



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)) at
the EUREC Meeting at Oslo on 7th of September 2012

EUREC is the European Network of Research Ethics Committees in Europe. EUREC welcomes the initiative of the European Commission to advance the existing framework for conducting clinical trials within the EU. Moreover, EUREC appreciates that the Commission acknowledges the importance of an ethical assessment of clinical trials, which proved to be both important and effective regarding the protection of research participants in the past and which is today a standard accepted world-wide. Equally EUREC appreciates that, at the same time, the Commission has to respect the different cultural traditions, particularly in relation to ethics, within the Member States and therefore as a matter of subsidiarity has a limited possibility for harmonising the whole governance of clinical trials at the EU level.

This diversity existing in all regions of the world is respected by international instruments like the Oviedo Convention on Human Rights and Biomedicine, by the Clinical Trials Directive 2001/20/EC or the ICH-GCP Guidelines, by Guidelines as published by CIOMS or by the principles as contained in the UNESCO “Universal Declaration on Human Rights and Bioethics” (2005) or in the Declaration of Helsinki. However these examples present unanimously a list of items to be followed in any ethical assessment of research projects involving human beings. These frameworks try to introduce at least a basic protection of human beings independently of national sights. A similar framework of conditions and structural provisions for ethics in research is not found in the proposal of the European Commission. It therefore should be amended for the following reasons:

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

Chair: Prof. Dr. Elmar Doppelfeld

Vice Chair: Prof. Dr. Eugenijus Gefenas

Head of EUREC Secretariat: Dr. Dirk Lanzerath

Members of the Board:

Prof. Dr. Gisela Dahlquist, Dr. Maria A. Ribeiro, Prof. Dr. Knut W. Ruyter

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1. EUREC believes that the choice of the Commission to undo the positive steps established through the current Directive by omitting the clear position of Research Ethics Committees (RECs) in the process is not acceptable. Research Ethics Committees are world-wide accepted bodies which should evaluate or assess all biomedical research. They are well established in the assessment of whether a clinical trial should start, should be changed, or should not proceed. The inclusion of RECs in this process is crucial for both the protection of research participants and for ensuring trust and confidence in the process of the development of new pharmaceutical products. EUREC is concerned that the proposal as it stands would allow a Member State to choose not to include independent ethical review by RECs in the assessment of clinical trials proposals, and finds it very difficult to understand why the Regulation does not require that all clinical trials, including those with low risk, must be assessed by RECs.
2. If the process of assessment is to be taken seriously, allowing for proper consideration by appropriate committees, realistic timescales must be given. The timescales proposed, for example under Article 6(4), are in practice much too short and therefore they run a very real risk that Member States will not be able to include effective review in their assessment process, defeating the very purpose of the Regulation.
3. One of the driving concerns expressed in the background papers for the proposed revisions is the different standards applied by Member States. EUREC is concerned that these different standards will persist into the operation of the new Regulation if Member States are given the proposed wide discretion in constituting their national assessment processes. Allowing sponsors to choose which Member State to nominate as the reporting Member State runs a very real risk of exaggerating the different standards as sponsors could well choose to nominate Member States with weak assessment regimes to this important role within the governance structure.

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4. EUREC welcomes the inclusion of informed consent in the Part 2 Assessment. The representatives of RECs wonder why the Commission has chosen not to include the full range of ethical principles that are included in the Directive with the aim to introduce a compulsory list of items to be addressed in the course of the ethical review process.
5. EUREC welcomes that the Commission has included 'level of care' and 'requirements of local law' (in conformity with Article 86) as reasons to allow Member States to register concern about proposals under Article 8(2). EUREC believes that a further reason should be added to allow a Member State also to register its concerns where a research proposal fails to gain a favorable opinion at the national REC.

Given the very tight timescale for comments on the proposal a full systematic critique is not possible, but EUREC has additional concerns about some of the drafting in the proposed Regulation. For example, there is no clear explanation of the Assessment Process. That the Assessment has two parts is initially indicated in the titles of Articles. This causes confusion in Article 11: is Article 11 intended to allow the sponsor to choose to apply first for a Part One assessment, and then at a later date for a Part Two assessment, or to choose whether both a Part One and Part Two assessment is necessary? The wording is, we feel, currently ambiguous.

EUREC is willing to make a full and enthusiastic contribution to the development of a robust governance structure for clinical trials in Europe, and is prepared to help in whatever way it can in relation to this proposed legislative revision.

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