COMITÉ PERMANENT DES MÉDECINS EUROPÉENS
STANDING COMMITTEE OF EUROPEAN DOCTORS

CPME/AD/Brd/030905/082/EN

At its Board meeting, Brussels, 3 September 2005, the CPME adopted the following policy: Testing medicinal products on incapacitated patients (CPME 2005/082 EN/FR)

CPME statement on Good Clinical Practice (GCP) directive[1]: Research in emergency situations on individuals from whom it is not possible to obtain consent

The CPME calls for a revision of the GCP directive with regards to research in emergency situation on individuals from whom it is not possible to obtain consent.

The GCP-directive inhibits important research in certain acute situations because it requires prior consent of the patients´ legal representative - in cooperation with the treating doctor - is given before testing, and demands that the direct benefit to the patient outweighs the risks.

The CPME proposes that the text of the GCP directive is amended in the way that it allows research to be done also in emergency situations when the patient is unable to give his/her informed consent fully respecting medical ethics and the rights and integrity of the patient.

The amendment should follow the lines of the declaration of Helsinki, which has also been the guiding principle in the Draft additional Protocol to the convention on Human Rights and Biomedicine, on biomedical Research of the Council of Europe.

The declaration of Helsinki of the World Medical Association reads (article 16 – 19 and 24 – 26):

16. Every medical research project involving human subjects should be preceded by careful assessment of predictable risks and burdens in comparison with foreseeable benefits to the subject or to others. This does not preclude the participation of healthy volunteers in medical research. The design of all studies should be publicly available.

[1] Directive 2001/20/EC of 4 April 2001

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17. Physicians should abstain from engaging in research projects involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians should cease any investigation if the risks are found to outweigh the potential benefits or if there is conclusive proof of positive and beneficial results.

18. Medical research involving human subjects should only be conducted if the importance of the objective outweighs the inherent risks and burdens to the subject. This is especially important when the human subjects are healthy volunteers.

19. Medical research is only justified if there is a reasonable likelihood that the populations in which the research is carried out stand to benefit from the results of the research.

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24. For a research subject who is legally incompetent, physically or mentally incapable of giving consent or is a legally incompetent minor, the investigator must obtain informed consent from the legally authorized representative in accordance with applicable law. These groups should not be included in research unless the research is necessary to promote the health of the population represented and this research cannot instead be performed on legally competent persons.

25. When a subject deemed legally incompetent, such as a minor child, is able to give assent to decisions about participation in research, the investigator must obtain that assent in addition to the consent of the legally authorized representative.

26. Research on individuals from whom it is not possible to obtain consent, including proxy or advance consent, should be done only if the physical/mental condition that prevents obtaining informed consent is a necessary characteristic of the research population. The specific reasons for involving research subjects with a condition that renders them unable to give informed consent should be stated in the experimental protocol for consideration and approval of the review committee. The protocol should state that consent to remain in the research should be obtained as soon as possible from the individual or a legally authorized surrogate.

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