



## DEPARTMENT OF HEALTH AND SOCIAL SECURITY

To: Regional Health Authorities  
Area Health Authorities  
Boards of Governors

June 1975

**SUPERVISION OF THE ETHICS OF CLINICAL RESEARCH INVESTIGATIONS  
AND FETAL RESEARCH****Summary**

This circular encloses at Appendix A a copy of the text of the 1973 Report of a committee of the Royal College of Physicians on the Supervision of the Ethics of Clinical Research Investigations and advises Health Authorities on the implementation of the recommendations in the Report. It also reminds authorities of a recommendation of the Advisory Group on the Use of Fetuses and Fetal Material for Research.

**Introduction**

1. General advice on the supervision of the ethics of clinical investigations was given in an earlier Report issued in 1967 by the Royal College of Physicians of London and drawn to the attention of Hospital Authorities in HM(68)33. In the 1967 Report the College recommended that in medical institutions where clinical research is carried out all projects should be approved by a group of doctors including those experienced in clinical investigation. The 1973 Report, which uses the term "clinical research investigation" to cover all forms of experiment in man, includes detailed recommendations on the composition and scope of such ethical committees.

**Composition**

2. The Secretary of State accepts the College's recommendations on the composition of ethical committees and asks Area Health Authorities and Boards of Governors to review with the medical staffs concerned the composition of ethical committees and to arrange for any changes which may be needed to put these recommendations into effect. The Secretary of State asks Area Health Authorities to consider choosing a member of the appropriate Community Health Council, as a lay member.

**Scope**

3. Health Authorities are asked to note particularly *and to bring to the attention of medical staff* the College's recommendation that *all* proposed clinical research investigations should be referred to an ethical committee. The issue of a clinical trial certificate under the Medicines Act 1968 does not mean that the licensing authority or the Committee on Safety of Medicines have considered the ethical aspects of the proposed trial. This applies whether the trial is undertaken at the instance of a pharmaceutical company, or on a doctor's own initiative.

4. Attention is also drawn to the Royal College of Physicians' recommendation that clinical research investigation of children or mentally handicapped adults which is not of direct benefit to the patient may be conducted only when the procedures entail negligible risk or discomfort and subject to the provisions of any common and statute law prevailing at the time and with the consent of the parent or guardian. Health Authorities are advised that they ought not to infer from this recommendation that the fact that consent has been given by the parent or guardian and that the risk involved is considered negligible will be sufficient to bring such clinical research investigation within the law as it stands.

5. The views of the Medical Research Council with regard to clinical research investigation of minors and mentally handicapped adults at present remain as set out in their 1962-63 Report (Cmnd 2382) of which an extract is given in Appendix B to this memorandum.

## Approval by Ethical Committees of Fetal Research

6. The Secretary of State wishes to remind Health Authorities that the Advisory Group on the Use of Fetuses and Fetal Material for Research, the report of which was sent to hospital authorities on 23 May 1972, recommended in paragraph 47 that all research using the fetus or fetal material should be approved by the ethical committee, who should use as a guideline a Code of Practice set out in the report. Paragraph 2 of the Code of Practice proposes that the minimum limit of viability be regarded as 20 weeks gestational age, corresponding to a fetal weight of 400-500 grammes. This was taken into account by the Committee on the Working of the Abortion Act who in their Report recommended an upper time limit for therapeutic abortion of 24 weeks. Since, however, the Code of Practice recommends that no fetuses other than previable ones weighing less than 300 grammes be used for research, its adoption should not be affected by these considerations

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## ROYAL COLLEGE OF PHYSICIANS

## SUPERVISION OF THE ETHICS OF CLINICAL RESEARCH INVESTIGATIONS IN INSTITUTIONS

In 1967 the College published the Report of the Committee on the Supervision of the Ethics of Clinical Investigations in Institutions. The present document gives the more detailed recommendations of the College on the composition and scope of ethical committees, as requested by the Chief Medical Officer.

## INTRODUCTION

The object of ethical committees is to safeguard patients, healthy volunteers and the reputation of the profession and its institutions in matters of clinical research investigation. This term is regarded by the College as covering all forms of experiment in man and is preferred to 'clinical investigation' since this is liable to be misinterpreted. Clinical research investigation includes studies, whether therapeutic, non therapeutic or diagnostic on patients or on normal subjects, and it also includes teaching exercises with students. It does not include the use of new or unestablished procedures intended to benefit an individual patient. This, as always, is a matter for which the consultant in charge accepts responsibility.

## COMPOSITION

To function efficiently ethical committees should be small and they must not be so constituted as to cause an unreasonable hindrance to the advancement of medical knowledge. The medical members should be experienced clinicians with a knowledge of clinical research investigation and in addition there should be a lay member. By layman we mean an individual who is not associated with the profession in any paramedical activity ie a biochemist or a psychologist would not be considered as a layman for this purpose. It is envisaged that the committee will sometimes have to seek expert help from specialist outside sources, for instance to ensure that a complex technique is being used ethically, but the College does not recommend the setting up of a central body to provide advice in difficult cases.

Supervision of ethics should normally be the sole function of an ethical committee, which might be a sub-committee of an established body, eg the Medical Advisory Committee, (or its functional successor) but an MAC as such is considered to be too large.\* An ethical committee is ultimately responsible to the managing or governing authority of the hospital or institute, as the case may be.

## SCOPE

Experience has shown that there is often uncertainty about the procedures that should be referred for approval, and the College is therefore of the opinion that applications should be made to an ethical committee for all proposed clinical research investigations. In this connection it should be noted that the fact that a drug has been granted a Clinical Trial Certificate or a Product Licence by the Licencing Authority (under the Medicines Act, 1968) on the recommendation of the Committee on Safety of Medicines in no way absolves the ethical committee from investigating the ethical aspects of that trial.

## EXPLANATIONS TO SUBJECTS OR PATIENTS WHO MAY PARTICIPATE IN CLINICAL RESEARCH INVESTIGATIONS

(a) *Patients*. Wherever the research investigation is not expected or is not intended to benefit the individual, a full explanation of the proposed procedure should be given and the patient must feel completely free to decline to participate or to withdraw at any stage.

Except for trivial procedures, eg venepuncture, an explanation should be given by a responsible person in the presence of a witness and the agreement of the subject or patient should be recorded with the signatures of the person who gave the explanation and of the witness.

Where the research is intended to benefit the patient, although consent should ordinarily be sought, there are sometimes circumstances in which it is inappropriate or even inhumane to explain the details and seek consent. Ethical committees should examine such cases with particular care.

\*The matter should be given further consideration in April 1974 and it may be that Area Health Authorities in non-teaching localities will at that time assume responsibility for setting up ethical committees. In AHA(T)s (teaching hospitals) where there may be more than one teaching hospital, as in London, the ethical committee should probably continue on an individual hospital and medical school basis.

If advances in medical treatment are to continue so must clinical research investigation. It is in this light therefore that it is recommended that clinical research investigation of children or mentally handicapped adults which is not of direct benefit to the patient should be conducted, but only when the procedures entail negligible risk or discomfort and subject to the provisions of any common and statute law prevailing at the time. The parent or guardian should be consulted and his agreement recorded. In the case of research procedures which may be of direct benefit to the patient, the ordinary criteria for other patients would apply.

(b) *Other subjects.* Consent, as in paragraph (a) above, should be sought. Freedom to refuse to participate or to withdraw at any stage is particularly important where the subjects are in any sort of dependent relationship to the investigator, eg students, laboratory technicians. Rarely, eg in certain psychological investigations, the seeking of consent would invalidate the investigations. Where this is thought to obtain, the investigations must be of a kind that cannot harm the subject and ethical committees should look particularly closely at such proposals.

## APPENDIX B

### EXTRACT OF REPORT OF MEDICAL RESEARCH COUNCIL FOR 1962-63 (CMND 2382)

The situation in respect of minors and mentally subnormal or mentally disordered persons is of particular difficulty. In the strict view of the law parents and guardians of minors cannot give consent on their behalf to any procedures which are of no particular benefit to them and which may carry some risk of harm. Whilst English law does not fix any arbitrary age in this context, it may safely be assumed that the Courts will not regard a child of 12 years or under (or 14 years or under for boys in Scotland) as having the capacity to consent to any procedure which may involve him in an injury. Above this age the reality of any purported consent which may have been obtained is a question of fact and as with an adult the evidence would, if necessary, have to show that irrespective of age the person concerned fully understood the implications to himself of the procedures to which he was consenting.

In the case of those who are mentally subnormal or mentally disordered the reality of the consent given will fall to be judged by similar criteria to those which apply to the making of a will, contracting a marriage or otherwise taking decisions which have legal force as well as moral and social implications. When true consent in this sense cannot be obtained, procedures which are of no direct benefit and which might carry a risk of harm to the subject should not be undertaken.

Even when true consent has been given by a minor or a mentally subnormal or mentally disordered person, consideration of ethics and prudence still require that, if possible, the assent of parents or guardians or relatives, as the case may be, should be obtained.

Investigations that are of no direct benefit to the individual require, therefore, that his true consent to them shall be explicitly obtained. After adequate explanation, the consent of an adult of sound mind and understanding can be relied upon to be true consent. In the case of children and young persons the question of whether purported consent was true consent would in each case depend upon facts such as the age, intelligence, situation and character of the subject and nature of the investigation. When the subject is below the age of 12 years, information requiring the performance of any procedure involving his body would need to be obtained incidentally to and without altering the nature of a procedure intended for his individual benefit.