

## ***Clinical research on Covid-19: bioethical aspects***

Prof. L. d'Avack (Monday, November 23rd 2020)

Prof. L. d'Avack is the Chair of Italian Committee for Bioethics, which recently released an Opinion on "Biomedical research for novel therapeutic treatments within the Covid-19 Pandemic: ethical issues" (October 22<sup>nd</sup>, 2020). During his lecture, Prof. d'Avack focused on informed consent in the context of trials currently in progress in the therapeutic field.

He recalled main **ethical and legal requirements** of biomedical experimentation for therapeutic purposes: all these requirements, even in the context of the pandemic emergency, should be respected with particular attention to the criterion of **justice** in the allocation of resources at different levels (prevention, diagnosis and treatment of Covid-19 patients, without forgetting research on other pathologies) and to the standards of quality and validity.

The possibility of accelerating research by enhancing translational research from the laboratory to the patient's bed should be carried on with **adequate information to the patient on potential risks**.

In addition, the speaker focused on the off-label use of drugs and compassionate care, emphasizing the need for clear communication of the risks for patients and the importance that every effort should be made to proceed according to ordinary experimental designs. Furthermore, **the experimentation aimed at therapeutic treatments for Covid-19 must include all subjects, without any exclusion** (while maintaining an adequate risk / benefit ratio as a prerequisite), considering that the exclusion of particularly vulnerable people from the experimentation is contrary to the principle of justice, as it deprives them of the same possibility of treatment (because no safe and effective treatment is currently available) and also in the future for possible exposure to risks.

Prof. L. d'Avack discussed as well the ethical issues related to research involving **biological samples** and to the use of **health data**. Another important issue mentioned and discussed has been that of **clinical research for a Covid-19 vaccine** and, assuming a safe and effective vaccine, the opportunity to establish or not as mandatory a vaccination against Covid-19.