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Guide for Research Ethics Committee Members

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Individual-Research-Society

- Primacy of the human being

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

  (Article 2, Oviedo Convention)

- Freedom of research – protection of participants
  - Scientific research in the field of biology and medicine shall be carried out freely, subject to the provisions of this Convention and the other legal provisions ensuring the protection of the human being.
    (Article 15, Oviedo Convention)
- Ethical review before 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 7, Protocol “Biomedical research”)

Fields of Biomedical Research

- With a physical intervention
  - potential direct benefit for the person involved
  - no potential direct benefit for the person involved

  → All kind of biomedical research **on** man!
- Without a physical intervention
  - research on stored biological material of human origin, associated data
  - medical epidemiology
  - medical observational research

Responsibilities of Research Ethics Committees

- Independent examination by an ethics committee
  - Submission of every research project for independent examination of its ethical acceptability to an ethics committee. Submission in each State in which research activity is to take place
  - Protection of the dignity, rights, safety and well-being of research participants. Appropriate range of expertise and experience adequately reflecting professional and lay views.
  - Opinion containing reasons for the conclusion
- "Independence of the ethics committee

  1. 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.
  2. 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."
- Information for the ethics committee
  - All information necessary for the ethical assessment of the research project in written form
  - For harmonization: Information on items contained in the appendix to the Protocol "Biomedical Research"
- Undue influence
  - No undue influence, including that of a financial nature, on persons to participate in research
  - Particular attention must be given to vulnerable or dependent persons

(Articles 9,10,11,12,Protocol "Biomedical Research")

Regulations of Research

Approach for International Implementation

- Shared ethical values
  - Autonomy
  - Beneficence /Non-maleficence
  - Justice
- International laws/treaties ratified
- Framework given by national law
- Harmonized procedure

→ Guide for Research
Ethics Committee Members

Intentions

- Assistance for capacity building
- Assistance for Research Ethics Committees (RECs) reviewing research proposals mainly involving human beings
- European view of key ethical issues that RECs are likely to face
- Highlighting the ethical basis of principles covering biomedical research as laid down in the relevant European instruments in conformity with an international level
- Operational procedures
- **No** definition of new principles

Biomedical Research

-description used in the guide-

- RECs may have to review a wide range of biomedical research projects involving human beings, from those involving interventions to those using stored biological samples and associated personal data. The Guide is mainly concerned with research involving interventions.
- However, sections of this guide e.g. confidentiality and right to information or access to research results, are relevant for all types of biomedical research projects involving human beings.

Legal Aspects

- Compliance with relevant national laws which must fulfil the requirements of any international laws/treaties ratified
- Non legally binding instruments – “soft law”
  - Declaration of Helsinki
  - Universal Declaration on bioethics and human rights (UNESCO)
  - International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS)
  - ICH E6 Good Clinical Practice guidelines
- Legally binding instruments
  - Convention on Human Rights and Biomedicine (Oviedo Convention) and its Additional Protocol concerning Biomedical Research
  - Directive 2001/20/EC concerning drug research in the EU-Member States

Research Ethics Committee

- Description -

- Multidisciplinary, independent groups of individuals
- Review of biomedical research protocols involving human beings
- Respect and protection of dignity, fundamental rights, safety and well-being of research participants
- Established at local, regional or national level
- Appointment by institutions or by regional or national authorities
- Scope as a local, regional or national REC defined by the appointing authority
- RECs should be established and function according to commonly accepted ethical principles and procedural standards

RECs in the Research Process

- Before research begins
  - Review of research proposals
    - Scientific quality - may be revised by a different body
    - Conformity with law - may be proven by a different body
    - Ethical acceptability
- During research
  - Conduct of research projects if appropriate according to national practice
  - Re-examination of the research project in the light of new developments and/or scientific results
  - Decision to continue, to change or to terminate the project
- After research – as aim for the future
  - Fulfilment of any obligations of researchers and/or sponsors to research participants, groups or societies from which they were recruited
  - Availability of results for participants, offer of information on health-related results
  - Publication of results in scientific journals

Composition of RECs

- Multidisciplinary composition
- Appropriate collective expertise to perform a review
- Balance of scientific expertise, philosophical, legal or ethical background and lay views
- Basic understanding of the importance of research
- Equal standing of professional and lay members
- Obligation to confidentiality
- Initial and continuing training of REC members adapted to individual needs
- Rules for appointment and renewal process
- Accountability of RECs in conformity with national law

Members of RECs

- Professional members e.g.
  - Scientists, health care professionals, lawyers, ethicists, epidemiologists, clinical pharmacologists, pharmacists, psychologists, sociologists, biostatisticians
- Lay members
  - No specific qualification in biomedical research, medicine or health care
- Initial and continuing training of REC members
  - Training relevant to the role in the REC
  - Training for all members adapted to individual needs and RECs specific needs in particular
    - Ethical principles and their application in biomedical research
    - Research design and methods
    - View of conducting research

Method of Working

- Statutes issued by the appointing body
- Rules of procedure developed by the REC
  - Plenary meetings
  - Appointment of ad hoc rapporteurs for specific proposal
  - External expertise
  - Administrative procedures
  - Archiving documents
  - Handling of conflict of interest
- Follow up of an ongoing research project
- REC self-evaluation
- Internal discussion on the work of the REC
- Independent audit of REC functioning
- Exchange with other bodies

Examination of a Research Project

-Formal requirements-

- Legal competence of the REC according to national law
- Applicant entitled to submit a proposal
- Interaction with authorities according to national law
- Application process
  - Application in writing and dated, electronic submissions should be accepted
  - Acknowledgement of receipt and safeguarding of confidentiality
  - Requirements for application fulfilled?
  - Contact person for the applicant
  - Notice to the applicant concerning begin and time table of assessment
- Before begin of the assessment declaration of conflicts of interest pertaining to the proposal to be reviewed

Information for the REC*

- Description of the project
- Justification for involving human beings
- Inclusion and exclusion criteria
- Healthy volunteers
- Justification for control groups
- Use of placebo
- Benefits and risks
- Recruitment arrangements
- Information for potential participants
- Potential undue influence
- Informed consent/authorization
  - arrangement for seeking, scope, documentation

*According to the Appendix to the Additional Protocol Biomedical Research

Safety and Supervision

- Information for the REC -

- Assessment of health status of participants
- Medical supervision of participants
- Information for the REC during the conduct of research
- New information and protection of participants

Confidentiality - Right to Information

- Information for the REC-

- Data protection
- Safety of removed and stored biological materials
- Right to know – right not to know

Availability of Research Results

- Information for the REC -

- REC
  - Information by the researcher on results, conclusions, conduct or premature termination of the research project; foreseen means for publication of results
- Participants
  - Overall conclusions in a comprehensible form on request of the participant
  - Respect of interests and rights of third parties
  - Offer of information on results with relevance to the health of the participant and/or his family; medical counselling!
- Scientific community and healthcare system

Other Points

- Payments and rewards
  - Participants: influence on free and informed consent
  - Researcher: independent judgement of the project
- Further uses, including commercial uses, of the research results, data or stored biological materials
- Compensation for damage

Persons not able to consent

- Specific assessment by the REC -

- Legal provisions
- System of legal representation
  - Participation of the represented person in the authorization procedure in relation to maturity and capacity to understand
  - Authorization only on full information; may be refused or withdrawn at any time without disadvantage for the represented person
  - No specific interests of the legal representative
- Justification for research on persons not able to consent
- Minimal risk and minimal burden as limiting factors for research without the potential direct benefit on persons unable to consent
- “Scientific quality – conformity with law – ethical acceptability”

Research in Specific Situations

- Clinical emergencies
  - Legal provisions
  - Delayed informed consent/authorization
  - Assessment of the project as an emergency project by an authority and by a REC
  - Principles of minimal risk and minimal burden for research without a potential direct benefit for the participant
- Persons deprived of liberty
  - Legal protective provisions
  - Justification for research on this group
  - Protection of autonomy!
- Pregnancy and breastfeeding
- Cluster randomised trials

Work in Progress

- Transnational research
  - Draft Declaration on the implementation of fundamental ethical principles in transnational biomedical research
- Research on biological materials of human origin
  - Recommendation Rec(2006)4 of the Committee of Ministers to member states on research on biological materials of human origin

Руководство для членовКомитетов по этической экспертизе исследований

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