Presidenza del Consiglio dei Ministri

Abstract

BIOMEDICAL RESEARCH FOR NOVEL THERAPEUTIC TREATMENTS WITHIN THE COVID-19 PANDEMIC: ETHICAL ISSUES

22 October 2020

Currently there are numerous ongoing trials in the therapeutic area, however the pandemic context and the consequent health emergency can constitute a challenge to respect the consolidated scientific, ethical and legal requirements of biomedical research for therapeutic purposes, shared by the international community, given the urgency of obtaining results.

In this opinion, the Committee reiterates that, even in the context of the pandemic emergency, these principles are to be respected with particular attention reserved to the criterion of justice in the allocation of resources at different levels (prevention, diagnosis and treatment of Covid-19 patients, without neglecting research on other pathologies) and the standards of quality and validity. The Committee identifies the possibility of speeding up research by strengthening translational research from the laboratory to the patient's bedside, with adequate information provided to the patient regarding the potential risks.

In particular, the ICB focuses on the *off-label* use of drugs and compassionate care, underlining the need for clear communication on the risks to patients and the importance of making every effort to proceed according to ordinary experimental designs. Furthermore, the Committee believes that the research aimed at obtaining therapeutic treatments for Covid-19 must include all individuals, without exclusion (while maintaining an adequate risk/benefit ratio as a prerequisite), considering that the exclusion of particularly vulnerable persons from the research is contrary to the principle of justice, as it deprives them of the same possibility of treatment today, as no safe and effective treatment is currently available, but also in the future for the possible exposure to risks. The relevance and role of ethical review by the ethics committees is also underlined, with particular reference to the Italian experience involving AIFA, in particular with the Technical-Scientific Commission, and the single national ethics committee for COVID-19 trials.

The Committee also analyses the transformations of informed consent for participation in trials in the emergency context of the pandemic, focusing on research on biological samples, genomic tests and the use of data. The Committee's hope is that, on various levels, it is essential to ensure, in the context of the pandemic, interdisciplinary research, collaboration, international coordination and the sharing of results and data for health as a "common global good".