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JOINT CNECV/CEIC OPINION ON THE ETHICAL ASPECTS OF CLINICAL RESEARCH IN EMERGENCY SITUATIONS

Executive Summary

March 2024

Conselho Nacional de Ética para as Ciências da Vida

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Executive Summary

The National Ethics Council for Life Sciences (CNECV) and the Ethics Commission for Clinical Research (CEIC) have approved a joint opinion on the possibility of carrying out clinical trials on medicines and clinical studies on medical devices in emergency situations, taking into account the direct application of European regulations in this area to the national legal order.

The European Regulation on Clinical Trials of Medicinal Products (Regulation (EU) No 536/2014 of 14 April 2014) came into force in the European Union, and thus also in Portugal, on 31 January 2022. Both this regulation and the one on Medical Devices (MD) (Regulation (EU) 2017/745 of 5 April 2017) provide for the possibility of conducting clinical research in emergency situations, taking into account well-defined ethical and legal criteria.

Clinical trials of medicines and clinical studies of medical devices in emergency situations are of great importance in the light of the principle of beneficence, given that a substantial part of the population suffers from cardiovascular diseases (including, for example, strokes and myocardial infarctions), which manifest themselves in a sudden and often fatal manner, and it is therefore important to carry out research for and with these populations - within strict ethical requirements.

Article 35 of the European Clinical Trials Regulation in particular, by introducing the possibility of including a person in a clinical trial of a medicine, in emergency situations, without the prior informed consent of the person or their legally authorised representative, establishes a new paradigm from an ethical point of view and poses new legal and regulatory challenges. The inclusion of people in studies without prior consent - accepted, exceptionally, by the aforementioned European Regulations - depends on strict and cumulative conditions, which include emergency, ignorance of previous objections, direct benefit with minimal risk to the person and the impossibility of recruiting participants capable of consenting to their inclusion in the research.

For this reason, the National Ethics Council for Life Sciences (CNECV) and the Ethics Commission for Clinical Research (CEIC) have decided to draw up and approve a joint opinion on the possibility of conducting clinical trials of medicines and clinical studies with medical devices in emergency situations, taking into account the direct application of European regulations in this area to the national legal order.

In this context, the CNECV and CEIC recommend that "all people who are incapable of giving consent in emergency situations and could benefit from being included in research protocols should, if they are included, enjoy increased protection measures, while respecting their dignity and situation of particular vulnerability".

In the joint opinion, the two bodies also take the view that "in the absence of advance directives (living wills and/or health care proxies) or other legally authorised representatives, namely companions with legitimacy to give consent in the situations in question, ethically appropriate solutions are required for the participation, if justified," of these people.

They also believe that, in order to carry out clinical trials or research studies with MDs in an emergency context, the respective exemption from obtaining informed consent prior to inclusion in the study from the person or their legally authorised representative may only be admitted extraordinarily if the following exceptional procedural conditions are cumulatively considered (in addition to those specifically provided for in the European Regulation on Clinical Trials of Medicinal Products and the European Regulation on Medical Devices): i) absence of a therapeutic or intervention that is proven to be safe and effective; ii) prospect of minimal risks and effective superior benefit for the patient; iii) impossibility of carrying out the research in question on patients capable of consenting in good time.

Verification of these conditions will be the responsibility of the Ethics Committee, which approved the clinical study and considered the inclusion of participants without prior consent to be acceptable, as an exception to the general rule established by the regulations.

The President, *Maria do Céu Patrão Neves*.

Rapporteurs:

André Dias Pereira,
CNECV Vice-President

António Lourenço,
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Margarida Silvestre,
CNECV member

Pedro Póvoa,
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Rui Nunes,
CNECV member

Maria do Rosário Zincke dos Reis, *CEIC Member*

Cíntia Águas
CNECV Executive Secretary

This opinion was approved by the CEIC plenary at a meeting on 8 March 2024 and, in a final overall vote, by the CNECV plenary and CEIC representatives at a joint meeting on 22 March 2024.