National Research Ethics Advisors' Panel

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

Date: **02 July 2014**
Time: **14:00 – 17:00**

Venue: Room HRA 1
Skipton House
Health Research Authority
Skipton House,
80 London Road,
London SE1 6LH

MINUTES

Present:
Andrew George (AG) (Chair)
Malcolm Boyce (MB)
Søren Holm (SH)
Ros Levenson (RL)
Mark Sheehan (MS)
Simon Woods (SW)

In attendance:

Clive Collett (HRA Ethics Guidance & Strategy Manager)
Hugh Davies

1. Apologies: Peter Heasman; John Keen
2. Declarations of Interest

   There were none
3. Minutes of meeting held on 02 April 2014

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

4. MATTER ARISING

5. NREA Activity Log

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

6. Action Register

Received for Review:

- NREAP Action Register

7. Feedback: Consistency in REC Review

Received for Discussion:

- Collated Feedback regarding NREAP Statement 'Consistency in REC Review'

the panel noted the feedback.

MS noted that one correspondent had raised the issue of RECs not fully taking into account contextualisation regarding the overall research approvals process i.e. that RECs need to be aware of the other approval processes the application has gone or will go through. However, MS felt that in many cases the review undertaken by bodies other than RECs often, and inappropriately, strayed into ethical and methodological review. HD noted that the forthcoming HRA approval process should minimise such inappropriate activity.

The feedback received also highlighted a concern regarding disagreements with past decisions made by RECs, raised during the review of an amendment, and how these should be dealt with. MS was of the opinion that the amendment reviewing REC could only legitimately question the decision of the previous REC if there was shown to be failing in the process of review. SH agreed, stating that ethical review is a permission giving system and that there would need to be something very wrong with a previous decision to allow that decision to be reviewed and changed from a favourable opinion.

RL noted that attitudes can change over time and that a mechanism did not exist for revisiting previous decisions in the light of a major change in attitude in society.

HD explained that there are informal mechanisms for raising concerns through HRA Operations and that other HRA staff can be included as necessary to discuss appropriate actions. The panel asked CC to contact the correspondent raising this issue to explain that such issues can be raised through operations.

SH thought that the correspondent's concern was problematic. Researchers should feel able to make amendments to their research in order to ensure that it continues to be fit for purpose and the best study it can be. If researchers felt that the submission of amendments would lead to wholesale review of their study and its existing favourable opinion then this might deter them from submitting amendments and thus improving their study.

The panel discussed the role of the appeals process in relation to ethical review. MS felt that any appeals process should only focus on matters of procedure. However, the current appeals process was essentially a second ethical review.

The panel asked CC to research the legal basis for the current appeals process as set out in the Medicines for Human Use (Clinical Trials) Regulations 2004 and report back to the panel.

Action: CC

8. Feedback: Payments & Incentives

Received for Discussion:

- Collated Feedback regarding NREAP Guidance on 'Payments & Incentives'
- Email from Dr Thomas Kabir on behalf of the NIHR CRN: Mental health

- NIHR Guidance: “Recruitment of participants to research studies who are in receipt of state benefits: rules regarding payment for participation”
- NIHR Guidance: “Taking part in research? Here are some helpful benefit tips”

The panel were asked to consider whether they wish to revise their previous statement of 17 October 2012 regarding the provision of information to research participants on the effect of payment for research participation on 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). 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.

The panel questioned whether the information provided in the NIHR guidance was entirely correct. It appeared to equate payment for participation in research with employment. It was felt that assurances should be sought regarding the veracity of the information provided. AG commented that if both researchers and participants followed the guidance to the letter it would make it difficult for people to take part in research due to the time required to seek a response from the participant's benefit office (the NIHR guidance for participants suggests that "*you should wait for a reply before agreeing to go ahead*").

AG asked the panel whether they wish to revise their previous statement on this issue.

The panel felt that the NIHR guidance should not be endorsed or referred to by NREAP or the HRA at this time until further advice had been obtained. The panel asked CC to contact Dr Kabir to find out where the legal information contained in the guidance had been obtained from.

In the meantime the panel decided that the previous statement should be amended as follows:

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.

Action: CC

9. HRA Response - DH Consultation: 'Protecting Health and Care Information'

Received for Discussion:

- Department of Health Consultation 'Protecting Health and Care Information'

NREAP were asked to provide comments on this consultation as part of a coordinated HRA response (including the Confidentiality Advisory Group (CAG) and others)

AG stated that it needed to be clearer under what circumstances it would be *voluntary* for data to be shared and when it would be not. For example, in terms of case management (section 3, para 40) it would seem to be essential that such data is shared amongst those responsible for an individual's care, including the case manager, and seeking specific consent to do so would seem to be unnecessary.

SH commented that it would be useful if the term "research" was used more explicitly throughout the document given the importance of such activity to the NHS.

RL noted that whilst the setting up of accredited safe havens (ASH) was a welcome initiative the detail provided was somewhat vague. For example, in paragraph 23 the stipulation that once an ASH had been accredited via the approval of the Secretary of State it "*would then be permitted to process data for appropriate purposes without further approvals*" was not sufficiently explicit regarding what the term "appropriate purposes" encompassed. In addition, the document did not explicitly address the role of private providers of healthcare.

RL also commented that the use of civil penalties, involving relatively modest sums of money, would be unlikely to deter large organisations from breaching the regulations.

In terms of the governance of ASHs RL noted that it would be important for this to include an independent component and thus include the public and patients as well as other experts.

SW noted that the "right to be forgotten" enshrined in the proposed EU data regulation might cause problems, particularly with regards the provision of long-term healthcare.

With regards the specific questions posed within the consultation:

Q1: "Purposes".

- There needed to be greater explicit emphasis placed on "research".

Q3: "Controls".

- The need for independent governance should be emphasised i.e. inclusion of patients and the public.
- Civil penalties (£5000) would be unlikely to deter large organisations from breaching the regulations.

Q4: "Who might become an ASH?"

- There may be reputational issues around allowing commercial companies to become an ASH. Patients may be reluctant to allow data to be passed to such companies

10. HRA Response Health & Social Care Information Centre (HSCIC) Code of Practice on Confidential Information -

Received for Discussion:

- HSCIC Draft Code of Practice on Confidential Information*
- Online Survey Consultation Questions*

The panel were asked to provide comments on the attached draft Code of Practice as part of a coordinated HRA response (including the Confidentiality Advisory Group (CAG) and others) to be submitted by 18 August 2014.

Background (from HSCIC website: http://systems.hscic.gov.uk/infogov/codes/cop):

> "We are inviting a wide range of stakeholders to review and provide feedback on a draft code of practice on confidential information.
>
> The laws and duties imposed on those who handle confidential health and care information are numerous and have become increasingly complex over recent years.
>
> Under the Health and Social Care Act 2012, we are required to publish a code of practice and organisations that handle confidential information about the provision of health and adult social care in England are required to have regard to it.
>
> We published a Guide to Confidentiality in Health and Social Care in September 2013, which provides patients and health and care staff with clear, accessible guidance on the handling of confidential information.
>
> The code of practice aims to complete the picture, by providing good practice guidance to those responsible for setting and meeting organisational policy on the handling of confidential health and care information (e.g. board members).
>
> It is necessarily a legally-precise document, as organisations are required to have regard to it. However, the document clearly outlines the steps in the information-handling life cycle that organisations must, should and may take to ensure that confidential information is handled appropriately.
>
> The code will apply to any organisation that collects, analyses, publishes or disseminates confidential information, ranging from GP practices and hospital trusts to commissioners and research organisations.
>
> It will help organisations to ensure that the right structures and procedures are in place, to help front-line staff follow the confidentiality rules.
>
> To provide your feedback on the draft code of practice (PDF, 254.3kB), please complete our short online survey before 18 August 2014.
>
> We have also developed an interactive overview of the code which sets the scene for people who are not familiar with the content and provides the key messages. This

first iteration of the interactive overview will be developed into an e-learning package once feedback on the code has been received.

All of the feedback we receive will be considered and used to further develop the code and supporting materials, before they are published at the end of September 2014. We will also publish the results of this exercise to our website."
RL noted that the basis for the use of the words "should" and "must" was unclear and they appeared to be used randomly and interchangeably. It might be preferable to simply refer to the legal requirements in place (as used in their definition: "the word **must** is used in this document to identify a legal requirement").

SH noted that with regards the "restricted sharing of information" the statement made in paragraph 40 (c) (and 24 (c) and 25 (c))was problematic:

> *"the public good that would be served by disclosure outweighs the public good of maintaining public trust in the NHS and adult social care as confidential services, and an individual's right to confidentiality."*

It would be extremely unlikely that, in a single case, it would be true to say that disclosure would outweigh the public good of maintaining public trust in the NHS and adult social care. Also the "individual's right to confidentiality" is not simply related to a single individual but is a right held by everyone.

In paragraph 30 the assertion that

> *"analysis of data should: a. be consistent with scientific principles"*

might be true if applied to the analysis of data for the purposes of scientific research but it would not necessarily be true in cases where the data was being analysed for other (non-scientific) purposes.

11. Simple and Efficient Trials in the NHS - Obtaining Informed Consent by Simplified Means - Minimum Information Sheet

Received for Discussion:

- Draft Consultation Document 'Simple and Efficient Trials in the NHS - Obtaining Informed Consent by Simplified Means' **including "Example Information Sheet for Obtaining Informed Consent by Simplified Means"**

The panel were asked to comment upon the draft "**Example Information Sheet for Obtaining Informed Consent by Simplified Means**" contained in the draft consultation/guidance document (page 10) and consider the minimum information required for such trials.

SH pointed out that for cluster trials conducted under the forthcoming EU Clinical Trials Regulation paragraph 3 (d) of Art. 30 states that "*there are no interventions other than the standard treatment of the subject concerned*". This would conflict with the specific condition stated in the draft guidance that "*the study involves little or no deviation from usual care*"

On page 4 of the draft consultation document the statement that "*The seeking of consent in such a manner will only be allowed in specific circumstances and will not apply to other*

types of drug trials nor trials that do not involve drugs" should be amended to make it clearer that the provisions within the regulation related to obtaining consent by simplified means would not *prohibit* the use of such procedures in non-drug trials, rather the regulation simply does not *apply* to non-drug trials.

RL considered that the statement in the general principles that "*...consent should be sought where the patient has the possibility to decline the intervention*" should be removed as the patient always has the possibility to decline the intervention. MS agreed. AG clarified that patients need not be asked to consent to interventions that they would receive anyway, in the event that they consent to clinical treatment, rather consent needed to be obtained for data collection.

The second general principle that "the use of simplified informed consent procedures should not *solely* be determined by the level of risk involved in the research" should be removed.

RL felt that explicit scenarios might need to be provided regarded what would constitute "*little or no deviation*". For example, taking an extra blood sample.

MS questioned exactly what "*little or no deviation from usual care*" could be taken to mean in the context of the NHS where patients may well be offered different treatments by different GPs. Such deviation in treatments is "standard practice". The statement included in the specific conditions (paragraph 3.3) should be revised to better define what "usual care" means.

The specific condition that "*the trial does not negatively affect patients' prospects for good clinical outcomes*" should begin with "as with other studies" or similar as this applied to all clinical trials.

SH wondered whether the use of additional follow-up visits or scans purely for the purposes of research might mean the research would not qualify as a "simple and efficient trial". AG felt that this consultation was really about the provision of *proportionate* information dependent upon what the participant was being asked to do. As the research involved increasing deviation from the patient's standard clinical care then increasing information would need to be provided.

On page 11 the statement in the example information sheet that "you can request the better drug" should be changed to "you will be offered the better drug".

The paragraph in the example information sheet headed "how will my information be kept confidential?" Should be changed is currently the wording did not necessarily answer the question. A shorter formulation of this paragraph would be preferable.

It was felt that the statement provided in answer to the question "do I have to take part?" could simply say "no". CC pointed out that the clinical trials regulations require a statement to the effect that the participant can withdraw at any time.

AG wondered whether we should construct a radical short information sheet for the purposes of this consultation. He wondered if we could ask whether it was broadly acceptable to have an information sheet that we felt was ethical even if it was not entirely legally compliant, with much of the information being available via a website or other means. SH pointed out that under the clinical trials regulations there was a requirement for information to be "given" and this was different to information merely being made "available".

SH noted that the title of the consultation could remove the phrase "by simplified means" as the intention was to provide guidance on obtaining informed consent in simple and efficient trials.

12. Proportionate Review Service (PRS): No Material Ethical Issues Tool (NMEIT) and Prospective Collection of Tissue for Research

Received for Discussion:

- No Material Ethical Issues Tool (NMEIT) v3.5
- Proportionate Review- Frequently Asked Questions
- Email regarding the taking of tissue explicitly for research from NHS participants

The panel were invited to discuss the current version of the No Material Ethics Tool (NMEIT) specifically in relation to the issue of taking tissue specifically for research from participants identified via the NHS as identified in the accompanying email.

The current version of the NMEIT would not permit such studies to be reviewed by PRS.

The panel were asked to consider whether the NMEIT should be revised to accommodate such studies.

SH pointed out that the ethical issues involved in taking blood would alter depending on whom you were taking blood from. For example, researchers may want to take blood from people who may be unknowingly at risk of disease that could be potentially identified through the research or the blood might be taken from participants who were aware that they were at risk of a condition that was the subject of the research. The ethical issues are different in each case.

MS suggested that category 7 could be revised to state "minimally invasive basic science studies involving healthy volunteers *or patients*". It was felt that the statement should also include an example of the type of interventions that this would include such as "a single blood sample. This could either be included in the "research type" explanation or provided as a footnote to this.

The panel agreed and suggested that category 7 of the NMEIT might be revised as follows:

"minimally invasive basic science studies involving healthy volunteers or patients. (e.g. which involve the taking of a single blood sample or other similar minimally invasive intervention)"

13. The Training Needs of New REC Members – Hugh Davies

Received for Discussion:

- The Training Needs of New REC Members – PowerPoint Presentation

Hugh Davies presented the attached presentation at the meeting.

The panel provided feedback to HD on the issues contained within the presentation.

14. Online/Smart Phone Research

Received for Information/Discussion:

- Email sent to RECs regarding internet research guidance
- Ethical Decision-Making and Internet Research - Recommendations from the Association of Internet Researchers (AoIR) Ethics Working Committee (Version 2.0) (2012)
- British Psychological Society - Ethics Guidelines for Internet-mediated Research (2013)

The HRA is occasionally approached by researchers and REC members to enquire whether there is any guidance available related to online research or the use of smart phones/apps for data collection. In addition, a recent email was sent to all RECs from Biomedcentral asking for their views on a possible editorial policy on such research (N.B. it is not proposed that the panel respond to this specific request).

The panel were asked to consider whether there is a need to prepare specific NREAP guidance on this topic or are the ethical issues involved sufficiently addressed either by existing guidance related to "traditional" research methods, or specific "online" guidance.

SH noted that much Internet research would currently fall outside the remit of NHS RECs. In addition, he felt that many of the ethical issues raised by such research were neither novel nor unique to online research. Data protection issues often appeared to be the main concern.

The panel noted, however, that a level of anxiety existed amongst REC members regarding this type of research.

The panel agreed that it would be useful to address the issues raised by online research and the use of smart phones through training rather than specific guidance.

15. NREAP/Chairs Network Meeting Minutes

Received for Information:

- South West – 28/11/2013
- NE Yorkshire & The Humber – 09/04/2014
- East Midlands - 09/05/2014
- West Midlands – 15/05/2014
- East Of England – 10/06/2014

The panel discussed whether the NREAP/Chairs network meetings, as currently conducted, were an efficient use of both the panel's and the HRA's resources. It was noted that at some meetings very few REC members attended (particularly in regions that consisted of few RECs).

However, it was recognised that these meetings were useful *in principle* i.e. they provided useful communication links between REC members and the HRA and NREAP. It was felt that some thought may need to be given to future meeting formats and it was suggested that it might be more efficient to have North and South regional NREAP/Chairs Network meetings twice a year at which more than one NREA attended.

16. Any Other Business

NREAP: Review of Working Procedures

AG asked how the NREAs felt the panel was working. MB queried how items reached the panel's agenda. AG explained that items for discussion came through various routes including HRA Operations, REC chairs: either directly or through chairs network meetings, pharmaceutical industry via operations or through Janet Wisely and also items directly initiated by NREAs and the Secretariat.

RL felt that the panel should be engaged in more horizon scanning activity. She felt that, currently, the panel is asked to quickly reach decisions without sufficient options to appraise.

SW noted that, in terms of horizon scanning, big data and the sharing of such data would become increasingly more important.

MB felt that the publication of a clinical trial data, particularly in relation to phase 1 research, is an increasingly important issue for industry in the light of the transparency requirements of the forthcoming EU Clinical Trials Regulation. He also felt that the ethical issues related to gene silencing might be usefully addressed as this promising new therapy area is likely to increasingly be the subject of research and RECs would need to get to grips with the issues raised by such therapies. In particular, it would need to be decided whether such research would require review by a GTAC REC.

RL wondered whether it would be useful to hold an awayday for NREAs to both discuss future work and help foster internal relationships within the panel. AG also suggested that such an event might include an invitation to an external speaker to address the panel on potential new therapy areas.

17. Date of Next Meeting:

8th October 2014