



National Patient Safety Agency

National Research Ethics Service

Notes of the first meeting of the National Research Ethics Advisory Panel held on Wednesday the 23rd September 2009 at the NPSA's Maple St offices 4 – 8 Maple St London W1T 5HD

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

In attendance: Dr Janet Wisely
Glyn Barnes

Apologies: Professor Peter Heasman

1 Welcome

Andrew George welcomed the Advisors to the first meeting.

2 Conflicts of interest

Andrew George considered that any individual and particular conflicts of interest should be discussed openly by the Advisory Panel at the time of the meeting although recognised that general conflicts of interest were recorded as part of the application process. A register of conflicts of interest would need to be maintained, and updated on an annual basis. Dr Art Tucker declared a potential conflict of interest.

3 Terms of Reference

The Terms of Reference for the advisory panel had been circulated. Andrew George noted that the advisory panel had been constituted as part of the national framework at

the request of the Department of Health through UKECA to advise NRES on ethical review issues to include transparency and proportionate review.

It was agreed that the terms of reference should be re-examined after 6 months in the first instance, and then annually. It was agreed that in general Dr Janet Wisely (or her representative) would be invited to attend the meeting.

In reviewing paragraph 4, the tasks that the panel would undertake, the following were noted and agreed.

1. Arbitration on ethical debates and disagreements arising from appeals by applicants and from within RECs (supporting and extending the presently isolated role of the NRES Ethics Adviser) - agreed.
2. Oversight of the 'shared ethical debate' external quality assessment programme for RECs – agreed and Hugh Davies requested that an advisor be nominated to join the shared ethical debate group.
3. Oversight of NRES training programmes and training delivery as appropriate – agreed and proposed that advisors be identified for overseeing the training programme.

Oversight of personal development programmes for REC Chairs
4. Advice to RECs on action when they encounter alleged fraud or misconduct in research - it was agreed that the advice should be to NRES or RECs
5. Provision of legal guidance where necessary by having embedded legal expertise in health law – It was suggested that this be amended to indicate that the panel 'would provide guidance on governance issues, where necessary obtaining outside legal advice'.
6. Support for NRES with business planning and strategy – Janet Wisely explained that the advisory panel would help advise on strategic issues on business planning, especially if there were any particularly difficult decisions to be made by NRES.
7. Support for NRES with relationships with RECs – noted that NREAs would also support RECs in their relationships with NRES.
8. Support for NRES with relationships with other regulators, research funders, universities, professional bodies and industry – agreed and to include AREC.
9. Support for NRES with Patient and Public Involvement.
10. Support for NRES with media enquiries and response to news items or journal articles about RECs – agreed that Janet Wisely would lead with NREAs requested to contribute as appropriate.
11. Representing NRES at events and conferences – agreed
12. Facilitating NRES events - agreed as requested for NREAs to attend after discussion

13. Chairing ad hoc Advisory Groups – agreed to include working parties as appropriate.

In reviewing paragraph 5, mode of operation, it was agreed that the advisory panel would meet monthly in London, or if needed, elsewhere in the UK.

After discussion it was agreed that there was no requirement for quorate numbers for meetings of the Panel. However, if the Panel were to arbitrate on ethical issues and disagreements then two thirds of the membership should be involved. This could be by email or phone.

Janet Wisely, after helpful discussion on expenses, agreed to consider what was expected within the core role (volunteer and expenses) and what activity may attract additional payment. The advisory panel agreed that giving general advice and support was within their remit. Representation of NRES at specific events, by invitation of NRES, would be subject to optional payment at the NPSA daily rate. Training provision would be at the procured training rates. There would be some grey areas to manage, for example, expert advice on an application. It was agreed there should be discussion when advisors were asked for the expert review on how long it was likely to take and payment offered as NRES would with another expert reviewer if it was agreed it was a significant amount of time.

Janet Wisely agreed to confirm the indemnity for advisors, although it was likely to be the same for non – executive directors of NHS bodies.

4 Nominated leads for key areas of business

The nominated leads for key areas of business were discussed and agreed as follows;

NHS Service Users and Carers and Attendance at the NIHR PPI forum

It was agreed that Jeremy Butler would lead on the work of NRES to include service users, and carers, researchers and healthy volunteers to include chairing the standing group agreeing terms of reference, and the next and final meeting of the Advisory Group.

Training

It was agreed that Simon Woods and Nalin Thakker would lead on training issues for the advisory panel to include a monitoring role and briefs from the training steering group on activity, priorities and feedback plus a specific remit to deliver training on request.

It was agreed that Frank Wells and John Saunders would lead on personal development programmes for REC chairs.

Quality Assurance

It was agreed that Peter Heasman, Sarah Dyer and Sue Wilson would discuss with Sandra Holley, Head of Quality Assurance, how they could contribute to the quality assurance programme.

Queries

It was agreed that Charles Warlow and Richard Tiner would provide guidance on a proposal to set up a Queries Steering Group.

Policy

Nalin Thakker agreed to be the advisor lead on policy issues to work with David Neal, Head of Policy.

Fraud and misconduct

It was agreed that Frank Wells would lead on fraud and misconduct.

Attendance at UKRIO Board

It was agreed that Frank Wells would attend the UKRIO Board as required. The NRES fraud register would be shared with the UKRIO Board.

Attendance at AREC NHS advisory committee

It was agreed that John Saunders would represent the advisory panel on the AREC NHS advisory committee.

Attendance at a research summaries meeting 9th December

Andrew George agreed to attend the research summaries meeting on the 9th December to be chaired by Iain Chalmers.

5 Review of Membership

It was agreed that the terms of membership should refer to representation from social science.

As noted under item 6 terms of reference, outside legal advice should be sought if necessary and item 6 amended.

It was also agreed that the Panel would examine the membership after 6 months to identify any missing expertise, and annually thereafter.

6 Any Other Business

It was agreed that e-mail addresses and contact details of advisors would be re-circulated.

It was noted that the expenses policy would be in line with those for REC members and Chairs.

It was noted that training that is available to REC members and Chairs would also be available to the advisors.

It was agreed that the minutes and agenda of the Panel would be made publically available.

7 Dates of Next Meetings

The dates of the next meetings were agreed as follows;

Tuesday 13th October 2009 10.30 - 12.30 Room 7 at Maple Street
Monday 23rd November 2009 3.00 - 5.00 (the evening before the NRES
Conference at Hotel Russell)
Wednesday 13th January 2010 2.00 - 4.00 Room 6 at Maple Street.

Andrew George explained that it was then planned to hold meetings on the second Wednesday of each month 2.00 - 4.00. The meetings would either take place at the Maple St offices or at a venue nearby. Lunch would be available before the meetings.