Strasbourg, 23 June 2003
[bioethics/textes publics/CDBI-INF/2003/
INF(2003)6e draft protocol research]

CDBI/INF (2003) 6

STEERING COMMITTEE ON BIOETHICS (CDBI)

Draft additional Protocol to the Convention on Human Rights and Biomedicine, on Biomedical Research

This document contains the draft additional Protocol to the Convention on Human Rights and Biomedicine, on Biomedical Research, as it was approved by the Steering Committee on Bioethics (CDBI) on 20 June 2003. The draft Protocol is going to be submitted to the Committee of Ministers. It is foreseen that that they will consult the Parliamentary Assembly for an opinion, prior to proceeding to examination of the draft Protocol in view of its adoption. The Explanatory Report to the draft Protocol will be available later.

Draft additional Protocol
to the Convention on Human Rights and Biomedicine,
on Biomedical Research

Preamble

The member States of the Council of Europe, the other States and the European Community signatories to this Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (hereinafter referred to as "the Convention"),

Considering that the aim of the Council of Europe is the achievement of greater unity between its members and that one of the methods by which this aim is pursued is the maintenance and further realisation of human rights and fundamental freedoms;

Considering that the aim of the Convention, as defined in Article 1, is to protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine;

Considering that progress in medical and biological sciences, in particular advances obtained through biomedical research, contributes to saving lives and improving their quality;

Conscious of the fact that the advancement of biomedical science and practice is dependent on knowledge and discovery which necessitates research on human beings;

Stressing that such research is often transdisciplinary and international;

Taking into account national and international professional standards in the field of biomedical research and the previous work of the Committee of Ministers and the Parliamentary Assembly of the Council of Europe in this field;

Convinced that biomedical research that is contrary to human dignity and human rights should never be carried out;

Stressing the paramount concern to be the protection of the human being participating in research;

Affirming that particular protection shall be given to human beings who may be vulnerable in the context of research;

Recognising that every person has a right to accept or refuse to undergo biomedical research and that no one should be forced to undergo it;

Resolving to take such measures as are necessary to safeguard human dignity and the rights and fundamental freedoms of the individual with regard to biomedical research,

Have agreed as follows:

CHAPTER I
Object and scope

Article 1 – Object and purpose

Parties to this Protocol shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to any research involving interventions on human beings in the field of biomedicine.

Article 2 – Scope

1. This Protocol covers the full range of research activities in the health field involving interventions on human beings.

2. This Protocol does not apply to research on embryos *in vitro*. It does apply to research on foetuses and embryos *in vivo*.

3. For the purposes of this Protocol, the term intervention includes:

i) a physical intervention,

ii) any other intervention in so far as it involves a risk to the psychological health of the person concerned.

CHAPTER II
General provisions

Article 3 – Primacy of the human being

The interests and welfare of the human being participating in research shall prevail over the sole interest of society or science.

Article 4 – General rule

Research shall be carried out freely, subject to the provisions of this Protocol and the other legal provisions ensuring the protection of the human being.

Article 5 – Absence of alternatives

Research on human beings may only be undertaken if there is no alternative of comparable effectiveness.

Article 6 – Risks and benefits

Research shall not involve risks and burdens to the human being disproportionate to its potential benefits.

In addition, where the research does not have the potential to produce results of direct benefit to the health of the research participant, such research may only be undertaken if the research entails no more than acceptable risk and acceptable burden for the research participant. This shall be without prejudice to the provision contained in Article 15 paragraph 2, sub-paragraph ii for the protection of persons not able to consent.

Article 7 – Approval

Research may only be undertaken if the research project has been approved by the competent body after independent examination of its scientific merit, including assessment of the importance of the aim of research, and multidisciplinary review of its ethical acceptability.

Article 8 – Scientific quality

Any research must be scientifically justified, meet generally accepted criteria of scientific quality and be carried out in accordance with relevant professional obligations and standards under the supervision of an appropriately qualified researcher.

CHAPTER III
Ethics committees

Article 9 – Independent examination by an ethics committee

Every research project shall be submitted for independent examination of its ethical acceptability to an ethics committee. Such projects shall be submitted to independent examination in each State in which any research activity is to take place.

The purpose of the multidisciplinary examination of the ethical acceptability shall be to protect the dignity, rights, safety and well being of research participants. The assessment of the ethical acceptability shall draw on an appropriate range of expertise and experience adequately reflecting professional and lay views.

The ethics committee shall produce an opinion containing reasons for its conclusion.

Article 10 – Independence of the ethics committee

Parties to this Protocol shall take measures to assure the independence of the ethics committee. That body shall not be subject to undue external influences.

Members of the ethics committee shall declare all circumstances that might lead to a conflict of interest. Should such conflicts arise, those involved shall not participate in that review.

Article 11 – Information for the ethics committee

All information which is necessary for the ethical assessment of the project shall be given in written form to the ethics committee.

In particular, information on items contained in the Appendix to this Protocol shall be provided, in so far as it is relevant for the research project. The Appendix may be amended by the Committee set up by Article 32 of the Convention by a two-thirds majority of the votes cast.

Article 12 – Undue influence

The ethics committee must be satisfied that no undue influence, including that of a financial nature, will be exerted on persons to participate in research. In this respect, particular attention must be given to vulnerable or dependent persons.

CHAPTER IV
Information and consent

Article 13 – Information for research participants

The persons being asked to participate in a research project shall be given adequate information in a comprehensible form. This information shall be documented.

The information shall cover the purpose, overall plan, possible risks and benefits of the research project, and include the opinion of the ethics committee. In addition, they shall be informed of the rights and safeguards prescribed by law for their protection, and in particular of their right to refuse consent or to withdraw consent at any time without prejudice to their right to medical care and without suffering any other detriment. They shall be specifically informed before consenting to participate in a research project, according to the nature and purpose of the research:

i) of the nature, extent and duration of the procedures involved, in particular, details of any burden imposed by the research project;

ii) of available preventive, diagnostic and therapeutic procedures;

iii) of the arrangements for responding to adverse events or the concerns of research participants;

iv) of arrangements to ensure respect for private life and ensure the confidentiality of personal data;

v) of arrangements for access to information relevant to the participant arising from the research and to its overall results;

vi) of the arrangements for fair compensation in the case of damage;

vii) of any foreseen potential further uses, including commercial uses, of the research results, data or biological materials;

viii) of the source of funding of the research project.

Article 14 – Consent

1. No research on a person may be carried out, subject to the provisions of both Chapter V and Article 19, without the informed, free, express, specific and documented consent of the person. Such consent may be freely withdrawn by the person at any phase of the research**.**

2. Refusal to give consent or the withdrawal of consent to participation in research shall not prejudice the right of the individual to receive medical care and shall not lead to suffering any other detriment.

3. Where the capacity of the person to give informed consent is in doubt, arrangements shall be in place to verify whether or not the person has such capacity.

CHAPTER V
Protection of persons not able to consent to research

Article 15 – Protection of persons not able to consent to research

1. Research on a person without the capacity to consent to research may be undertaken only if all the following specific conditions are met:

i) the results of the research have the potential to produce real and direct benefit to his or her health,

ii) research of comparable effectiveness cannot be carried out on individuals capable of giving consent,

iii) the person undergoing research has been informed of his or her rights and the safeguards prescribed by law for his or her protection, unless this person is not in a state to receive the information,

iv) the necessary authorisation has been given specifically and in writing by the legal representative or an authority, person or body provided for by law**,** and after having received the information required by Article 16, taking into account the person's previously expressed wishes or objections. An adult not able to consent shall as far as possible take part in the authorisation procedure. The opinion of a minor shall be taken into consideration as an increasingly determining factor in proportion to age and degree of maturity,

v) the person concerned does not object.

2. Exceptionally and under the protective conditions prescribed by law, where the research has not the potential to produce results of direct benefit to the health of the person concerned, such research may be authorised subject to the conditions laid down in paragraph 1, subparagraphs ii, iii, iv, and v above, and to the following additional conditions:

i) the research has the aim of contributing, through significant improvement in the scientific understanding of the individual's condition, disease or disorder, to the ultimate attainment of results capable of conferring benefit to the person concerned or to other persons in the same age category or afflicted with the same disease or disorder or having the same condition.

ii) the research entails only minimal risk and minimal burden for the individual concerned; and any consideration of additional potential benefits of the research shall not be used to justify an increased level of risk or burden.

3. Objection to participation, refusal to give authorisation or the withdrawal of authorisation to participate in research shall not prejudice the right of the individual concerned to receive medical care.

Article 16 – Information prior to authorisation

Those being asked to authorise participation of a person in a research project shall be given adequate information in a comprehensible form. This information shall be documented.

The information shall cover the purpose, overall plan, possible risks and benefits of the research project, and include the opinion of the ethics committee. They shall further be informed of the rights and safeguards prescribed by law for the protection of those not able to consent to research and in particular of the right to refuse or to withdraw authorisation at any time, without prejudice to the person's right to medical care, and without the person suffering any other detriment. They shall be specifically informed according to the nature and purpose of the research of the items of information listed in Article 13.

The information shall be provided to the individual concerned, unless this person is not in a state to receive the information.

Article 17 – Interventions with minimal risk and minimal burden

For the purposes of this Protocol it is deemed that, in terms of the nature and scale of the intervention, the research bears a minimal risk if it is to be expected that it would result, at the most, in a very slight and temporary negative impact on the health of the person concerned.

It is deemed that it bears a minimal burden if it is to be expected that the discomfort will be, at the most, temporary and very slight. **I**n assessing the burden for an individual, a person enjoying the special confidence of the person concerned shall assess the burden where appropriate.

CHAPTER VI
Specific situations

Article 18 - Research during pregnancy or breastfeeding

1. Research on a pregnant woman which does not have the potential to produce results of direct benefit to her health, or that of the embryo or foetus or child after birth, may only be undertaken if the following additional conditions are met:

i) the research has the aim of contributing to the ultimate attainment of results capable of conferring benefit to other women in relation to reproduction or to other embryos, foetuses or children,

ii) research of comparable effectiveness cannot be carried out on women who are not pregnant,

iii) the research entails only minimal risk and minimal burden.

2. Where research is undertaken on a breastfeeding woman, particular care shall be taken to avoid any adverse impact on the health of the child.

Article 19 – Research on persons in emergency clinical situations

1. The law shall determine whether, and under which protective additional conditions, research in emergency situations may take place when:

i) a person is not in a state to give consent, and

ii) because of the urgency of the situation, it is impossible to obtain in a sufficiently timely manner, authorisation from his or her representative or an authority or a person or body which would in the absence of an emergency situation be called upon to give authorisation.

2. The law shall include the following specific conditions:

i) research of comparable effectiveness cannot be carried out on persons in non-emergency situations;

ii) the research project may only be undertaken if it has been approved specifically for emergency situations by the competent body;

iii) any relevant previously expressed objections of the person known to the researcher shall be respected;

iv) where the research has not the potential to produce results of direct benefit to the health of the person concerned, it has the aim of contributing, through significant improvement in the scientific understanding of the individual's condition, disease or disorder, to the ultimate attainment of results capable of conferring benefit to the person concerned or to other persons in the same category or afflicted with the same disease or disorder or having the same condition and entails only minimal risk and minimal burden.

3. Persons participating in the emergency research project or, if applicable, their representatives shall be provided with all the relevant information concerning their participation in the research project as soon as it becomes possible. Consent or authorisation for continued participation shall be requested as soon as reasonably possible.

Article 20 – Research on persons deprived of liberty

Where the law allows research on persons deprived of liberty, such persons may participate in a research project in which the results do not have the potential to produce direct benefit to their health only if the following additional conditions are met:

i) research of comparable effectiveness cannot be carried out without the participation of persons deprived of liberty;

ii) the research has the aim of contributing to the ultimate attainment of results capable of conferring benefit to persons deprived of liberty;

iii) the research entails only minimal risk and minimal burden.

CHAPTER VII
Safety and supervision

Article 21 – Minimisation of risk and burden

All reasonable measures shall be taken to ensure safety and to minimise risk and burden for the participants.

Research may only be carried out under the supervision of a clinical professional who possesses the necessary qualifications and experience.

Article 22 – Assessment of health status

The researcher shall take all necessary steps to assess the state of health of human beings prior to their inclusion in research, to ensure that those at increased risk in relation to a specific project be excluded.

Where research is undertaken on persons in the reproductive stage of their lives, particular consideration shall be given to the possible adverse impact on a current or future pregnancy and the health of an embryo, foetus or child.

Article 23 – Non-interference with necessary clinical interventions

Research shall not delay nor deprive participants of medically necessary preventive, diagnostic or therapeutic procedures.

In research associated with prevention, diagnosis or treatment, participants assigned to control groups shall be assured of proven methods of prevention, diagnosis or treatment.

The use of placebo is permissible where there are no methods of proven effectiveness, or where withdrawal or withholding of such methods does not present unacceptable risk or burden.

Article 24 – New developments

1. Parties to this Protocol shall take measures to ensure that the project is re-examined if this is justified in the light of scientific developments or events arising in the course of the research.

2. The re-examination shall establish whether:

i) the research project should be discontinued or if changes to the research project are necessary for the research to continue,
ii) research participants, or if applicable their representatives, should be informed of the developments or events,
iii) an additional consent or authorisation for participation is required.

3. Any new information relevant to their participation shall be conveyed to the research participant, or if applicable to the person’s representative, in a timely manner.

4. The competent body shall be informed of the reasons for any premature termination of a research project.

CHAPTER VIII
Confidentiality and right to information

Article 25 – Confidentiality

Any information of a personal nature collected during biomedical research shall be considered as confidential and treated according to the rules relating to the protection of private life.

The law shall protect against inappropriate disclosure of any other information related to the research that has been submitted to the ethics committee in compliance with this Protocol.

Article 26 – Right to information

Research participants shall be entitled to know any information collected on their health in conformity with the provisions of Article 10 of the Convention.

Other personal information collected for a research project will be accessible to them in conformity with the law on the protection of individuals with regard to processing of personal data.

Article 27 – Duty of care

If research gives rise to information of relevance to the current or future health or quality of life of research participants, this information must be offered to them. That shall be done within a framework of healthcare or counselling. In communication of such information, due care must be taken in order to protect confidentiality and to respect the wish of the participant not to receive such information.

Article 28 – Availability of results

At the completion of the research, a report or summary shall be submitted to the ethics committee or the competent body.

The conclusions of research shall be made available to participants in reasonable time, on request.

The researcher shall take appropriate measures to make public the results of research in reasonable time.

CHAPTER IX
Research in States not party to this Protocol

Article 29 – Research in States not party to this Protocol

Sponsors or researchers within the jurisdiction of a Party to this Protocol that plan to undertake or direct a research project in a State not Party to this Protocol shall ensure that, without prejudice to the provisions applicable in that State, the research project complies with the principles on which the provisions of this Protocol are based. Where necessary, the Party shall take appropriate measures to that end.

CHAPTER X
Infringement of the provisions of the Protocol

Article 30 – Infringement of the rights or principles

The Parties shall provide appropriate judicial protection to prevent or to put a stop to an unlawful infringement of the rights or principles set forth in this Protocol at short notice.

Article 31 – Compensation for damage

The person who has suffered damage as a result of participation in research shall be entitled to fair compensation according to the conditions and procedures prescribed by law.

Article 32 – Sanctions

Parties shall provide for appropriate sanctions to be applied in the event of infringement of the provisions contained in this Protocol.

CHAPTER XI
Relation between this Protocol and other provisions and re-examination of the Protocol

Article 33 – Relation between this Protocol and the Convention

As between the Parties, the provisions of Articles 1 to 32 of this Protocol shall be regarded as additional articles to the Convention, and all the provisions of that Convention shall apply accordingly.

Article 34 – Wider protection

None of the provisions of this Protocol shall be interpreted as limiting or otherwise affecting the possibility for a Party to grant research participants a wider measure of protection than is stipulated in this Protocol.

Article 35 – Re-examination of the Protocol

In order to monitor scientific developments, the present Protocol shall be examined within the Committee referred to in Article 32 of the Convention no later than five years from the entry into force of this Protocol and thereafter at such intervals as the Committee may determine.

CHAPTER XII
Final clauses

Article 36 – Signature and ratification

This Protocol shall be open for signature by Signatories to the Convention. It is subject to ratification, acceptance or approval. A Signatory may not ratify, accept or approve this Protocol unless it has previously or simultaneously ratified, accepted or approved the Convention. Instruments of ratification, acceptance or approval shall be deposited with the Secretary General of the Council of Europe.

Article 37 – Entry into force

1. This Protocol shall enter into force on the first day of the month following the expiration of a period of three months after the date on which five States, including at least four member States of the Council of Europe, have expressed their consent to be bound by the Protocol in accordance with the provisions of Article 36.

2. In respect of any State which subsequently expresses its consent to be bound by it, the Protocol shall enter into force on the first day of the month following the expiration of a period of three months after the date of the deposit of the instrument of ratification, acceptance or approval.

Article 38 – Accession

1. After the entry into force of this Protocol, any State which has acceded to the Convention may also accede to this Protocol.

2. Accession shall be effected by the deposit with the Secretary General of the Council of Europe of an instrument of accession which shall take effect on the first day of the month following the expiration of a period of three months after the date of its deposit.

Article 39 – Denunciation

1. Any Party may at any time denounce this Protocol by means of a notification addressed to the Secretary General of the Council of Europe.

2. Such denunciation shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of such notification by the Secretary General.

Article 40 – Notifications

The Secretary General of the Council of Europe shall notify the member States of the Council of Europe, the European Community, any Signatory, any Party and any other State which has been invited to accede to the Protocol of:

a. any signature;
b. the deposit of any instrument of ratification, acceptance, approval or accession;
c. any date of entry into force of this Protocol in accordance with Articles 37 and 38;
d. any other act, notification or communication relating to this Protocol.

In witness whereof the undersigned, being duly authorised thereto, have signed this Protocol.

Done at Strasbourg, this ...., in English and in French, both texts being equally authentic, in a single copy which shall be deposited in the archives of the Council of Europe. The Secretary General of the Council of Europe shall transmit certified copies to each member State of the Council of Europe, to the non-member States which have participated in the elaboration of this Protocol, to any State invited to accede to the Convention and to the European Community.

Appendix to the draft Protocol on Biomedical Research

Information to be given to the ethics committee

Information on the following items shall be provided to the ethics committee, in so far as it is relevant for the research project:

Description of the project

i) the name of the principal researcher, qualifications and experience of researchers and, where appropriate, the clinically responsible person, and funding arrangements;

ii) the aim and justification for the research based on the latest state of scientific knowledge;

iii) methods and procedures envisaged, including statistical and other analytical techniques;

iv) a comprehensive summary of the research project in lay language;

v) a statement of previous and concurrent submissions of the research project for assessment or approval and the outcome of those submissions***;***

Participants, consent and information

vi) justification for involving human beings in the research project;

vii) the criteria for inclusion or exclusion of the categories of persons for participation in the research project and how those persons are to be selected and recruited;

viii) reasons for the use or the absence of control groups;

ix) a description of the nature and degree of foreseeable risks that may be incurred through participating in research;

x) the nature, extent and duration of the interventions involved, and details of any burden imposed;

xi) arrangements to monitor, evaluate and react to contingencies that may have consequences for the present or future health of research participants;

xii) the timing and details of information for those persons who would participate in the research project and the means proposed for provision of this information;

xiii) documentation intended to be used to seek consent or, in the case of persons not able to consent, authorisation for participation in the research project;

xiv) arrangements to ensure respect for the private life of those persons who would participate in research and ensure the confidentiality of personal data;

xv) arrangements foreseen for information which may be generated and be relevant to the present or future health of those persons who would participate in research and their family members;

Other information

xvi) details of all payments and rewards to be made in the context of the research project;

xvii) all circumstances that might lead to conflicts of interest that may affect the independent judgement of the researchers;

xviii) of any foreseen potential further uses, including commercial uses, of the research results, data or biological materials;

xix) all other ethical issues, as perceived by the researcher;

xx) any insurance or indemnity to cover damage arising in the context of the research project.

The ethics committee may request additional information necessary for evaluation of the research project.