

COUNCIL OF EUROPE



CONSEIL DE L'EUROPE

Strasbourg, 14 April 2020

DH-BIO/INF(2020)2

COMMITTEE ON BIOETHICS (DH-BIO)

DH-BIO Statement on human rights considerations relevant to the COVID-19 pandemic

DH-BIO Statement on human rights considerations relevant to the COVID-19 pandemic

- The current COVID-19 crisis is affecting all countries in Europe and worldwide. This pandemic has and will continue to have a severe impact on individuals and societies. Health care systems are under extreme constraints facing very acute and complex situations daily. The increasing number of severe cases raises major ethical challenges that professionals and competent authorities have to address in the health care of patients. Difficult decisions have to be taken at collective and individual levels in a context of uncertainties and scarce resources, which may have important impact on individuals.
- Expert groups and ethics committees in European countries have rapidly addressed some of these major challenges. At international level, independently of the important actions carried out by WHO and its relevant guidance, such as [Guidance for managing ethical issues in infectious disease outbreaks](#) (2016), independent expert bodies have also issued relevant statements. UNESCO International Bioethics Committee (IBC) and World Commission on the Ethics of Scientific Knowledge and Technology (COMEST) have made public their [joint Statement on COVID-19: Ethical consideration from a global perspective](#), and the European Group on Ethics in Science and New Technologies (EGE) has published its [Statement on European solidarity and the protection of Fundamental Rights in the COVID-19 Pandemic](#). These documents underline important guiding ethical principles for decisions and practices in this context.
- It is essential that such decisions and practices meet the fundamental requirement of **respect for human dignity** and that **human rights** are upheld.
- The [Convention on Human Rights and Biomedicine](#) (Oviedo Convention) is the only legally binding instrument at international level addressing human rights in the field of biomedicine. It provides a unique human rights framework, including in a context of emergency and health crisis management, to guide decisions and practices both in clinical and research fields.
- In this Statement, the Council of Europe Committee on Bioethics (DH-BIO) wishes to highlight some of the human rights principles laid down in the Oviedo Convention which are particularly relevant and require particular vigilance in their application in the current pandemic.
- The principle of **equity of access to health care** laid down in Article 3 of the Oviedo Convention must be upheld, even in a context of scarce resources. It requires that access to existing resources be guided by medical criteria, to ensure namely that vulnerabilities do not lead to discrimination in the access to healthcare. This is certainly relevant for the care of COVID-19 patients, but also for any other type of care potentially made more difficult with confinement measures and the reallocation of medical resources to fight the pandemic. The protection of the most vulnerable people in this context is indeed at stake, such as persons with disabilities, older persons, refugees and migrants. This concerns decisions to allocate scarce resources, to provide necessary assistance to those most in need, as well as protecting and supporting vulnerable individuals affected heavily by the consequences of confinement measures.
- The collection and processing of health-related data is an essential component of the fight against the COVID-19 pandemic including the use of digital technologies, big data and artificial intelligence. However, as underlined in the [Joint Statement on the right to data protection in the context of the COVID-19 pandemic](#) by the Chair of the Committee on Convention 108¹ and the Data Protection

¹ Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (CETS No.108)

Commissioner of the Council of Europe, “the threat resulting from the COVID-19 pandemic [has to be addressed] in respect of democracy, rule of law and human rights, including the rights to privacy and data protection”. Article 10 of the Oviedo Convention concerns the **right to privacy of information** in the health field, thereby reaffirming the principle introduced in Article 8 of the European Convention of Human Rights. In accordance with the Modernised Convention for the Protection of Individuals with regard to the Processing of Personal Data, personal health related data are sensitive data and their processing is therefore subject to specific protective conditions.

- A possibility to make **restrictions on the exercise of the rights and protective provisions** contained in the Oviedo Convention, including the right to privacy, is provided in its Article 26. These exceptions are aimed at protecting collective interests² and include the protection of public health. However, any such restriction shall be prescribed by law and be necessary in a democratic society for the protection of the collective interest at stake. These conditions are to be interpreted in the light of the criteria established by the European Court of Human Rights, in particular those of necessity and proportionality.
- Article 8 of the Oviedo Convention is applicable to **emergency situations**, such as those which healthcare professionals are regularly facing in the context of the COVID-19 pandemic. Where, because of urgency, the appropriate consent of the person concerned cannot be obtained, any medically necessary intervention may be carried out immediately for the benefit of the health of the individual.
- At a time where **research** efforts in biomedicine are rightly increased with a view to develop appropriate therapeutic and preventive measures, the DH-BIO wishes to reiterate the requirement to respect human rights in this context. These rights are duly reflected in the Oviedo Convention, which does not provide for any exception to the respect of the protective conditions laid down in articles 16 and 17 for the protection of person undergoing research. Some of the conditions to be met are that there is no alternative of comparable effectiveness to research on humans, the risks are not disproportionate to the potential benefit, the research project has been approved by the competent body after multidisciplinary review of its ethical acceptability, the persons undergoing research must be informed of their rights and their appropriate consent has to be obtained.
- The [Additional Protocol to the Oviedo Convention concerning Biomedical Research](#) complements the Convention by defining in its Article 19 the conditions under which **research on persons in emergency clinical situations** can be carried out. Such research, intended to improve emergency response or care, is important as without it the outcome for patients in a clinical emergency situation in which the risk of death may be high, is unlikely to improve. In such situations, the person concerned may not be in a state to give consent and, because of the urgency of the situation, it may not be possible to obtain in a timely manner the appropriate authorisation of a representative or authority provided for by law. The Article specifies the additional protective conditions to be met by such research project compared to the ones provided for other types of research. Those conditions, that have to be stated in the law, include namely the approval of the project specifically for emergency situations by the competent body, the respect of any relevant previously expressed objections of the person known to the researcher, and the need to provide appropriate information and request the consent or authorisation for continued participation as soon as possible.

² In accordance with Article 26 and subject to the conditions specified in this article, the purposes for which restrictions may be placed on the exercise of the rights and protective provisions contained in the Oviedo Convention are public safety, the prevention of crime, the protection of public health or the protection of the rights and freedoms of others

- The principles underlined in this Statement together with the other principles laid down in the Oviedo Convention reflect and reinforce the fundamental and indissociable link between **human rights, solidarity** and **responsibility** which are essential in addressing the current crisis caused by the COVID-19 pandemic.
- In this connection, certain elements of the preamble to the Oviedo Convention have never been more important, namely the achievement of a greater unity between Member States for the maintenance and further realisation of human rights, the need for international cooperation, and the rights and responsibilities of all members of society.
- The unprecedented situation that all countries are facing with the COVID-19 pandemic is calling for urgent and coordinated actions including addressing important ethical challenges. Through the unique platform for exchange the DH-BIO provides at an intergovernmental level, the Committee is committed to facilitate exchange of information to that end. It will also contribute to the necessary further analysis of the ethical challenges raised during and in the aftermath of this pandemic, in particular under the Equity pillar of its [Strategic Action Plan on Human Rights and Technologies in Biomedicine \(2020-2025\)](#), and on the basis of the reference Council of Europe human rights legal corpus developed in particular around the Oviedo Convention.