



National Patient Safety Agency

National Research Ethics Service

Minutes of the fourth meeting of the National Research Ethics Advisory Panel held on Wednesday 13 January 2010, Room 6, NPSA, 4-8 Maple Street, London W1T 5HD

Present: Andrew George (Chair)
Frank Wells
Peter Heasman
Charles Warlow
Simon Woods
Sarah Dyer
Jeremy Butler
Hugh Davies
Art Tucker

In attendance: Dr Janet Wisely

By phone: John Saunders and Richard Tiner

1 Apologies: Nalin Thacker,
Sue Wilson
Glyn Barnes
Sandra Holley
David Neal

2 Notes of the third meeting held on the 23 November 2009 at the Hotel Russell

Approved with one edit to page 2 under policy publication to take out detailed comment on methodology. Revised minute to read:

Charles Warlow drew the panel attention to a suggestion in a letter from Dr Al-Shahi Salman in Edinburgh to Janet Wisely. The proposals were discussed and options on methodology and effectiveness discussed.

3 Matters Arising

HD advised of a meeting that will be hosted by NRES in April to look at measurement of outcome from REC review in terms of effective outcome to improve participant safety. The meeting will look at appropriate methodology, test ideas and seek collaboration. NREA panel agreed support to explore if tools could be designed to determine measurement of outcome. Support was given for the event and NREA attendance suggested.

PH advised the panel on a recent proposal to add observation of meeting to next SHED, opportunity presented as small number of flagged Prison RECs. NREA service user update – questions to 14.1 – JW gave high level brief on the responses and REC review of 14.1

Clinical Genetics – HD announced a one day training event – to be held in Manchester and London

4 NRES Director Update

JW provided an update on progress on organisational change, staffing, business planning meeting and strategic planning meeting.

All NREA are sent details of NRES training events. Clarification was requested on NREA requirement to attend NRES training, it was advised that all events optional unless a specific request to attend made through NREA secretariat.

5 GAfREC

JW gave update. The comment and consultation periods are closed. NRES is providing additional support to DH in collating comments and revising drafting. JW explained that harmonised version so will be for UK wide approval and is a DH document.

NREA considered the proposed revision by NRES on RECs and the Law, paper tabled. There was concern that the ambiguous draft issued for consultation has been subject to unhelpful different interpretations and has led to further publications suggesting a division of opinion within DH. Panel welcomed NRES revised drafting and considered it compatible with published joint letter on the matter.

Clinical trials update

JW – provided update on timing and meeting scheduled in February and attendance of REC representative, UKECA to nominate representative.

6 Strategic discussion

AG introduced the Leicester project findings and summary of opinion template for discussion. The NREA panel discussed the findings of the project, production of minutes and letters and how the template may be used to improve quality of review. JW clarified that the purpose of the template is to provide a framework for the published summary opinion, although the pilot had shown that use of the template does influence minutes and letters.

Views were offered for NRES consideration. The template categories were broadly welcomed, although it was suggested that greater emphasis on role to protect rights, safety, dignity and wellbeing could be made within the template. Some concern raised that may tempt the committee to consider issues outside of the key competences and this had been an early concern of Royal College. It was also acknowledged that it may not represent an exhaustive list and care would be needed to avoid a check list approach. There was suggested value in using the template for training and induction.

It was agreed that a key requirement is to be able to describe review and ethical comment in a defensible way. The NREA considered if the check list would help formulate the description of the opinion?

In summary, NREA support for NRES to proceed to take further action towards the publication of the summary of opinion. Agreement that the template was a good starting point and NRES should roll out the template to generate this summary of opinion, but continue to review use and options on generating the opinion. It was further agreed that further work was required on how the minutes and letters were generated and drafted. NREA requested that training provided for Chairs as well as coordinators.

JW agreed to share information from the minute training package
JW / HD to feed comments back to NRES DMG and training steering group

Action: JW/HD

7 Allowances paper

The paper was discussed and approach supported by NREA panel. The panel requested JW write to INVOLVE to note NREA support for work to further clarify and resolve issues around volunteering and payments for contribution for those on benefits.

8 Partnership document

Introduced by JW and welcomed and fully supported by the NREA panel. Some minor editing points offered:

‘Optimal time for decision before time keeping’

Add ‘working collaboratively’ in introduction

‘and Students’--- (not in particular)

9 Pandemic flu

Noted.

10 Any Other Business

Extranet – agreed benefit group focus for REC group Chaired by Art Tucker

The NREA panel considered the latest Christopher Roy-Toole article in Research Ethics Review regarding member indemnity. The DH view does not support Roy – Toole and no revision to terms and conditions is expected. While the weight of legal opinion is supportive of the DH view, the NREA panel considered that ultimately where legal opinion differed a definitive interpretation would only be achieved in a Court of Law. As the arguments presented by Roy-Toole were largely theoretical this was unlikely to happen.

The NREA panel recognises the risk that members may be concerned at Roy-Toole interpretation. The panel agreed they should consider again a response to the REC community if further reassurance was required.

11 Date of Next Meeting

The date of the next meeting would be the 10 February 2010, venue to be confirmed.