

The main focus of this meeting is to bring together those involved in conducting medical device studies with members of the Research Ethics Committees who review device studies. In doing so, we hope that both parties will go away with a better understanding of each other's requirements.

Medical Device REC Applications

7 January 2010

Institute of Clinical Research, Bourne End

Objectives

- To help those conducting medical device research/studies complete research ethics documentation correctly, including the application form and patient/participant information sheets
- To provide insight into the ethical issues considered by RECs when reviewing a research application, specifically related to medical device applications.
- To bring together medical device applicants and REC representatives with the aim to promote understanding of each parties issues and challenges.
- To receive guidance from REC members in small group exercises.

Learning outcomes

- Learn how RECs review a medical device application form and participant information sheet
- Understand how RECs review ethical issues and reach decisions
- Understand how to complete the research ethics application form
- Understand better the issues surrounding medical device studies

Who should attend?

- Anyone involved in applying for ethical approval from an NHS REC for medical device studies
- Anyone involved in reviewing medical device REC applications.
- Medical device industry, NHS and researchers and REC members

Programme

- 09.30 COFFEE & REGISTRATION**
- 10.00 Welcome and Introduction** (*Hugh Davies, Chair*)
- 10.10 Group Introduction** with Work Group Facilitators
- 10.20 Demonstration:** The Research Ethics Application Form for Medical Device Studies (*David Neal, NRES*)
- 10.40 Introduction to Group Work** (*Hugh Davies*)
- 11.00 REFRESHMENT**
- 11.30 Group Work 1:** From Protocol to Application Form; *Using Medical Device study example* (*breakout tables*)
- 12.30 Feedback** from Group Work and Summary (*Plenary*)
- 13.00 LUNCH**
- 13.45 Presentation:** The National Research Ethics Service (*David Neal*)
- 14.15 Group Work 2:** Reviewing an Application Form and Patient Information Sheet; *Medical Device Example* (*breakout tables*)
- 15.15 REFRESHMENTS**
- 15.30 Feedback** from Group Work (*Plenary*)
- 16.00 Summary and Q&A** (*Hugh Davies*)
- 16.30 CLOSE**

Day Facilitators

- **Hugh Davies** – Chair, Research Ethics Adviser to NRES
- **David Neal** – Deputy Director (Policy) NRES
- **Janette Benaddi MICR CSci** – Chair, Institute of Clinical Research

Registration

To register to attend this informative event, log in to www.icr-global.org and click on "Book an event".

Prices

- ICR members: £50
- Non-members: £60

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