National Patient Safety Agency

National Research Ethics Service

Minutes of the third meeting of the National Research Ethics Advisory Panel held on Monday the 23rd November 2009 at the Hotel Russell, Russell Square, London WC1B 5BE

Present: Professor Andrew George (Chair)
Jeremy Butler
Dr Sarah Dyer
Professor Peter Heasman
Professor John Saunders
Professor Nalin Thakker
Dr Richard Tiner
Dr Art Tucker
Professor Charles Warlow
Dr Frank Wells
Dr Simon Woods

In attendance: Dr Janet Wisely
Glyn Barnes
Sandra Holley for item 5
David Neal for item 12

1 Apologies: Professor Sue Wilson
Dr Hugh Davies

2 Notes of the second meeting held on the 13th October 2009 at the NPSA's Maple St offices

It was agreed that the notes of the second meeting held on the 13th October were a true and reasonable record.

3 Matters Arising

Item 2 Conflicts of interest

Andrew George reminded advisors that any conflict of interest should be declared.

Item 4 Nominated leads

Janet Wisely reported that confirmation from Marc Taylor, DH for the attendance of Frank Wells at the UKRIO Board meetings was still to be confirmed and agreed to follow up.

4 Revised Terms of Reference

Janet Wisely reported that letters to confirm indemnity for advisors had been sent last week to all advisors.

6 Update on NRES

Andrew George reported that he would be speaking at the NRES Conference on the challenges for the REC community.

8 Policy publication

Andrew George proposed that Hugh Davies' paper on the publication policy for research would be discussed at a future meeting

Charles Warlow drew the Panel's attention to a suggestion in a letter from Dr Rustam Al-Shahi Salman in Edinburgh to Janet Wisely. This was to the effect that rather than a 'before and after' design, randomised allocation to the fast track ethics review system vs the present system would provide a more robust estimate of its effectiveness. Charles Warlow added that Hugh Davies felt that with the present plan the results will be all too obvious and that randomisation would not be necessary.

4 Update on NRES

Janet Wisely presented an update on NRES business.

Organisational change

The REC changes had been communicated to REC members by letter.

The NPSA / SRES manager consultation had been completed and staff at risk had been notified with three staff given notice of redundancy.

The appointment process to available posts was ongoing with interviews next week.

Optional appraisals had been issued with closing dates for all before Chistmas.

Local staff consultation on REC centre moves was ongoing.

The NRES risk register had been updated to reflect risks to service delivery in this time of significant change.

AREC survey and event

Janet Wisely had attended the AREC Winter Conference on the 13th November.

AREC wished to have improved communications from NRES to their membership.

AREC had launched a survey to ascertain the views of REC members in response to the ongoing NRES merger and closures programme.

The rationale for change to the mergers and closures to RECs due to the reducing workload and the move towards REC Centres had been questioned by AREC although after discussion the proposals were supported and the consultation timeframes explained.

AREC would issue a statement of findings from their members on the changes to RECs proposed by NRES.

Ministerial Industry Strategy Group – Clinical research sub group and other feedback

Janet Wisely reported that feedback from the sub group was that the concern was still largely with R&D timelines, reduction in CTIMPs and start up and recruitment.

Other concerns for NRES was the consistent use of decision making options, consistency of letters and the need to meet 'minor' but from the researcher's perspective, unhelpful changes.

Business planning

Janet Wisely reported that the business planning cycle for next year had started with a meeting planned for the 21st January with Andrew George attending. Issues to be discussed were the use of decisions, consistency and increased member involvement. The highlights of the business plans would be shared with Advisors at the meeting on the10th February.

Chief Executive advert

Janet Wisely noted that the advert for the Chief Executive for the NPSA had been advertised on the 22nd of November.

5 NRES presentation – Quality Assurance Programme

Sandra Holley, Head of Quality Assurance gave a presentation on the current Quality Assurance Programme which included;

- Analysis of feedback from users of our service
- Analysis of Appeals and Complaints
- The Shared Ethical Debate Exercise
- Feedback from REC members
- The Accreditation of NHS RECs
- Development of Quality Control
- Delivery of QA Training to support the programme
- The IS0 9001:2008 certification of QA activities and the development of ISO 9001 compliant procedures for NRES
- The development of a Personal Development process for REC Chairs

The presentation would be circulated to advisors with the minutes.

Sandra Holley noted that the findings from feedback was positive and would welcome feedback and advice from the advisors to help with feedback to RECs on observing meetings, shared ethical debate, workshops, focus groups, the review of QA reports and the personal development and appraisal for Chairs.

Richard Tiner noted that from January, for doctors, revalidation and the role of the responsible officer would come into effect.

6 How best to achieve consistency and appropriateness of review

Andrew George suggested that there should be discussion on how best to achieve consistency and appropriateness of review at a future Advisory Panel meeting.

7 Communicating to RECs

Andrew George informed the advisors that a section on the NRES website had been created for NREAs.

Options for communicating to RECs also included use of the NRES News Letter.

Andrew George proposed that his newly created e-mail address andrewgeorge@nhs.net be used for REC members to raise concerns and issues.

Janet Wisely informed the advisors that this would be compatible with the NRES proposals to develop a framework for raising concerns.

Janet Wisely suggested that a section for members on the proposed NRES extranet could be an option and it was agreed that Art Tucker would be the

NREA to Chair a member reference group to advise on the development of a member extranet. Liz Clements, Project Manager was the NRES lead for this development.

Janet Wisely explained that it was planned for REC members to be able to access committee papers electronically and that members' e-mail addresses would eventually be used for communications from NRES.

8 The role of NREA Panel in endorsing or commissioning guidelines

Andrew George led a discussion on the role of the NREA in either endorsing or commissioning guidelines.

In discussion, it was agreed that guidance for professional groupings was already in place and that it would not be necessary for NREAs in general to commission or provide guidance. However, the use of FAQs as developed by Hugh Davies for some issues might be useful.

9 Report back from NREA leads

Jeremy Butler, as service user lead, gave a report on recent developments and explained that the last meeting of the NHS Service Users Advisory Group had been held on the 27th of October and he would chair a new group. .

This group would have a membership of twelve people to include users and carers, INVOLVE and research participants and would meet twice a year.

Jeremy Butler asked if it would be possible to audit the responses given to question 14.1 in IRAS that asks about how service users have been involved in the development of research projects. Janet Wisely agreed to check this and report back to Jeremy Butler.

10 Clinical Genetics

Andrew George raised an issue from a researcher in the field of clinical genetics. He had been advised by his REC that he would need to seek ethical approval for each separate disease he chose to research regardless of the similar approaches and methodology.

Nalin Thakker advised that although the REC was quite correct in the advice it had offered to the researcher, there was a further issue about the difficulty in distinguishing between research and diagnosis in clinical genetics which to some extent was a reflection of the limitations of the analytical technologies available.

Nalin Thakker did not feel that there should be special dispensation for groups of diseases as this would set a bad precedent. Thinking about how researchers could be helped in this situation within current operational protocols, Nalin Thakker felt that the Advisory Panel should advise researchers to seek a tissue bank generic approval from the HTA which would

permit research within a specified remit without requiring further ethics approvals for individual projects that fall within the remit.

It was generally agreed that this would be a sensible way forward and Nalin Thakker and David Neal would draft a statement to this effect for the Panel.

11 Fraud and misconduct register

The Fraud and misconduct register had been circulated to inform Advisors and for the next meeting Frank Wells would review with Janet Wisely and forward to the UKRIO.

12 Revision of the EU Clinical Trials Directive

David Neal introduced papers circulated on the review of the Clinical Trials Directive and the European Commission's public consultation paper.

David Neal explained that a UK position on the document and the specific questions posed by the Commission will be developed by the MHRA in consultation with the DH and NRES. In coming to a UK position views had been requested from RECs. Advisors were also welcome to comment either to David Neal, the MHRA or direct to the Commission.

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The response would include the view that a single ethical opinion for clinical trials undertaken in the Member States would be unacceptable and unworkable.

Frank Wells noted that a feature of the arrangements in the UK is that ethics committees were not expected to review SUSAR reports.

13 Any Other Business

There was no any other business.

14 Date of Next Meeting

The date of the next meeting would be the 13th January 2010 in room 6 at the Maple St offices.