Psychiatric Bulletin (1990), **14**, 48–61

The College

Guidelines for Research Ethics Committees on psychiatric research involving human subjects

Research is as essential in psychiatry as in any other branch of medicine. While there are ethical problems in carrying out research, it is unethical for the profession to fail to do research because this deprives present and future patients of the possibility of more informed and better treatment as well as the (more distant) prospect of prevention of psychiatric disorder. Since much psychiatric research can be carried out only with patients or healthy human subjects, it is important to consider the ethical problems involved in such research.

In most respects, the ethical problems of psychiatric research resemble those of research in general medicine. The majority of psychiatric patients are as capable of giving consent as are other patients. Also, these problems are to do with balancing the possible benefits from an increase in knowledge against the possible harm that might occur in the research; and the person's right to take part in research against his right to be able to refuse to take part. The general issues in medical research are discussed thoroughly in a report of the Royal College of Physicians (1990), and it is not necessary to repeat all these arguments and conclusions here. However, the College of Physicians' document does not address in detail some problems that are particularly important in psychiatric research with adults or with children. It is the special problems that are the principal concerns of the present report which, like the College of Physicians' report, is directed to the conduct of Ethics of Research Committees. *It is emphasised that members of Ethics of Research Committees should be familiar with, and follow the advice in the document of the Royal College of Physicians of London in addition to the present guidelines.*

Definition of research

To decide what activities should be subject to the scrutiny of these Committees, it is necessary to consider how research is to be defined. Research can be defined in more than one way. One set of definitions is concerned with procedures: for example, systematic enquiries based on scientific principles resulting in accurate data. Another set of definitions depends on the intentions of the person carrying out the research: for example, the intention of adding to knowledge about a condition and its treatment rather than the sole intention of assisting the recovery of the person taking part. From the standpoint of ethics of research, an intentional definition is more useful because it covers all the enquiries that should go to an Ethics of Research Committee. Its disadvantage is that it also includes some inquiries that have minimal ethical problems, for example observations by nurses of the behaviour of patients in hospital. In fact such studies can be identified without difficulty, and it is better to have a criterion that is over-inclusive in this way, than one that fails to identify cases which are the proper concern of an Ethics Committee. The definition appropriately excludes the everyday evaluation of routine clinical practice.

The tasks of the Ethics of Research Committee

The essential tasks of the Committee are three in number: to balance the benefit of the likely advance in knowledge against the discomforts and risks of taking part in the research; to ensure appropriate confidentiality; and to decide whether and how the subjects of research will be able to give free informed consent. It is important that the Committee's decisions are seen to be unprejudiced and adapted to the particular group of patients and research. They should be educative to applicants whose proposals are turned down.

Weighing benefit, discomfort and risk

Part of the difficulty in assessing the potential benefit of research is that it requires a scientific judgement, and an Ethics Committee is not constituted as a scientific review body. Even if some of its members are scientists with relevant knowledge, others will be laymen. In many cases, the Committee will have available an assessment of the scientific merit of the proposal made by a Research Council or comparable body to which the work has been submitted for funding; in other cases it will have to form its own view, if necessary with advice from outside experts. There are three questions to be answered in deciding the likely benefit from a piece of research. The first is whether the research is likely to solve the problem that is being

addressed. The second question is whether there is an alternative feasible way of obtaining the knowledge that is more acceptable ethically. The third question is what benefits are likely to follow the increase of knowledge. Benefits can be to the person concerned, or to the class of patients concerned. These benefits are not limited to an immediate improvement in treatment; increased understanding of psychiatric disorder is another important benefit.

In all cases, the Committee should make a careful assessment of the discomforts and risks of harm from the research. In judging these it is useful to consider (a) how *invasive* the research will be (for example intravenous infusions), and (b) how *intrusive* it will be (for example by asking about details of intimate behaviour). The assessment of risk of harm may require additional information from the applicants or external advice, for example about the possible hazards of a new drug.

Confidentiality

It is essential to preserve confidentiality. The interviewer should indicate clearly to the subject which persons might receive information from the research (this point is elaborated below). Ethics of Research Committees should satisfy themselves on this point and also ensure that the degree of confidentiality and the means of achieving it are appropriate.

Some special problems arise. Investigations using case notes are likely to contain personal information that is not essential to answer the research questions, and similar problems may arise with computerised records. The confidentiality of such information should be safeguarded, and precautions taken to ensure that identifying data are never revealed beyond the research unless the person has given consent. In publications requiring illustrative case histories it may be necessary to change some personal details to remove the chance of recognition of an individual case, with a note to this effect. If this cannot be done, the patient's consent should be obtained, after a full explanation.

Interviews seeking details of personal circumstances and behaviour are a part of much research into psychosocial aspects of psychiatry. Some genetic studies may involve interviews with relatives who may not previously have known the patient's illness. Appropriate consent should be obtained for these procedures.

Difficulties arise when, in a research interview, information is obtained that should be passed on: for example, a statement of suicidal intent or plans to harm another person. In these circumstances, the interviewer should apply the principles generally agreed for dealing with the problem when it arises in a clinical interview. These principles are to try to persuade the interviewee to reveal the information to the appropriate person (usually the family doctor) and, if this fails, weigh carefully the risks of failure to disclose against the duty to keep confidence. The Ethics Committee should consider whether it is appropriate for the interviewer to explain, before the interview, that these and perhaps other kinds of information would be communicated to the general practitioner.

Consent

The third task is to establish whether consent will be free and informed. Unless this is established the research should not be carried out, except in certain special circumstances when the patient is unable to give or withold consent (see below under 'incompetent patients'). This is a complicated matter and it is not possible to construct detailed guidelines to cover every case; it is more useful to list questions that should be asked about every project. These questions are: how much information should be given to the subjects? What could prevent the subjects from understanding this information? Will subjects who have acquired the appropriate information be able to decide freely whether to take part? Some issues raised by each of these questions require discussion. Of course in some projects additional special questions may arise.

Information

The main purpose should be explained, and important risks should be made clear. There can be no general rule about the exact extent of the risks that should be explained. The Ethics of Research Committee can apply commonsense criteria to decide what level of risk would be likely to affect a reasonable person's decision. Assessment of the level of risk should include not only the probability of an adverse event but also its seriousness.

A special problem arises occasionally with research designs involving incomplete disclosure of information (this kind of design is used in some psychological investigations). In these cases, the important question is whether knowledge of the retained information would be expected to alter the subjects' decision about taking part in the research; if it would, the research should not be carried out.

Understanding

Several factors can prevent a person understanding the information given. First, it may not be sufficiently clear or complete; or it may be given at a time when the subject is unable to concentrate adequately upon it. Second, the subject may have a special difficulty in understanding caused, for example, by anxiety, depression, low intelligence, or dementia. It is important to remember that although serious mental illness may impair understanding in some cases, it does not necessarily have this effect.

Decision making

Several factors can affect the ability to decide freely after having acquired appropriate information about the research. There may be covert pressures to take part, for example to please a doctor who has helped, or might help the person: this problem might arise between a patient and a doctor or, in forensic psychiatry research, between a prisoner and a research worker who is perceived as being able to influence the prisoner's future; or between a senior member of staff and students or employees. It is good practice to allow a period for reflection between the explanation of the study and the final decision. Usually this period should be about a day, though in exceptional cases it may be impractical to wait so long. It is often appropriate to provide written information to remind the person of the discussion with the research worker. This written information should be accompanied by a spoken explanation and an opportunity for the person to ask questions. It is important to explain that consent can be withdrawn at any time, without affecting in any way the patient's usual treatment, the prisoner's sentence, or the career of a student or employee.

The payment of fees to healthy volunteers or patients could affect their decision to take part in research. In general, fees should not be paid nor should reward in kind be given. Expenses should be limited to an amount sufficient to recompense actual losses incurred in taking part in the research.

Features of the *mental state* are relevant to decision making. Delusions can affect a patient's ability to decide whether to take part in research, but neither delusions nor other psychotic symptoms necessarily do so. There is no general state of incompetence to consent: the matter has to be decided knowing the nature of the decision to be taken and the influence that the delusional belief would be expected to have on the decision. Thus a patient with depressive delusions might consent to research that he considers unpleasant and hazardous because he believes that he is unworthy and should be punished. However, other kinds of delusion need not affect the person's decision.

Other aspects of the influence of mental state on decision making are discussed under 'incompetence'. Developmental age is also relevant to decision making; this issue is considered later in the section on research with children.

Special problems

1. *Detained patients*

When a patient is detained in hospital under the Mental Health Act, particular care should be taken in relation to informed consent. However, it would not be ethical to deprive automatically all detained patients of the opportunity to contribute to research that could improve their own or other patients' care in the future. In these cases, the task of the Ethics Committee is to answer the same questions as apply to non-detained patients, paying particular attention to the special circumstances of the detained patient, the nature of the illness that led to detention, and the effect of both of these on the person's ability to give free informed consent.

2. *'Incompetent' patients*

Some patients, who may or may not be detained, are not competent to give free informed consent to research. They present difficult problems since many suffer from conditions for which advances in knowledge are needed most, and cannot be obtained by studying other patients. Patients with severe mental handicap and severe dementia are examples of this group.

If the general points considered above are taken into account, this class of patients will be small: to suffer from severe dementia or mental handicap does not necessarily imply incompetence; and incompetence to make one kind of decision does not necessarily mean incompetence to make another kind. Although the group is small, the ethical problems related to research with these patients are very important and proposals for research involving them require very careful consideration by the Ethics Committee.

When research with 'incompetent' patients involves physical contact (including the administration of drugs), the problems are greater because in these circumstances there is a potential legal problem as well as an ethical one. Procedures of this kind could be deemed a battery. However, legal opinion indicates that the law of battery is unlikely to be applied to such cases, provided due procedures of approval by an Ethics of Research Committee have been completed (see Brooke, 1986). (It is important to stress that many kinds of psychiatric research do not involve physical contact.)

The problem of research with incompetent patients was addressed in the Declaration of Helsinki, which recommends that consent be obtained from a legal guardian. This recommendation is not helpful in the United Kingdom because the law does not recognise this kind of guardian except in cases where special steps have been taken to appoint a guardian in law. No person other than a legally appointed guardian can give consent on behalf of the patient, and there is no clear legal guidance about the best way of proceeding in cases in which none has been appointed. In the absence of such guidance, the following is a commonsense approach to the issues.

The Ethics Committee should decide in the usual way whether the research is acceptable in terms of the balance of benefits, discomforts and risks. Then it should consider the question of consent. No one else can consent on behalf of the patient. However, it would be good practice in most cases for the research worker to discuss the research with one or more close relatives, and discover their views. If there is no relative, or the patient expresses the wish that his relatives should not be consulted, it may be appropriate to consult an independent person who knows the patient well and will protect his interests (for example, a nurse). The choice of such a person should be approved by the Ethics of Research Committee. These people should attempt to form a judgement, based on the patient's known previous opinions about research and on his recent behaviour, as to whether the patient would be likely to consent were he able to do so. Any patient who indicates refusal either in words or in actions should be excluded from the research whatever opinion is voiced by the others who have been consulted.

3. *Research with children*

The ethical problems of medical research with children have been considered by the Institute of Medical Ethics (see Nicholson, 1986). Their report recommends that (as with adults) such research should be undertaken only when there is a specific and demonstrable need to do the research and there is no other way of obtaining the information. The process of weighing benefits and risks should be gone through, as it is with research on adults. In judging the amount of discomfort that is acceptable in the research, due account should be taken of other discomforts for the children resulting from their illness.

In deciding when the child can give consent, the stage of development and degree of understanding rather than chronological age should be taken into account as guidelines; most children over 14 years of age, and some over the age of 7 have the necessary understanding. For children aged 7–14, consent by the child should be confirmed by the parent or guardian, but consent by the latter should not override the child's refusal. Children over 14 years of age, although legally minors, are generally as competent as adults to decide, and their views should be given as much consideration as those of their parents. It is emphasised again that although these ages can guide the investigator, the important point is the child's level of psychological development.

In all respects, the research should be a partnership with the child and parents, not an activity undertaken on the child. Throughout the research, a careful watch should be kept for signs of distress or discomfort in the child. No financial inducement should ever be given to parents or guardians that might affect their decision whether to enter the child for research.

When considering research with children, the Committee should adopt the procedures recommended for its work with adults, and in addition should pay particular attention to the explanations given to parents and children. The explanation to the children should be in language and terms that are appropriate to the child's stage of development. Parents and, where appropriate, the children should have written information to study as well as a spoken explanation.

The constitution of Ethics of Research Committees

The Royal College of Physicians has published guidelines for the constitution and working practices of Ethics of Research Committees. The College of Psychiatrists endorses these recommendations. In particular, it is agreed that specialties within medicine should generally not set up independent Ethics of Research Committees. If the amount of research in psychiatry warrants a separate Ethics of Research Committee, this should be a sub-committee of the District Ethics of Research Committee, reporting to it, and following its rules. Only in this way can uniform standards be achieved; in any case, one of the desirable features of an Ethics of Research Committee is that specialists should have to persuade others that their work is ethical. On the other hand, because there are special issues in psychiatric research, it is highly desirable that at least one psychiatrist should be present when psychiatric research is discussed.

An exception to the general arrangements may be needed in a special Health Authority where there may be no obvious 'parent' general Research Ethics Committee. In these circumstances, there could be a specialist committee with additional membership from disciplines outside the special field.

Mode of working of Ethics of Research Committees

Committees should meet regularly. It is not satisfactory to conduct all business by correspondence; meetings are essential if lay members are to be fully involved. However, there may be some occasions when applications which appear to the Chairman to be without ethical problems could be dealt with by correspondence. Decisions reached in this way should be reported to the Committee at its next meeting, and should only take place within guidelines agreed by the Committee in advance. Research workers should be able to appear before the Committee if the issues are particularly complex

and extensive changes or reappraisal are being recommended by the Committee.

The names and qualifications of members, and the Chairman should be in a public document. The Committee should have a quorum and this should include two lay members. Decisions should be reached by a simple majority of those present and voting. Decisions should be notified in writing to the applicant.

When an adverse decision is made, it should be accompanied by advice to the applicant, who should be able to submit revised proposals. If the applicant wishes, he should be able to appear before the Committee to discuss relevant issues. This discussion should be carried out in a way that is educative.

It is not easy for Ethics of Research Committees to monitor the outcome of their work. If it is difficult to review every project in detail, a minimum requirement is that reports be obtained of any accidents or adverse reactions, and of any complaints made about research. Projects that appear to the Committee to raise difficult issues may require more detailed follow-up enquiry, and reporting to the parent body.

The Committee has no power to prevent research being carried out, but if it learns that its advice is ignored, or investigators are failing to refer research to it, the Chairman should report this to the parent Health Authority.

The Committee should report annually in writing to the Health Authority to which they are responsible. The form of the report will be decided by that Authority but should generally contain a list of members, numbers of meetings (perhaps with numbers of members attending each), a note of any issues of general importance, and a list of the titles of the research projects considered, with the decisions reached.

Responsibility in law of Ethics of Research Committees

The Royal College of Physicians has pointed out that the members of Ethics of Research Committees could be regarded as having responsibilities in law. This is a strong reason for ensuring that Committees are properly constituted, and carry out their business thoroughly. It also indicates that the appointing Authority should, in the letter of appointment to Committee members, formally agree to indemnify them for any loss (including the costs of legal representation) arising out of their function as members of the Committee.

June 1989

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Autumn Quarterly Meeting, 1989

The Autumn Quarterly Meeting was held at Kensington Town Hall, London on 25 and 26 October 1989 under the Presidency of Dr J. L. T. Birley.

Business Meeting

The business meeting was held on 26 October 1989, attended by 37 Members of the College.

https://doi.org/10.1192/pb.14.1.48 Published online by Cambridge University Press