

## National Research Ethics Advisors' Panel

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

**Date:** 13 July 2011

**Time:** 11:00 – 12:00

**Venue:** The Seminar and Learning Centre (SALC 6)  
5th floor Sherfield Building  
Imperial College  
Exhibition Road  
South Kensington  
London SW7 2AZ

## MINUTES

1. Apologies: Hugh Davies; Sarah Dyer; Nalin Thakker; Sue Wilson

2. Declarations of Interest

There were none

3. Minutes of meeting held on 08 June 2011

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

### 4. Matters Arising

#### 4.1. CFS/ME Research

Richard Tiner drew the panel's attention to a recent article in the BMJ entitled "Living with CFS/ME"<sup>1</sup> by Ollie Cornes which he felt would be of interest. CC would circulate the article to the panel by e-mail.

It was also pointed out that the MRC has highlighted Chronic Fatigue Syndrome/Myalgic Encephalomyelitis (CFS/ME) as a high priority and will be making available up to £1.5M for new research into the mechanisms of CFS/ME. The MRC has also set up a new group, the CFS/ME Expert Group (chaired by Professor Stephen Holgate, chair of the MRC Population and Systems Medicine Board), to consider how new high-quality research into CFS/ME and partnerships between researchers already working on CFS/ME and those in associated areas might be encouraged.<sup>2</sup>

#### 4.2. Disruption of Research

Janet Wisely explained that she had met with Barbara Davies (Communications Director, Understanding Animal Research) to discuss possible ways forward with regards ensuring that medical research may be carried out without fear of harassment. This issue would be discussed further at a future meeting of the panel.

### 5. NRES Update – Janet Wisely

<sup>1</sup> BMJ 2011;342:doi:10.1136/bmj.d3836 (Published 22 June 2011)

<sup>2</sup> <http://www.mrc.ac.uk/Ourresearch/ResearchInitiatives/CFSME/index.htm>

JW informed the panel that the setting up of the Special Health Authority and the HRA was currently on track. The ALB Transition Programme team (part of the DH Transition Programme Board) are expected to approve implementation plans on 1 August.

JW continued to hold online webinars to update staff and members on the progress towards the setting up of the HRA and would augment this with a series of REC centre visits during July.

JW recently attended the 'Research Volunteers Workshop' hosted by UCL which attracted a wide range of people who had been involved in research. She explained that many of the participants stated that they would have been happy simply to have received a "thank you" letter from the researchers following the completion of their participation in the trial. In addition many attendees put forward the view that NRES and others should be "selling" the benefits of research as many felt that such benefits were often underplayed. She explained that Sir Iain Chalmers had drawn her attention to a previous trial involving a relatively small risk that had experienced low recruitment rates in the UK because that risk was given undue prominence in the participant information documents. JW would investigate further and supply details to the panel.

SiWo sounded a note of caution and explained that many participants often fail to appreciate the difference between what is 'research' and what is 'treatment' (the "therapeutic misconception") and that it is important for research participants to understand key concepts related to the conduct of research. JW acknowledged this but felt that the benefits of research were sometimes played down whilst the risks were highlighted. AT agreed and felt that RECs were often obsessed with protecting participants from things that they themselves were not concerned about e.g. data protection. As a consequence of this he felt that any vaguely optimistic statements placed in information sheets were routinely removed by RECs.

JW suggested that it might be useful for NRES to hold an event to explore and reflect upon these areas with other stakeholders.

CH commented that there appeared to be a definite tide towards re-addressing the "fetish" for consent and that the panel should anticipate this and review how research information is presented to participants and consent obtained. She emphasised the need for robust empirical evidence in this area to inform such a debate.

JS felt that this issue was about the culture of RECs. He felt that the REC community was out of line with the majority of professional bodies on this issue. Such professional bodies were moving towards the view that participation in research was a civic duty, particularly where there was genuine uncertainty regarding the best treatment. AG agreed but emphasised that we must always remember that RECs are charged with protecting research participants and therefore any duty on behalf of participants must be balanced by this need to ensure that they are adequately protected.

#### **Agreed:**

The panel agreed that it would be useful for NRES to host an event to explore these issues with other stakeholders

### **6. Future possibilities for NREAP: a discussion paper**

Received for discussion:

- "Future possibilities for NREAP: a discussion paper"

AG led a discussion on whether there might be a more efficient way to conduct business that makes best use of the expertise of the panel. Several possibilities were discussed, including reducing the frequency of the meeting, being bolder in the minuted statements and guidance, separating out strategy from business and using NREAs to work independently on specific issues. It was agreed that the NREA-hosted Chairs network meetings were a good way to gather opinion and issues.

**Agreed:**

It was agreed that the format of meetings should be explored further, particularly with regards the suggestion that longer meetings be held on alternate months but with specific ring fenced sections of the agenda for NRES business and other, more strategic, items.

There was general support for the suggestion that the panel engage more widely with stakeholders, including inviting others to address the panel, and for the idea that individual NREAs should consult on specific issues outside of the panel meetings in order to bring focussed, informed papers to the panel for debate.

Minutes of all NREA-hosted chairs network meetings would be brought to the panel for information.

**7. Any Other Business**

There was none.

**8. Date of Next Meeting:**

The next meeting of the National Research Ethics Advisory Panel will be held on 10 August 2011.

Time: 14:00 – 17:00

Venue: Ground Floor  
National Research Ethics Service  
National Patient Safety Agency  
4-8 Maple Street  
London W1T 5HD