Reprint from *The EFGCP News,* Summer 2001, page 2

Editorial

Making Ethics into Law
The Draft Protocol on Biomedical Research

The Steering Committee on Bioethics (CDBI) at the Council of Europe has made public the Draft Protocol on Biomedical Research (dated 18 July 2001). This Protocol is being drafted as an addition to the *Convention on Human Rights and Biomedicine*, itself open for signature and ratification since April 1997. It is preceded by two other protocols, one on the Prohibition of Human Cloning and a draft on the Transplantation of Organs and Tissues of Human Origin.

The *Convention* is a legal instrument having a stature similar to that of a treaty. It is not binding on a country until it has been ratified by its Parliament. To date, 10 of the 43 member countries of the Council of Europe have ratified the *Convention*. The additional protocols all need to be ratified individually for them to come into force. At present, only 8 of the 10 countries ratifying the Convention have ratified the Protocol on the Prohibition of Human Cloning.

The Protocol on Biomedical Research aims to extend the protections of human dignity and human rights already expressed in the *Convention* into further detail and specificity regarding biomedical research. The draft text presents broad legal requirements regarding ethical principles, ethical review, informed consent, patient/subject information protections, and the care and treatment of research participants.

In general, the requirements for research expressed in the draft protocol are in keeping with existing safeguards for promoting human dignity and protecting human rights. In most instances the safeguards asked for by the draft Protocol are weaker than existing laws and regulatory requirements. Significantly, there is no reference in the draft Protocol to existing international or European texts aside from a preambular 'taking account of national and international professional standards' and an, all too often used on important issues, 'as prescribed by/in conformity with national law'.

In many places the draft Protocol repeats, usually verbatim, sentences already present in the parent document, the *Convention*. The intention of the drafting group was to have a text that could stand alone regarding biomedical research. However, *de juris* this could never be the case, and in practice one should expect researchers to know the full extent of the law governing their engagements. The repetition might be useful if it added clarity on existing difficulties in the *Convention*, but this is not the case. For example, both the *Convention* and draft Protocol assert the following:

> Every research project shall be submitted for independent examination of its scientific merit**,** including assessment of the importance of the aim of the research, and ethical acceptability to an ethics committee.

The responsibilities and activities of an ethics committee are expressed quite differently here than in, for example, the *Declaration of Helsinki,* ICH or WHO Good Clinical Practice Guidelines, the EU Directive on GCP, or the WHO *Operational Guidelines for Ethics Committees That Review Biomedical Research.* While ethics committees should take into

consideration the science of a research proposal, in Europe (as in other places in the world today) they are rarely constituted to evaluate scientific merit. The repetition would be beneficial if it clarified how the original statement of the *Convention* could be implemented into the present context of European research.

On the question of control arms and placebos, the draft Protocol proposes the following:

> Research shall not delay or deprive participants of medically necessary preventive, diagnostic or therapeutic procedures.
> In research associated with prevention, diagnosis and treatment, patients assigned to control groups shall be assured of proven methods of prevention, diagnosis and treatment.
> Placebo treatment may only be used in cases where there is no treatment of proven effectiveness, or where withdrawal or withholding of active treatment does not present unacceptable risk or burden.

The language adopted here clearly comes from the *Declaration of Helsinki*. However, the approach and stated requirements are quite different. Should this draft text become law, it is likely to put the European physician – who is obligated to follow *Helsinki* – into an untenable situation as researcher or member of an ethics committee.

Significantly the roles and responsibilities of researchers, sponsors, and public health authorities for promoting research are not systematically addressed and many of the minimum requirements for protecting patients/research participants are missing. In addition, the importance of research for people suffering from orphan or terminal diseases is not addressed, nor is there any mention of considerations for research in either the paediatric or geriatric populations. Entirely missing is the ethical principle in the *Declaration of Helsinki* that medicine continually advance research in the patient's interest.

Many of the most important questions needing to be addressed today in the ethics of biomedical research are not present: the role of ethics committees and DSMBs in monitoring studies, the compassionate use of products in the research setting, and specific issues relating to participant care and product availability following research are not presented.

The most important concern Europe will have in adopting the Protocol on Biomedical Research will be as to whether this legal text actually enhances protections for the European citizen and promotes much needed research that addresses important public health issues. If the ethical standards proposed here are lower and less complete than existing standards for protecting research participants, then much of the hoped for advantage of the Protocol will be lost. If in addition the draft Protocol fails to stimulate research where Europe's patients are very much needing (and asking for) improved healthcare, then the ethical weight of the *Convention* will be undermined.

Making law of ethics is not an easy task. Certainly today there is a need for laws that guide ethical conduct in biomedical research. These laws should, however, provide a framework that enhances the ethical dimension of existing practices and codes of conduct. Adding 36 articles to the *Convention on Human Rights and Biomedicine* would be commendable should those articles promise a genuine advancement in promoting the dignity of the European citizen in biomedical research and improved healthcare for the future.

The *Draft Additional Protocol to the Convention on Human Rights and Biomedicine, on Biomedical Research* may be viewed at the following website: http://www.legal.coe.int/bioethics/gb/pdf/CDBI-INF(2001)5E.pdf.

Francis P. Crawley, Chairman, Ethics Working Party, EFGCP; e-mail: fpc@pandora.be