A RESEARCHER'S LEGAL LIABILITY : ETHICAL AND LEGAL CONSIDERATIONS

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Medical law, more specifically the area of doctors' liability, is a field which has known many developments during the last few years in Quebec. But what about researchers' liability, that is to say the liability of those specialists devoted to medical research on human beings? This article will provide a brief overview of different aspects of a researcher's liability from a legal standpoint and also from an ethical point of view.

1. Legal Aspects: Main Duties of the Researcher

The duties imposed on medical researchers towards their subjects are largely inspired by a doctor's duties towards his patients. Since there are very few differences between the duties of a doctor and those of a researcher, we can say that these duties originate from a common source: an individual's rights to the inviolability and integrity of his or her person. Moreover, it is important to note that duties imposed on researchers are at least equal if not superior to those imposed on doctors and surgeons towards their patients (*Halushka* v. *University of Saskatchewan* (1965), 53 D.L.R. (2d) 436 (Sask. C.A., J. Hall)).

Firstly, the researcher has a duty to inform his subject. In order to fulfil this duty, the researcher has to meet four main requirements : he has to clearly set out to the subject the purpose of his experiment and make sure that the subject understands the meaning and the impact of this purpose; he must set out to the subject what the benefits of the experiment are for him or her and for society; he must inform the subject of the risks related to the experiment keeping in mind that "the duty to inform in matters relating to purely scientific experimentation is the most exacting possible. This duty includes the revelation of all risks, including those which are rare or remote and especially

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those risks which may entail serious consequences." (*Weiss* c. *Solomon*, (1989) R.J.Q. 731 (S.C.Que., J. De Blois at p. 743), and finally, in the case of therapeutic research, the researcher has to inform his subject about all possible research alternatives.

Secondly, the researcher has to obtain a written, free and clear consent from his subject. This second obligation is unquestionably the corollary of the first one as the subject to an experiment must have received all the relevant information in order to give a clear consent.

Thirdly, owing a duty of care to his subject, the researcher has to respect a certain "code of conduct". Throughout the course of the experiment, the researcher's behaviour must be objective and the research must be carried out with reasonable care. Any failure to respect these pre-set standards could lead to the researcher's liability, whether professional liability, or civil or contractual responsibility.

Finally, the researcher has an obligation of confidentiality towards his subject. This obligation, which is directly related to professional secrecy, finds its source in the trust which must be found between the researcher and the subject and also in the right to privacy and dignity, two rights provided for in sections 4 and 5 of the Quebec *Charter of Human Rights and Freedoms.*

2. Ethical aspects

2.1 History of the development of ethical considerations regarding experiments

The Nuremberg Code (1948) and the Declaration of Helsinki (1964), which are still today considered as guidelines intended for doctors and other medical researchers interacting with human beings, have inspired recent ethical developments concerning experiments with human subjects. The legal considerations mentioned above put aside, these medical researches must also meet ethical criteria.

2.2 Ethical approval criteria of research protocols

In order to evaluate the "ethical content" of research protocols, the main objective of which is to give a detailed description of the researches to be carried out, ethical committees have established ethical approval criteria. Even though the nature and the number of these criteria can vary from one research to another, some criteria are essential in evaluating a research protocol.

Since experimental research on human beings is only ethical if it is acceptable on a scientific basis, the first criterion concerns the determination of the scientific value of the research protocol. It is up to the researcher to justify the performance of research on his subject by demonstrating that such research is necessary for the advancement of scientific knowledge and the enhancement of the quality of human life. Secondly, an ethical committee has to balance the risks and benefits of the experimental research and such research will only be ethical if the benefits outweigh the risks for the subject or for society at large. Thirdly, in order to be ethically acceptable, a research protocol has to ensure the confidentiality of the facts collected for the purpose of the experiment. Among other things, the researcher has to establish measures which will guarantee that the subject's anonymity will be protected and determine in advance, as precisely as possible, the instances where the researcher will be exempted from the duty of confidentiality towards his subject. Finally, the researcher will also have to make sure that the subject gives a free and clear consent by asking him or her to sign a consent form which he or she fully understands and to which he or she liberally adheres to.