Psychiatric research, especially applied research the results of which will have immediate clinical relevance, cannot be done without patients. The sufficient information of such research patients is requested by the Declaration of Helsinki/Tokyo. But particularly in psychiatric patients the validity and extent of informed consent may be restricted:

a) either by the patient's reduced ability to understand or to consent,

b) by a therapeutic privilege in respect to a patient's limited endurance capacity, or

c) by methodological necessities, e.g. the use of a placebo.

The less valid informed consent is, and therefore the control of what is going on by the patient himself, the more it seems justified to control the ethical admissibility of a research investigation. The control may concern the design, performance and results of research including the sufficiency of informed consent and the confidentiality of personal data of patients. But by whom, how and when will or should ethical control be performed? During the last two decades different modes of ethical control have been developed and according to an inquiry in Europe a different degree of its institutionalization, declining from north to south, can be recognized.

Control generally operates on two or three levels: on a local and/or on a regional level as well as on a national level. On the local level in any case there seems to be control by the head of the department, who is lastly responsible for the care of the patients. Besides this, there may be experienced colleagues especially appointed, or research conferences with members of the hospital. These conferences do not deal with ethical questions.
alone but will discuss all questions of a research project as e.g. its scientific aim and value, the necessary methodology, and the organizational problems with its realization. Therefore not only the researchers but also the doctors and nurses of the involved patients participate in such conferences. Apparently these conferences are not formalized very strongly.

On the regional level formal committees operate for a hospital, a region, or a special research area.

Central or national ethical committees are established in a few countries such as Belgium, Denmark, Norway. Mostly they are affiliated with national research foundations or councils. The national committees mainly will be asked by regional committees for help in difficult problems or by authorities for advice on basic problems.

Composition of Ethical Committees varies broadly. There are committees with medical doctors alone, particularly pharmacologists, anaesthesiologists, psychiatrists, specialists in internal and in forensic medicine. Other committees have parity between scientific and nonscientific members; the latter, as in Denmark, will be nominated by the local county boards. To others there belongs one representative of the nurses or one lay member. In the Federal Republic of Germany the participation of a lawyer is requested at least for therapy research projects which will be supported financially by federal authorities.

Access to and competence of the committees are rather different, too. Some committees seem to evaluate only ethical questions, others comment on scientific as well as on ethical aspects of research projects. In some countries there is an obligation to send protocols of all research projects involving patients or human volunteers to such a committee. In others the committee can be asked for advice if a research is in doubt. It is not clear whether some committees have the competence to decide in principle on research projects or whether the competence of all committees is limited to commentary on a research project and to counseling the researcher. In fact such comment may exert an efficacious control in case financial support depends on it. In the German Research Association each reviewer of an application for a research grant has to evaluate it along the principles of the Declaration of Helsinki/Tokyo.

It seems necessary to evaluate the benefits and possible harms of these procedures.

Benefits of control by committees seem to be:

a) to make the researcher more sensitive to ethical questions by forcing him to explicate the problems involved and the criteria used for decisions;

b) to meet the need for the public to be protected against misuse as a guinea pig and to diminish the public distrust against research by giving evidence of an efficient control, and - at least in the case of lay members of the committee - to develop an understanding of the aims, methods, and results of clinical research.