



Health Research Authority/National Research Ethics Service RECs and how they function

Sheila Oliver – Head of NRES

Objective

To provide a brief overview of the Health Research Authority and the National Research Ethics Service within it.

To advise delegates (who are not REC members) how Research Ethics Committees (RECs) work; their constitution and remit.



The Health Research Authority (HRA)

- Established as a Special Health Authority in December 2011 (will become an NDPB in January 2015). At its establishment NRES was the core delivery function.
- Its role is protecting and promoting the interests of patients and the public in health research, and streamlining the regulation of research (HRA assessment and Approval)



Functions of HRA in Care Act 2014

- Co-ordination and standardisation of practice relating to the regulation of health and social care research:
 - Reduce duplication
 - Streamline
- Guidance – including replacement of RGF – NHS and local authorities must ‘have regard’
- Promote transparency in research
- Confidentiality Advisory Group (CAG)



Vision and ambition

To make the UK a great place to do research, where more money invested in research goes into carrying out relevant, good quality research .

- Greater numbers of people can and do take part in health research, and continue to feel safe when they do
- Researchers find it easier to do high-quality, ethical research
- Less resource is invested in getting studies started
- Clinical trials are registered and research gets published
- The NHS appreciates the benefits of health research



The role of NRES

Protecting the rights, safety,
dignity and well-being of
research participants

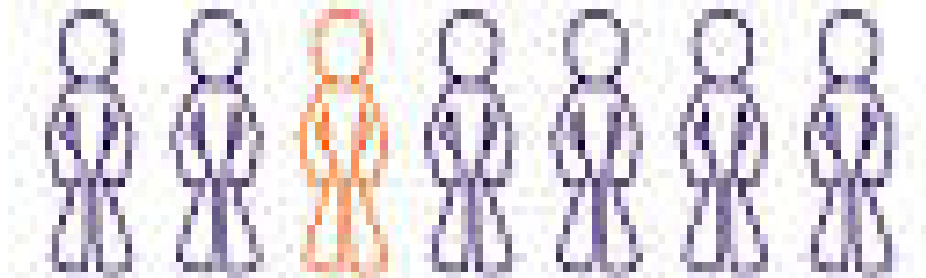
and

Facilitating ethical research



Research Ethics Committee (REC)

- Appointed by an NHS Appointing Authority
- Meet monthly (up to 11 times per year)
- Up to 18 Members appointed to a Committee
- Some expert (for example - doctors / nurses / pharmacists, professions allied to medicine, social scientists), some lay(+) (for example retired nurses, teachers, engineers, airline pilots) who work outside of healthcare and research), statisticians
- Approximately 12 expert & 6 lay (at least one third are lay members)
- Minimum of 7 members at a meeting (at least one lay member)



The work of NRES

- NRES' work is carried out through 68 Research Ethics Committees (RECs) which review and give an opinion on research applications
- REC members (1000) are a mixture of lay and expert volunteers and RECs are independent
- RECs are administered by REC Managers in 5 REC Centres in England



The Law, Guidance and RECs

RECs deliver an ethical opinion within a legal framework.

The next slide highlights key areas that impinge on research and the RECs' work.



The NHS Ethical Review Process

- Governance Arrangements for RECs (GAfREC)
- Research Governance Framework
- Standard Operating Procedures
- National Research Ethics Advisors' Panel Guidance



Relevant law

Handling personal data – the Data Protection Act and common law duty of confidentiality

Working with tissue – The Human Tissue Act 2004

European Clinical Trials Regulations – the UK Clinical Trials Regulations 2004 and amended 2006

Research involving those who lack capacity – the Mental Capacity Act 2005 (the Adult with Incapacity Act in Scotland 2001)



Research Ethics Committees

- Some Committees authorised to review Clinical Trials of Investigative Medicinal Products (CTIMP)



- Some Committees only review healthcare related research other than CTIMPs (for example – non drug interventional clinical trials / qualitative research)



- Some Committees have specialist experience in either paediatric research, medical device research, qualitative research, research involving adults who are unable to give consent



Research Ethics Committee – review process

- All studies booked centrally and allocated to an appropriate Committee
- Approximately 6 studies reviewed per meeting.
- Ethical opinion to be give < 60 days from receipt of the application (Medicines for Human Use (Clinical Trial Regulations) 2004)
- Target < 40 days.



Research Ethics Committee – review process

- Proportionate Review
 - Studies with no real ethical issues
 - Ethical opinion in < 14 days
 - Studies reviewed by 3 members (expert & lay members)
 - Approximately 20% of all studies reviewed this way



What does NHS ethical review involve?

- Ethics Committees consider applications under key ethical domains:
 - The validity of the research
 - » How important is the research question?
 - » Can the research answer the question being asked?
 - The welfare of the research subjects
 - » What will participation involve?
 - » Are any risks necessary and justified?
 - Dignity of the research subject
 - » Will confidentiality be respected?
 - » Will consent be sought?



What issues do RECs review?

- Relevance and value of trial
- Adequacy of peer review
- Risks and benefits
- Selection criteria
- Inclusion of minors or adults lacking capacity
- Approach to potential participants
- Information sheets and consent forms
- Consent process
- Notifying other professionals
- Rewards/payments to subjects
- Chief Investigator and sponsorship
- Conflicts of interest
- Insurance, indemnity and compensation
- Patient involvement, e.g. in trial design
- Trial registration and publication of results
- Protocol



Decisions available to the Committee (All NHS healthcare related research and all clinical trials MUST have a favourable ethical opinion before they start)



Favourable Ethical Opinion (or with additional conditions)



Provisional Ethical Opinion – further information needed



Unfavourable Ethical Opinion (option to appeal decision)



Research Ethics Committee

How do we know that the research is being conducted as it was approved and that participants' safety is being protected?



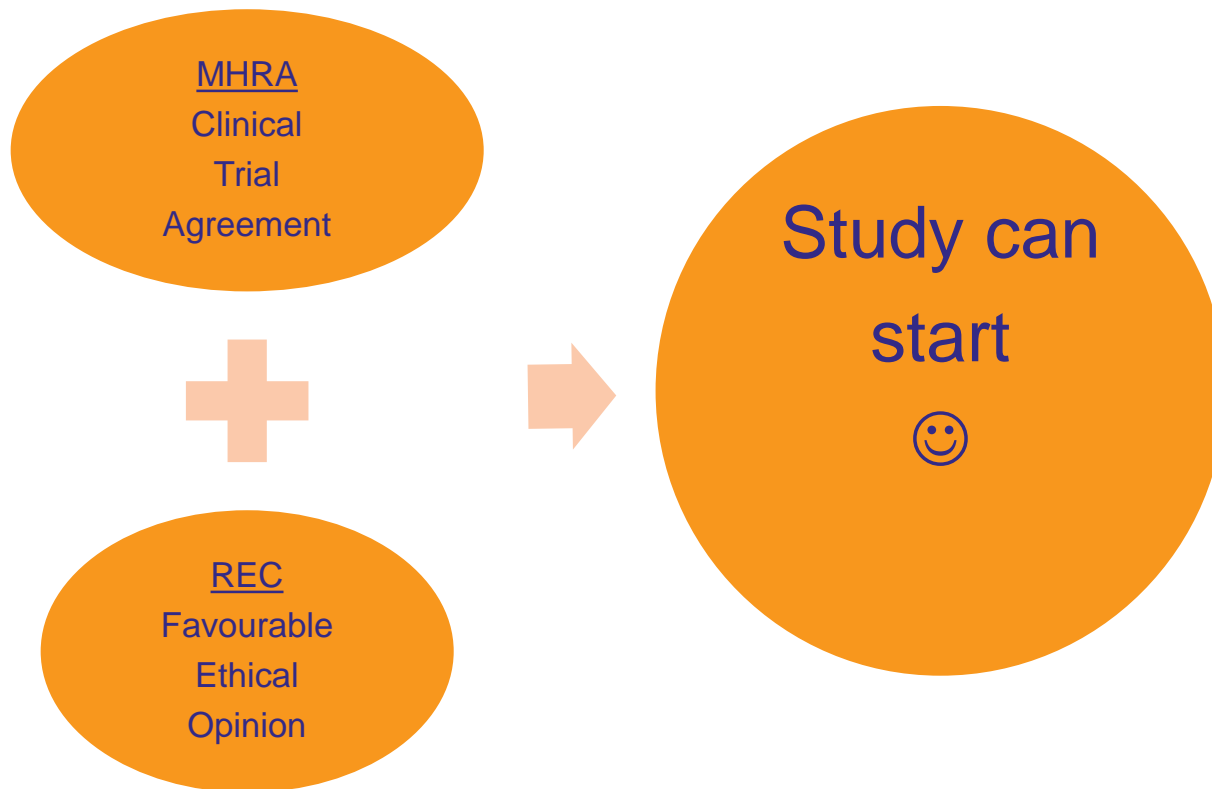
Research Ethics Committee

Amendments to research given a favourable ethical opinion

- Substantial Amendment
 - MUST have a favourable ethical opinion from the Ethics Committee before being implemented
 - Amendment which would change the research to a ‘significant degree’.
- Minor Amendment
 - Does not need to be notified to the Committee but may be notified for information only



Drug Trials



Any Questions?

- How do I become a member of a REC?
 - HRA Web-site
 - Ask for an application form (sharon.melbourne@nhs.net)
 - Attend a REC meeting as an observer

