

Letter to the Editor . . . and his reply

The Journal received the following communication from Kate Casey and Andrew Smith of the Research and Development Department in respect of an article published in the last issue. The letter is reprinted in full and the editor accepts full responsibility for the error in methodology and reporting to which the correspondence refers. He wishes to apologise for the error and reassures the readership that editorial policy now reflects the views stated below.

Dear Editor,

The May 2005 issue of the Morecambe Bay Medical Journal included a research article by Meena Agarwal (p308-312). The article states:

'This was not a randomised double blind control clinical drug trial in an experimental setting putting children at risk of having potentially serious side effects, and these children were not directly involved in this study without the involvement and permission of their parents. This is why it was not considered necessary to seek the approval of the Ethics Committee.'

It must be stressed that the implications of this statement are erroneous. All research being carried out in the NHS requires two forms of approval, namely R & D approval from the trust(s) where the research is to be carried out and approval from a Research Ethics Committee.

Decisions about whether a project/study needs ethical approval should not be taken by individual researchers. Advice can be obtained from R & D departments and/or Local Research Ethics Committees.

What is Research?

Research can be defined as a structured activity which is intended to provide new knowledge which is generalisable and intended for wider dissemination.

Research is not just about randomised double blind control clinical drug trials but encompasses basic science, experimental medicine, clinical trials, health technology assessment, service delivery and preventive care/public health.

Research Governance

The Research Governance Framework for Health and Social Care (DH 2001)⁽¹⁾ was introduced as a guide for good practice for all research activity within health and social care and to ensure that the public can have confidence in and benefit from quality research.

The Research Governance Framework was introduced partly as the result of scandals such as Alder Hey (storing of organs for research) and North Staffs (research into a new type of incubator in a special care baby unit).

Individuals who embark on research projects without the requisite approvals put both patients and themselves at risk.

Ethics

'Ethical advice from the appropriate NHS REC is required for any research proposal involving:

- a) patients and users of the NHS. This includes all potential research participants recruited by virtue of the patient or user's past or present treatment by, or use of, the NHS. It includes NHS patients treated under contracts with private sector institutions
- b) individuals identified as potential research participants because of their status as relatives or carers of patients and users of the NHS, as defined above
- c) access to data, organs or other bodily material of past and present NHS patients
- d) fetal material and IVF involving NHS patients
- e) the recently dead in NHS premises
- f) the use of, or potential access to, NHS premises or facilities
- g) NHS staff – recruited as research participants by virtue of their professional role.'⁽²⁾

R & D Department Contact

There is a committee which gives R & D approval for research projects to be undertaken in Morecambe Bay Hospitals NHS Trust and Morecambe Bay Primary Care Trust.

The administrator for this committee is:

Shirley Richardson

R & D Department

Royal Lancaster Infirmary

LA1 4RP

Tel 01524 583917 Fax 01524 847535

Email Shirley.Richardson@mbht.nhs.uk

Shirley is happy to answer queries about R & D issues or forward them to the relevant person in either Trust.

Useful Websites

www.rdfunding.org.uk/flowchart/Ethics.htm

www.corec.org.uk/

www.dh.gov.uk/PolicyAndGuidance/ResearchAndDevelopment/fs/en

www.rdforum.nhs.uk/home.htm

REFERENCES

1. Research Governance Framework for Health and Social Care. 2nd Ed., London: Department of Health; April 2005
2. Governance arrangements for NHS Research Ethics Committees, London: Department of Health; 2001