Spain Country Report

Clinical Trials in Medicine in Spanish Law

Carlos Maria Romeo Casabona

I. General overview

Research in Medicine and in the Biological Sciences has gradually improved well-being and indeed the life expectancy of mankind. This is why nobody today disputes the importance of research in the field of the biomedical sciences, since progress in the latter depends largely on the results obtained through research. For this reason, biomedical research – leaving aside for the moment other considerations which I shall address further on – is viewed as first and foremost an asset of mankind in that it enables us to understand better the mechanisms of disease and illness, their causes and the means to prevent, combat or alleviate them. Research also helps fulfill one of the most burning desires of human nature: the quest for new knowledge. All this has received recognition in law. International and, more explicitly, national legal instruments recognize and protect freedom of scientific enquiry as a right, in many cases a fundamental one, and the authorities pledge themselves to the promotion of research.

Secondly, the results of research help enhance the prestige of researchers and encourage them to continue their work, and in this way healthy competition among peers is promoted.

Lastly, it should be recalled that research requires considerable funding, although the sums spent do not always guarantee that the desired results, or other results of interest to science, will be obtained. A consequence of this is that a clash of opposing interests may well arise.

One of the problems raised by research on new drugs and procedures for combating disease and illness is that, once tests are completed in laboratories and on animals, the final step must be taken and efficiency must be tested using human beings, on whom research of new techniques or substances – to which beneficial or therapeutic effects are attributed – must be carried out before authorization can
be given for the product to be used in treatment. Indeed, experimentation on humans is often an indispensable requirement for the granting of the corresponding permission to market a drug. Testing and experimentation can pose a variety of risks and dangers for the health of the experimental subjects (healthy or otherwise), ranging from harmful secondary effects, which are known and therefore controllable to unknown ones, in which case the danger is greater and it becomes more difficult to control or prevent such effects; even though these risks need not necessarily affect the experimental subjects themselves.

Thus, a potential conflict of interests or of crucial values arises: on the one hand there is the need to carry out research with the obvious benefits that this brings to society and, on occasions, to the individual who has acted as an experimental subject; on the other, there is the right of these individuals not to sustain any damage to their health or to expose their lives to grave dangers, not to mention the protection of other individual rights or interests that may be affected, such as freedom.

Furthermore, the strong tendency to be fascinated by science and the possibilities it affords often means that all other aspects are subordinated to the progress of science and research, on the grounds that anything should be permitted that leads to the attainment of this lofty goal. To put it another way, there is an extremely powerful temptation to commit abuses during the course of research, and this is very serious if it involves experimentation on humans. Far from being pure speculative, regrettably there is an abundance of old and recent examples of such abuses and doubtless there are many others which have not yet come to light.

One reaction to the potential danger of abuse might be a complete ban on research of this kind when performed on human subjects. However, no one today supports or defends this radical approach, and rightly so. As it has been pointed out, there are two reasons for this. The first has to do with the notion of utilitarianism. The argument goes that to deny the possibility of experimentation on humans would ultimately paralyze scientific and medical progress, the value of which is acknowledged by all. It is accepted therefore, that laboratory research or research on animals is insufficient. The second consideration is of a more ethical and philosophical nature and runs along the lines that humans have a collective social and ethical duty to agree to take part in scientific experiments and thus help benefit mankind as a whole. This second argument stresses the duty of human solidarity, although this does not mean that participation should not be subject to the guarantees and conditions normally set out in national legal instruments and in international ethical texts.

Most national legislation includes provisions on clinical trials of drugs and similar products and put in place a series of guarantees, procedures and conditions which are designed to ensure protection for individuals used in experiments and to assure