Membership of a Research Ethics Committee

…the evidence you need

Helen Barlow

Library and Knowledge Service Manager, TRFT

My involvement

- Have served on Research Ethics Committees for over fifteen years
- Started on the Rotherham REC, now serve on the South Yorkshire REC
- Lay member (a term used to describe people who are not registered healthcare professionals and whose primary professional interest is not in clinical research – at least one third of members must be lay)
- Worked for a charity for people with head injuries.

Why are research ethics important?

- 1930s-1960s: untreated syphilis study in Tuskegee, South of America
- Human experiments throughout the Holocaust
- Prisoners & military personnel
- Pharmaceutical trials carried out in developing countries
- Up to the 1970s: studies of “treatments for homosexuality”
- Alder Hey Hospital scandal.

(Shaw, S et al. 2005)

Role of the Research Ethics Service

- Primary role is to protect and promote the interests of patients and the public in health research, and to streamline the regulation of research.
- In the UK, review by an ethics committee is one of a series of safeguards set out in a series of documents and guidance:
- Declaration of Helsinki (World Medical Association, as amended 2013) Sets out ethical principles for medical research involving human subjects, including research on identifiable human material and data.
- UK Policy Framework for Health and Social Care Research (HRA and the UK Health Departments, published October 2017)
- Governance Arrangements for NHS Research Ethics Committees: a harmonised edition (GAfREC) (Department of Health, published May 2011)

What research is considered by a REC?

- Potential research participants identified from, or because of, their past or present use of the NHS
- Potential research participants identified because of their status as relatives or carers of past or present users of the NHS
- Collection of tissue (i.e. any material consisting of or including human cells) or information from users of the NHS
- Use of previously collected tissue or information from which individual past or present users of the NHS could be identified.

Also where there is a legal requirement….

- Adults lacking capacity to give consent
- Processing confidential information without consent where this would otherwise breach confidentiality.
- Material consisting of or including human cells
- Patients who are cared for in private and voluntary sector nursing homes
- Exposure to ionising radiation
- Medical devices that are not CE-marked or have been modified or are being used for a new purpose
- Investigational medicinal products
- Protected information from the Human Fertilisation and Embryology Authority register.

To help researchers decide

- Is your project research?

  http://www.hra-decisiontools.org.uk/research/

- If research, does your research require NHS REC approval?

  http://www.hra-decisiontools.org.uk/ethics/

- If in doubt… R&D department

What happens at a REC?

- 64 RECs in England made up of between 7 and 18 volunteer members (lay and expert)
- Up to six studies reviewed per meeting – paperwork circulated to members in advance
- Lead reviewer presents study and discussion takes place
- Researchers are invited into the room to take questions
- Decision taken and relayed to the researchers by letter
- Up to 10 full committee meetings per year
- Members also take part in Proportionate Review sub committees.

What ethical issues are considered?

- Social or scientific value of the study
- Recruitment arrangements and access to health information, and fair research participant selection
- Favourable risk benefit ratio: anticipated benefits/risks for research participants (present and future)
- Care and protection of research participants
- Informed consent process and the adequacy and completeness of research participant information
- Suitability of the applicant and supporting staff
- Independent review
- Suitability of supporting information

How can we get involved?

…the evidence you need

Becoming a REC member

- The HRA are looking for people with a strong commitment to protecting patients and the public and also a commitment to promoting good ethical research.
- You will need to commit to attending monthly REC meetings, sub-committee work (2 or 3 times a year), undertaking induction and annual training.
- Becoming a REC Member HRA Web link

Supporting REC members within your organisation

- Further information on tests, procedures and methods used in the study
- Full text of articles to further explore the social or scientific value of the study
- Training on research methods and critical appraisal
- Support with five hours self-directed CPD – reading on research ethics, e-learning modules
- Updates on latest articles on research ethics.

Supporting researchers with research ethics

- Signpost to key websites including www.hra.nhs.uk; www.myresearchproject.org.uk
- Literature searches to establish what research already exists and evidence that the question is important and necessary
- Books on research ethics and research methods
- Space to conduct PPI.

References

- The Only Way is Ethics – presentation by Neil McCaffery, Deputy Regional Manager, Health Research Authority
- HRA website
- Shaw, S et al. Research Governance: where did it come from, what does it mean? J R Soc Med 2005;98:496-502.

The Rotherham NHS
NHS Foundation Trust

Library &
Knowledge
Service

Any questions?

…the evidence you need