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# Opinion

On 7th November, 1988, the National Consultative Ethics Committee for Health and Life Sciences had made recommendations concerning the missions of Ethics Committees. Four had been listed: evaluation of research projects, clinical practice, general problems, information and training.

Since that time, the law of 20th December 1988, setting up Committees for the protection of persons in the context of biomedical research, has made it mandatory to request these bodies to assess research projects.

Trial protocols will therefore probably no longer be submitted to Ethics Committees. However, several years of activity should enable them to provide the new organisations with the benefit of their experience if required.

As to other missions outlined above, they are not within the purview of the Committees for the protection of persons. However, the National Consultative Ethics Committee considers these remaining missions to be of sufficient importance to justify the continuation of existing Ethics Committees' existence, or their creation where they do not, or no longer, exist.

It would therefore be desirable that some official recognition should be given to them, for instance through an accreditation procedure which would, inter alia, make it possible to respect the essential principles of pluralism and pluridisciplinarity.

The National Consultative Ethics Committee considers, in fine, that this procedure could also be adopted for Committees whose task is limited to a special medical domain or special field of research, generally known by the name "Specialist Committees".

Extract of recommendations of the National Consultative Ethics Committee of 7th November, 1988.

## **Evaluation of research projects**

Any research protocol involving humans must be submitted for assessment to an Ethics Committee, be it originated by hospital centres, or public and private research institutions.

The two-fold aspect of opinion due to required complementarity brings up an essential issue concerning the proper functioning of Committees: the scientific nature of projects. In other words, can the various missions described above be left to a single Committee or should different structures be organised?

In the United States, in hospitals there are International Review Boards which assess research protocols, and there are Institutional Ethical Committees which have a say in medical practice.

At this point of developments in France, it does not seem necessary to introduce this distinction. It is true that certain missions will be more prominent depending on local situations, but a free rein must be given to Committees regarding their consideration of problems submitted to them by doctors or researchers.

As has been said over and over again: "if it is not scientific, it is not ethical". This approach leads to breaking down into two phases the evaluation of a protocol and raises two questions: is it scientific? is it ethical? The two phases can be undertaken by the same Committee. On the other hand, there could be prior consultation of a scientific council composed of a few individuals who would themselves be able to consult, if necessary, outside experts. This is akin to the concept of speciality commissions, but the cascade of opinions would not always be required and in any event, should not introduce delays which would be detrimental to researchers.

### Clinical practice

As regards the evaluation of research projects, the mission of Ethics Committees is universally accepted, but this is not always the case if their competence is extended to other areas. They may for instance have a say in clinical or therapeutic decisions.

Should the question be restricted to relations between a practitioner and his patients, obviously the Committees cannot intervene. However, it is quite conceivable that when a doctor encounters a particularly complex ethical issue, he may wish to consider it with the assistance of the Committee to facilitate his own decision. This consideration would be all the more pertinent and fruitful if multidisciplinary qualifications, not necessarily medical, are to be found within the Committee.

In such a case, care must be taken not to wrongfully cross the frontiers which separate deontology and ethics on the one hand, and medical practice and research on the other. These distinctions are not always obvious since several of these activities may be intertwined.

## Problems of a general nature

It is up to the National Consultative Ethics Committee to formulate advice and recommendations concerning moral issues raised by progress in fundamental research and clinical research. When this kind of problem is submitted to them, local Committees should refer to the National Consultative Ethics Committee. They can, however, play a major role if a consensus is sought. As they are close to research and medical practice activities, they are an ideal structure to reflect on these subjects with their authors. In such a case, however, the conclusions and recommendations of a local Committee should be seen not so much as an opinion, but rather as a contribution to more ample reflection.

### Information and training

Ethical reflection must be neither confidential nor confined to specialists. It is connected to problems which sometimes may affect the future of human beings and of society. It is for this reason that Ethics Committees must be involved in information and training.

It would be paradoxical if their members had no vision of the outside world.

In France, they already participate in education and meetings for the purpose of giving information at all levels. It therefore seems appropriate to define two areas where their intervention is particularly desirable: research and health professions, and education in both schools and universities.

Although participation of members of local Committees in training activities is natural and desirable, there are also other people who can do this, and it is not their main mission.

A certain amount of leeway must be given to them to adapt their intervention to local situations, for example by setting up a documentation centre.