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STEERING COMMITTEE ON BIOETHICS (CDBI)

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

This text constitutes the draft additional Protocol to the Convention on Human Rights and Biomedicine, on Biomedical Research, as declassified for the purpose of consultation by the CDBI during its 20th meeting (5-8 June 2001). CDBI delegations will carry out consultations on the national level and submit comments to the CDBI. The Council of Europe Secretariat will carry out consultation with Pan-European non-governmental organisations. The consultation period will extend to March 2002. Afterwards, the CDBI will review the Protocol in June 2002. If agreed, the draft Protocol will be submitted to the Parliamentary Assembly for consultation prior to submission for final adoption by the Committee of Ministers.

DRAFT PROTOCOL 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 on Human Rights and Biomedicine"),

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 on Human Rights and Biomedicine, as defined in Article 1, is to protect the dignity, the identity, and other rights and fundamental freedoms of all human beings 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 in this field;

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

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

Affirming that particular protection should 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 fundamental rights and 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

This Protocol covers the full range of biomedical research activities involving any kind of intervention on human beings.

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

CHAPTER II
General principles

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 of other legal provisions ensuring the protection of the human being.

Article 5 - Justification for research

Research is only justified if it has the potential to generate scientific understanding that may be a basis for improvements in human health.

Article 6 - Absence of alternatives

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

Article 7 - Risks and benefits

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

Article 8 - Research on persons without potential direct benefit

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 authorised subject to the following additional conditions:

i) the research has the aim of contributing, through significant improvement in the scientific understanding of health, disease, or disorder to the ultimate attainment of results capable of conferring benefit to the health of others; and

ii) the research entails acceptable risk and acceptable burden for the research participants.

Article 9 - Approval

1. Research may only be undertaken if the research project has been approved by the competent body in conformity with national law, after independent examination of its scientific merit, and multidisciplinary review of its ethical acceptability by an ethics committee in conformity with Articles 10 and 11.

2. Consideration shall be given to the relevance of the research to the health needs of the local community.

Article 10 - 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 11 - Independent examination by an ethics committee

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. Such projects shall be submitted to independent examination in each country 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 the research participant. The assessment shall draw on an appropriate range of expertise and experience adequately reflecting professional and lay views.

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

Article 12 - Independent review of ethical acceptability

Parties to this Protocol shall take measures to assure the independence of the ethics committee which reviews the ethical acceptability of research projects. That body shall not be subject to undue external influences. The 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 13 - Information for the ethics committee

Clear, documented information on the proposed research shall be provided to the ethics committee as the basis for assessment of the ethical acceptability of each research project including:

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 record 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;

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 which may be incurred through participating in research;

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

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

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 relevant issues, particularly those of ethical importance, 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.

Article 14 - Undue influence

The ethics committee must be satisfied that no undue influence, including financial gain, will be exerted on persons to participate in research.

Article 15 - Undue influence on dependent persons

The ethics committee must be satisfied that dependent persons and vulnerable groups will not be subjected to undue influence.

CHAPTER IV
Consent and information

Article 16 - Information for research participants

The persons being asked to participate in a research project shall be given adequate information in a documented and comprehensible form on the purpose, overall plan and methods to be applied in the research project, including the opinion of the ethics committee, according to national law. They shall also be specifically informed before consenting to participate in research:

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

ii) of the risks involved;

iii) of the rights and safeguards prescribed by law for their protection;

iv) of their right to refuse consent or to withdraw consent at any time, without prejudice to their right to appropriate and timely medical care;

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

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

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

viii) of the arrangements for appropriate compensation in the case of damage;

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

Article 17 - Consent

1. No research on a person may be carried out under the provisions of this Chapter 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 participate in research shall not prejudice the right of the individual to receive appropriate and timely medical care.

3. Where the capacity of the person to give informed consent is in doubt, arrangements must 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 18 - 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) where possible, the persons undergoing research have been informed of their rights and the safeguards prescribed by law for their protection,

iv) the necessary authorisation has been given specifically and in writing by the legal representative or an authority, person or body provided for by national law**,** and after having received the information required by Article 19, taking into account 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 to participating in the research.

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 appropriate and timely medical care.

Article 19 - Information prior to authorisation

Those being asked to authorise participation of a person in a research project shall be given adequate information in a documented and comprehensible form on the purpose, overall plan and methods to be applied in the research project, including the opinion of the ethics committee. They shall also be specifically informed of the items of information listed in Article 16. Where possible, the information shall be provided to the individual concerned.

Article 20 - 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 symptoms or unpleasantness will be, at the most, temporary and very slight.

In assessing the burden for an individual, a person enjoying the special confidence of the person concerned shall assess the burden where appropriate.

CHAPTER VI
Special situations

Article 21 - Research in emergency clinical situations

If the research is of a nature such that it can only be undertaken in emergency situations, and where a person is not in a state to give consent and it is impossible to obtain the authorisation referred to in Article 18 paragraph 1. iv, the law shall determine whether, and under which conditions, this research can take place.

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 not be undertaken if it has not been approved specifically for emergency situations by the competent body.

Persons participating in the emergency research shall be provided with all the relevant information as soon as it becomes possible.

Consent or authorisation for continued participation shall be obtained as soon as reasonably possible.

Article 22 - Persons deprived of liberty

Where such research is allowed by law, the research may only be undertaken on persons deprived of liberty exceptionally and under the protective conditions prescribed by law if the following specific conditions are met:

i) the research:

- has the potential to produce a significant benefit to their health; or

- is aimed at benefiting the health of people deprived of their liberty and can only be undertaken if it could not be carried out on those not deprived of their liberty;

ii) particular attention is paid that the condition of Article 15 is fulfilled; and

iii) approval has been given by all competent bodies provided for by law.

CHAPTER VII
Research during pregnancy or breastfeeding

Article 23 - Research during pregnancy or breastfeeding

Research involving interventions on pregnant or breast-feeding women or embryos or foetuses may only be carried out if the following additional conditions are met:

i) the informed consent and/or authorisation required by law has been obtained;

ii) the research

- will potentially benefit significantly and directly the health of the woman or that of the embryo, foetus or child; or

- has the aim of contributing, through significant improvement in scientific understanding, to the ultimate attainment of results capable of conferring benefit to other embryos, foetuses, children or women and research of comparable effectiveness cannot be carried out on women who are not pregnant or breast feeding;

iii) the research entails for the pregnant or breast feeding woman and/or embryo, foetus or child

- a risk which is not disproportionate to the potential direct benefits of that research; or

- only minimal risk and minimal burden where the research would not have the potential to produce results of significant and direct benefit for the woman or the embryo, foetus, or child.

Chapter VIII
Confidentiality and right to information

Article 24 - Confidentiality and right to information

Any information of a personal nature obtained during biomedical research shall be considered as confidential and treated according to the rules relating to the protection of private life and subject to law on the protection of individuals with regard to processing of personal data.

Information collected on their health shall be accessible to research participants, in conformity with the provisions of Article 10 of the Convention[1], and law on the protection of individuals with regard to processing of personal data. All other personal information collected for a research project will be accessible to them in conformity with law on the protection of individuals with regard to processing of personal data.

Article 25 - Availability of results

The researcher shall make the results and conclusions of research available to participants in reasonable time, on request.

At the conclusion of the research, a summary or report of the research shall be submitted to the ethics committee or the competent body in all cases.

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

Article 26 - Protection of information related to the research

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

CHAPTER IX
Safety and supervision

Article 27 - Safety

All appropriate measures shall be taken to protect the safety, health and well being of those participating in research.

Research may only be carried out if all necessary preconditions as to its safety have been fulfilled.

Research may only be carried out under the direct supervision of a professional who exercises clinical responsibility and who possesses the necessary qualifications and experience to respond appropriately to clinical contingencies.

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[1] **Article 10 - Private life and right to information**

1 Everyone has the right to respect for private life in relation to information about his or her health.

2 Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed.

3 In exceptional cases, restrictions may be placed by law on the exercise of the rights contained in paragraph 2 in the interests of the patient.

Article 28 - Re-examination

Those participating in research or their representatives, and the competent body according to national law, shall be informed immediately of any relevant developments, in particular of any risks, which have become apparent in the course of the research.

If unforeseen adverse events arise in the course of the research, their causes and severity shall be promptly evaluated.

The research may be continued, after amendment of the protocol if necessary, if the risks are still not disproportionate to the potential benefits of the research.

Continued participation in the research shall be conditional on an additional informed consent or authorisation, if appropriate given the developments that have arisen.

Article 29 - 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 or foetus.

Article 30 - Non-interference with necessary clinical interventions

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.

Article 31 - Duty of care

If research gives rise to information of relevance to the current or future health and 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 32 - Ethics follow-up

The researcher shall inform the ethics committee of unforeseen events giving rise to new ethical issues.

Progress reports shall be provided to the ethics committee, as required. When justified, the ethics committee may re-examine a research project.

The ethics committee shall be informed about, and may require justification for, premature termination of the research project.

Article 33 - Research in States not party to this Protocol

Sponsors and researchers based in the territory of a Party to this Protocol who plan research in a State not party to this Protocol, shall satisfy both the conditions applicable in the State or States in the territory of which research is to be carried out and the fundamental ethical standards and safety guarantees laid down in this Protocol.

CHAPTER X
Infringement of the provisions of the Protocol

Article 34 - Infringement of the rights and principles

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

Article 35 - Compensation for damage

Persons participating in research shall be appropriately compensated in the event of damage according to the conditions and procedures prescribed by law.

Article 36 - 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

Article 37 - Relation between this Protocol and the Convention

As between the Parties, the provisions of Article 1 to 36 of this Protocol shall be regarded as additional articles to the Convention on Human Rights and Biomedicine, and all the provisions of that Convention shall apply accordingly.

Article 38 - 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 on Human Rights and Biomedicine no later than five years from the entry into force of this Protocol and thereafter at such intervals as the Committee may determine.

Article 39 - Wider protection

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

CHAPTER XII
Final clauses

Article 40 - Signature and ratification

This Protocol shall be open for signature by States which have signed the Convention. It is subject to ratification, acceptance or approval. A State Signatory may not ratify, accept or approve this Protocol without previously or simultaneously ratifying the Convention. Instruments of ratification, acceptance or approval shall be deposited with the Secretary General of the Council of Europe.

Article 41 - 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 5 States have expressed their consent to be bound by the Protocol in accordance with the Provisions of Article 40.

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 42 - Notifications

The Secretary General of the Council of Europe shall notify the member States of the Council of Europe, 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 or approval;
c. any date of entry into force of this Protocol in accordance with Article 41 ;
d. any other act, notification or declaration relating to this Protocol.

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

Done at Strasbourg, this ...., in English and 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 and to any State invited to accede to the Convention.