



National Patient Safety Agency

National Research Ethics Service

**Minutes of the second meeting of the National Research Ethics Advisory
Panel held on Tuesday the 13th October 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
Dr Richard Tiner
Professor Charles Warlow
Dr Frank Wells
Dr Simon Woods

In attendance: Dr Janet Wisely
Glyn Barnes

Apologies: Professor Peter Heasman
Professor John Saunders
Professor Nalin Thakker
Dr Art Tucker
Professor Sue Wilson
David Neal

1 Welcome

Andrew George welcomed the Advisors to the second meeting.

2 Notes of the first meeting held on the 23rd September 2009

It was agreed that the notes of the first meeting held on the 23rd September were a true and reasonable record.

In reply to a request from Frank Wells, Andrew George agreed that as a formally constituted panel by NRES on behalf of the DH, the record of the Panel meetings should be titled minutes instead of notes.

The agendas and minutes would be published on the NRES website.

3 Matters Arising

Item 2 Conflicts of interest

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

Item 4 Nominated leads

It was noted that Sarah Dyer would be the third nominated lead on training for the advisory panel.

Frank Wells reported that he would be attending the UKRIO Board meetings following confirmation from Marc Taylor, DH.

4 Revised Terms of Reference

The revised Terms of Reference for the advisory panel had been circulated. Andrew George noted that reference should be made to NRES having appointed the Advisors.

Sarah Dyer noted that under membership, item 4 should read Social science.

Richard Tiner noted that item 5 should be revised to read UK ethics service.

Janet Wisely reported that confirmation on the indemnity of advisors had been sought from Marc Taylor, DH.

5 Report back from NREA leads and priorities

Andrew George proposed that a rota be produced for lead advisors to report on their activities and priorities at the advisory panel every three months.

6 Update on NRES

Janet Wisely tabled an update on NRES business.

Consultation on the changes to RECs for NPSA staff and SRES managers (NPSA and hosted) was launched on the 23rd September. Announcements on the outcome would be made after the 30th of October.

Written communications had been sent to: DH, SHA leads, NHS hosts, all staff and the REC community. All affected staff have scheduled 1-1 consultation meetings. Face to face briefing meetings had been held in all patches.

Responses from staff had been generally accepting and supportive with a professional response from staff who were affected by the proposals.

There had been 138 comments received from REC Chairs and members on the proposals for RECs which would be considered by DMG with likely announcements in December. Allowances were seen as a key issue. It was

proposed that all REC members should provide an e-mail address for direct communication.

Janet Wisely tabled a copy of research applications and reported on a meeting held to discuss pandemic flu. Research applications were to be considered by RECS, the MHRA and the CSP for prioritisation and an extended minute had been circulated to explain the process.

Janet Wisely presented the NRES Roadshow agenda which included an explanation of the NREA panel and a summary of the proportionate review pilot which included the no material ethics issues tool (NMEIT). It was agreed that Andrew George would draft a letter from the NREA panel to RECs to explain the Panel's terms of reference.

7 NRES presentation

Due to the unavailability of David Neal, Head of Policy, Janet Wisely took the opportunity to introduce the NRES Head office staff to the advisors.

The staff were;

Jenny Powell, Head of Business Unit
Doreen Sharpe, Training Delivery Manager
Stephanie Kraus, Business Manager
Sam Wigand, Project Support Officer
Sheila Reay, PA to the Director
Ben Redclift, Policy implementation Officer
Gavin Crump, Training Administrative Assistant
Carla Denny, Training Co-ordinator
Paula Myers, Business Support Officer

It was noted that claim forms had been sent to Advisors and that BACs forms were available on request.

Training could now be booked on line via the home page on the NRES website.

8 Policy publication

Hugh Davies introduced a paper on the publication policy for research proposals and results.

There was a need and moral argument for trial registration which was now accepted.

The outstanding issue now was the need to ensure public posting of protocols and results.

The paper was an attempt to provide RECs with questions to consider and pose to the researcher when reviewing a project.

A framework for RECs was proposed with the questions for consideration.

- Where will the trial be registered or how will it be publically accessible?
- Will research results be publically available?
- Where will the study results be reported?

The paper also outlined the evidence and argument for prior publication of protocols and provided guidance on a potential way forward.

Richard Tiner advised that there was a UK Gateway for registration of all trials.

It was accepted that the results of research should be in the public domain. It was agreed that there should be consideration of publishing the results of studies on line, possibly linked to summary of opinion. It was agreed that ways of monitoring publication of research results should be developed, and that RECs could have a role in scrutinising final reports. If data were available the Advisory Panel could review the publication history of a project.

It was agreed that this was a useful paper, and provided a good framework for the Panel to consider ethical issues.

NRES was asked to consider how RECs may monitor more closely publication of results.

9 Appeals register

Janet Wisely introduced the Appeals Register and explained that it was part of governance for NRES.

10 Any Other Business

Hugh Davies reported that he would bring back 'burning issues' from the queries line for the advisors to consider.

11 Dates of Next Meetings

The dates of the next meetings were noted as follows;

Monday 23rd November 2009 3.00 - 5.00 (the evening before the NRES Conference at Hotel Russell)

The second Wednesdays for 2010 have been booked as follows.

13th January room 6 Maple St.
10th February venue to be booked
10th March room 6 Maple St
14th April venue to be booked
12th May venue to be booked
9th June venue to be booked
14th July venue to be booked

11th August room 6 Maple St
8th September room 6 Maple St
13th October room 6 Maple St
10th November venue to be booked
8th December room 7 Maple St

The meetings will either take place at the Maple St offices or at a venue nearby.