



**Position of the
European Network of Research Ethics Committees (EUREC)
on the
Responsibility of Research Ethics Committees
during the COVID-19 Pandemic**

The COVID-19 pandemic is an enormous and extraordinary challenge for societies, economics, politics, healthcare systems, and in particular, for medical research. The diverse actions to contain the pandemic in Europe and worldwide must include the development and testing of effective drugs and vaccines. This is a particularly urgent matter. However, pharmaceuticals that are to be approved in the future to be used to cure COVID-19 must be as *effective* and *safe* as possible. Therefore, the European Commission, the European Medicines Agency (EMA) and national Head of Medicines Agencies (HMA) have published “Guidance on the Management of Clinical Trials during the COVID-19 (Coronavirus) pandemic” (https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/guidanceclinicaltrials_covid19_en.pdf) for sponsors on how to manage the conduct of clinical trials in this particular context and how to address questions of safety, risk assessment and informed consent.

This recent mode in medical research also leads to a tremendous challenge for *European Research Ethics Committees (RECs)*. RECs are aware that they must contribute accordingly. This contribution is based, in particular, on the fact that the *administrative processes for reviewing research protocols must be accelerated and simplified* if these protocols are related to the treatment, prevention or diagnosis of infections caused by SARS-CoV-2. However, all this must be guided by the principle that RECs, even under these specific circumstances, will not compromise the *quality* of the review; an accelerated procedure cannot be at the expense of *safety*, notably that of the research participants. The recognised *ethical principles* of autonomy, beneficence, non-maleficence and justice must always be respected.

In particular, the following rules should be applied.

1. RECs should give clear *priority* to the assessment of submitted studies that are linked to the prevention or treatment of COVID-19 and COVID-19-related illnesses. The assessment of trials on other serious diseases with no satisfactory treatment option should also be prioritised.
2. The *free and informed consent procedure* must remain in accordance with European and national regulations. It is recognised that national regulations and their application may differ across Europe. The proposals in section 8 of the above mentioned European “Guidance” on how to deal adequately and in a simplified manner with informed consent under the conditions of COVID-19 should be taken into account by the European RECs.

EUROPEAN NETWORK OF RESEARCH ETHICS COMMITTEES (EUREC)
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3. In the current pandemic situation, the traditional meetings of ethics committees cannot necessarily be organised in the usual, often face-to-face, manner. The RECs should therefore *adopt new working methods*, such as secure video conferencing, that are appropriate to the current situation and respect the new rules of conduct concerning the pandemic. Where necessary, provision should be made accordingly for changes to the rules of procedure.
4. It should be possible for RECs to hold *extraordinary meetings* outside the regular cycle to discuss research protocols relating to the treatment, prevention or diagnosis of infections caused by SARS-CoV-2.
5. Responsible RECs must be composed of experts with the appropriate expertise. With regard to the assessment of trials concerning COVID-19, relevant experience and expertise must also be ensured within the REC.
6. *Digital communication technologies* can speed up administrative procedures. However, the information and communication technology used must be designed in such a way that GDPR-compliant transmission of data is guaranteed.
7. In the course of the study, the *recording of undesired events and effects* and their forwarding and evaluation must also be guaranteed by the investigator. The responsible REC must also be involved accordingly in pending decisions and modifications, e.g. of the protocol in the event of subsequent changes. It is advisable to document all deviations from the inspection plan that are attributable to the pandemic situation. All participants, including the RECs, should be informed, without delay, of any changes that are relevant to them during the course of the clinical trial. Where appropriate, a new informed consent may be required.

The overarching mission of all ethics committees is the *protection of the dignity, rights, safety and well-being of research participants*, namely patients and healthy volunteers, in medical trials. This also applies against the background of the current pandemic situation. Therefore, the pressure currently being exerted on medical research must not lead to research or testing of pharmaceuticals on humans without complying with the *ethical standards applicable to medical research*.

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