BRITISH JOURNAL OF HOSPITAL MEDICINE
MMC Modernising Medical Careers

MODERNISING MEDICAL CAREERS

IN NEXT MONTH'S MMC SUPPLEMENT

Frequently used investigations: calcium and phosphate

Parathyroid surgery

How to insert a central line

Understanding the metabolic response to trauma

So you want to be... an otorhinolaryngologist

Research governance: a guide for the foundation year doctor

Introduction

The primary aim of research is to understand the aetiology and pathogenesis of disease and to improve prophylactic, diagnostic and therapeutic procedures. Continuous research is necessary for improvement of efficiency, effectiveness and accessibility of pre-existing procedures. Biomedical research has transformed medicine from a simple caretaking role to that of curing serious life-threatening diseases. Medical progress is based on research involving experimentation with human subjects (Schucklenk and Ashcroft, 2000; Beauchamp and Childress, 2001).

Research is performed because of this pursuit for knowledge with a reasonable balance of benefits to the subject and society over risk to the subject. Research participation places subjects at risk for the purpose of benefiting society in general. There are several historical examples which illustrate the reasons for the prominence given to research ethics, such as:

- The Nuremberg trial, which showed how Nazi doctors conducted medical experimentation in German concentration camps
- The Tuskegee syphilis study in which 400 impoverished black men diagnosed as having syphilis were left untreated to observe the natural course of the disease, leading to irreversible damage or even death (Beauchamp and Childress, 2001).

All such events triggered the international community to set up various regulatory frameworks and codes regulating the standards of research clinical trials. The Nuremberg code was the first international normative framework stressing strict requirements on voluntary consent. This was followed by the Declaration of Helsinki, a code for research and experimentation issued by the World Medical Association in 1964 and amended at various points since. This introduced 'best interests' criteria' that were supposed to apply to incompetent subjects and also raised questions over the applicability of informed consent standards to competent subjects. In 1993, the Council of Medical Organisations of Medical Science and the World Health Organization supported the Declaration of Helsinki.

Dr Walter Andreatta *is Foundation Year 2 Doctor,* **Ms Alka Kothari** *is Research Nurse and* **Miss Deepali Trivedi** *is Ophthalmologist, Sandwell and West Birmingham Hospitals NHS Trust, Birmingham B18 7QH and* **Dr Rachel Hooke** *is Working Time Directive (WTD) Implementation Manager, Airedale NHS Trust, Keighley, West Yorkshire*

Correspondence to: Miss D Trivedi

Research governance

Research governance is aimed at continuous improvement of standards and the reduction of unacceptable variations in research practice across health and social care. The aim of research governance is to:

- Set standards
- Define mechanisms to deliver standards
- Describe monitoring and assessment arrangements.

Research governance improves research quality and promotes good practice by enhancing ethical and scientific quality, reducing adverse incidents and preventing poor performance and misconduct (Department of Health, 2005).

Standards for research governance are based on five domains:

1. Ethics – the dignity, rights, safety and wellbeing of participants must be the primary consideration in any research study
2. Science – existing sources of evidence, especially systematic reviews, should be considered before undertaking research, in order to avoid unnecessary duplication
3. Information – free access to information, both on the research being conducted and on the findings of the research, once it has been subjected to appropriate scientific review

4. Health and safety – research may involve the use of potentially dangerous or harmful equipment, substances or organisms. The safety of participants and other staff must be given priority at all times
5. Finance – financial probity for the use of public funds in research is important.

Research ethics committees

The research ethics committee plays an important role in facilitating and promoting ethical research. The research must conform to recognized ethical standards, which include respecting the dignity, rights, safety and wellbeing of the people who take part and assuring scientific quality of the proposed research.

Each research ethics committee within the Research Ethics Service is made up of members of the public, as well as people with specific knowledge that can help the committee understand particular aspects of research proposals. All committee members are given training to understand research ethics.

Researchers must satisfy a research ethics committee that the research they propose will be worthwhile and safe. The committee has to be assured that any anticipated risks, burdens or intrusions will be minimized for the people taking part in the research and are justified by the expected benefits.

Responsibilities of people and organizations

Principal investigator and other researchers

- Developing proposals that are ethical and seeking research ethics committee approval
- Conducting research to the agreed protocol and in accordance with legal requirements and guidance, e.g. on consent
- Ensuring participant welfare while in the study
- Feeding back results of research to participants.

Sponsor

- Ensuring research ethics committee approval is obtained
- Ensuring that arrangements are in place for the management and monitoring of research.

Employing organization

- Promoting a quality research culture
- Taking responsibility for ensuring the research is properly managed and monitored where agreed with sponsor.

Protecting participants

Protecting participants' interests

- In medical research, the wellbeing of the human subject should take precedence over the interests of science and society
- It is the duty of the physician in medical research to protect the life, health, privacy and dignity of the human subject
- Medical research involving human subjects should be conducted only by scientifically-qualified people and under the supervision of a clinically-competent medical person
- Research into conditions not linked to incapacity should never be undertaken with adults who lack mental capacity unless it could be of direct benefit to their health or people with the same state of health (General Medical Council, 2002).

Protecting participants' autonomy

- No pressure should be put on the volunteer to participate in the research
- Ensure that the participants' right to withdraw from the research is respected at all times.

Consent

- The subject must be adequately informed of the aims, methods, source of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and the potential risks of the study.
- It must be ensured that the subject has freely given informed consent, preferably in writing. If consent cannot be obtained in writing, non-written consent must be formally documented and witnessed.

Data protection

The name, address and full postcode must be removed together with any other information which, in conjunction with other data held by or disclosed to the recipient, could identify the patient. Unique numbers may be included only if recipients of the data do not have access to the 'key' to trace the patient's identity.

Confidentiality

Any patient information which might be private and sensitive must not be given to others unless the patient consents or the disclosure can be justified.

Conclusions

Research is intended to benefit society and further the understanding of disease and aetiology. However, subjects' needs must be taken into account, hence a strict governance framework and code. Foundation doctors must be aware of these when participating in or conducting research. BJHM

Conflict of interest: Dr Hooke has worked in both management and medicine. Her views are her own and do not necessarily reflect those of her employer or any other organization that she is associated with.

Beauchamp TL, Childress JF (2001) *Principles of Biomedical Ethics.* 5th edn. Oxford University Press, Oxford

Department of Health (2005) *Research Governance Framework for Health and Social Care.* 2nd edn Department of Health, London (www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108962 accessed 12 June 2009)

General Medical Council (2002) *Research: The Role and Responsibilities of Doctors.* GMC, London (www.gmc-uk.org/guidance/current/library/research.asp accessed 12 June 2009)

Schucklenk U, Ashcroft R (2000) International Research Ethics. *Bioethics* **14:** 158–72

World Medical Association (1964) Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects (as amended at the 52nd WMA General Assembly, Edinburgh, Scotland, October 2000). http://www.wma.net/e/policy/b3.htm (accessed 6 July 2009)

KEY POINTS

- Research is important for progressing in understanding disease and devising treatment.
- Governance controls are in place to prevent subjects being exploited or disadvantaged, as in the past.
- Confidentiality and ethics must be adhered to.
- Appropriate consent must be obtained.
- Doctors must follow General Medical Council guidance in relation to research.