



Proposal for a  
**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**  
**on clinical trials on medicinal products for human use, and repealing Directive**  
**2001/20/EC**

Comments formulated by the European Network of Research Ethics Committees (EUREC)  
after the EUREC Meeting in Lisbon adopted by the Board on July 12<sup>th</sup>, 2013  
based on the revised draft and the amendments of the First Reading  
of the European Parliament

EUREC appreciates that the European Parliament (EP) has taken the weaknesses of the EC's draft of a "Proposal for a Regulation on clinical trials" into account. In particular, we were troubled that the EC's draft proposed to undo positive steps established through the current Directive in substantially removing Research Ethics Committees (RECs) from the Regulation. Since Research Ethics Committees are accepted world-wide as bodies which evaluate or assess the ethics of all biomedical research independently, the EP amendments to the Proposal of the Regulation recorded in the Report by Glenis Willmott make significant progress to reintroduce RECs in the assessment of clinical trials applications.

EUREC fully supports that by the proposed EP amendments,

- safety standards for vulnerable persons would be strengthened,
- the sponsor cannot choose the reporting member state,
- the results of all trials would be made publicly available,
- the Commission will facilitate cooperation between ethics committees and the sharing of best practices on ethical issues including the procedures and principles of ethical assessment.

The consequent formulations, through the EP's proposed amendments, would thereby mostly comply with European and International Regulations and the new wording takes core principles of research ethics into account to a slightly greater extent.

EUROPEAN NETWORK OF RESEARCH ETHICS COMMITTEES (EUREC)  
<http://www.eurecnet.org>

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However, EUREC still sees a critical need for further strengthening of independent ethical evaluation in the governance of clinical trials before the regulation comes into force:

- The Regulation still only considers Ethics Committees of the concerned Member States as consultation bodies in the authorization process, since they are only required to “examine” part II of the submission, covering mainly informed consent issues. EUREC, in line with international requirements and amendment to Article 4a of the Regulation, argue that RECs must be included as independent bodies that deliver an ethical assessment in a concerned member state independently from the competent authority. Thus it is absolutely essential that RECs assess both parts I and II of the trial authorization dossier. Only when the REC gives a favourable opinion should a biomedical research project be authorised to be carried out. There is still a need to clarify and strengthen the exact impact of an REC’s assessment for the granting of a favourable opinion for the whole assessment process.
- The modified timescales proposed in the amendment, for example under Article 6(4), are still in practice much too short and therefore run a very real risk that Member States will not be able to include effective ethical review in their assessment process, defeating the very purpose of the Regulation.
- Persons involved in research in emergency clinical situations (regulated in Article 32) should only be included with appropriate legal protection, as for example, contained in Article 19 of the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research.

EUREC is willing to contribute to the development of a durable governance structure for clinical trials in Europe. As a representation of the national Networks and Associations of European Research Committees, EUREC is prepared to help in whatever way it can in relation to developing this proposed legislative revision. In line with the “Explanatory Statement” of the Report, EUREC will push forward and strengthen the communication and exchange among European RECs to develop best practice models of ethical evaluation of clinical trials.

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