetings in each year.
   7. Members are required to notify the HRA Ethics Guidance & Strategy Manager in advance wherever possible if they are unable to attend any scheduled meeting.
   8. In the event that any member fails to attend two scheduled meetings in a row, without a reasonable excuse, their appointment will be terminated by the HRA.
   9. Where appropriate stakeholders, and other individuals, may be invited to panel meetings to present to the NREAs and take part in discussions.
   10. The agenda will be distributed electronically to members at least two weeks in advance of the meeting date.
   11. The Minutes of each meeting will be approved by the Chair/Deputy Chair and ratified by the panel at the next available meeting. The minutes will be published on the HRA website and distributed to all HRA staff, HRA Executive Management Team and the HRA Board.
   12. The HRA will not in any event record the meeting and any member of the group may only record the meeting with the explicit consent of all present and this must then be noted in the minutes.
3. **Quorum**
   1. There is no formal quorum for panel meetings, however where the panel is asked to arbitrate on ethical debates and disagreements arising from appeals by applicants and from within RECs the quorum should be regarded as a majority of the current panel membership. Where the panel has an even number of members, a majority means 50% of the members plus one.
   2. A member who is unable to be present at the meeting may participate by telephone or send written comments when the member has received a copy of the documents that are to be reviewed at the meeting. In such cases they will be considered to contribute to the quorum.
   3. For items other than arbitration on ethical debates and disagreements, the quorum may be decided by the Chair, taking into account the importance of the items under consideration, the presence of appropriate stakeholders, and the advisability of taking decisions if few NREAs are present.

1. **Declarations of Interest** 
   1. Members should declare to the panel any material interests they may have in relation to any item under 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 and HRA Ethics Guidance & Strategy Manager 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 panel’s judgement about the matter concerned. 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
   2. In the case of any declared interest, the Chair (unless it is the Chair who has the potential interest), following consultation with the panel, should consider whether it is a material interest and, if so, whether it is appropriate for the member concerned to take any part in discussion of the item. Account should be taken of the closeness of the member’s interest to the item 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 deliberation of the panel is not unduly influenced.
   3. The Chair has the following options:
      1. The member should leave the meeting room and take no part in the discussion or any vote on the item.
      2. The member may remain in the meeting room in order to provide any relevant information requested by other members, but may not vote.
      3. The member may remain in the meeting room and take a full part in the discussion.
   4. The minutes should record any declaration of interest the Chair considers to be material, and the decision on the procedure to be followed. If the Chair is in any doubt, it is recommended that the member should leave the meeting room as in paragraph 7.3.1 above.
2. **Payment of Expenses** 
   1. All panel members will have their expenses reimbursed in accordance with the current version of the “Reimbursement of HRA Committee Members Expenses” policy.
3. **Review**
   1. These Terms of Reference should be reviewed at least annually.

1. N.B. Whilst the Health Research Authority Directions 2011 apply only in England (by virtue of section 271 of the National Health Service Act 2006) NREAP, appointed by UKECA, will continue to be a resource available to all RECs funded by the UK Health Departments within England, Wales, Scotland and Northern Ireland. [↑](#footnote-ref-1)