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NOTE EQUIVALENT TO AN OPINION

ETHICS OF RESEARCH AND CARE EN

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NOTE EQUIVALENT TO AN OPINION ON THE PERFORMANCE OF THE ARDA STYDY (ANOMALIES IN THE FAT DISTRIBUTION OF HIV-INFECTED PATIENTS)

The National AIDS Council has been notified by the TRT-5 inter-association collective of the conditions in which a biomedical research project involving human subjects is being conducted at Archet General Teaching Hospital in Nice.

The aim of the ADAD (French acronym = ARDA) study is to arrive at a better understanding of the metabolic mechanisms underlying anomalies in the distribution of adipose deposits observed in HIV-infected patients receiving antiretroviral multitherapy. Apparently, the study involves invasive procedures whose object is to take adipose and muscle samples from HIV-positive and HIV-negative subjects. These surgical acts are, it would appear, carried out under general anaesthetic. Two or three successive periods of anaesthesia are induced in HIV-positive subjects purely for research purposes.

As input for their consideration of the matter, the members of the Medical Affairs Committee of the National AIDS Council requested that the appropriate department of the Ministry of Health provide them with the information given by the instigator of the study, who is also the principal researcher, in accordance with articles R. 2032 et seq. of the Public Health Code. In view of the need for secrecy imposed on civil servants by the law concerning the protection of persons volunteering as subjects for biomedical research projects (article L. 1123-3 of the Public Health Code), the relevant department at the Ministry has not provided the documentation required for assessment of the validity of the approach adopted.

Nevertheless, the members of the Council were of the opinion that the use of general anaesthesia purely for research purposes, and only on HIV-positive subjects, in the context of a study which offers no direct benefit at the individual level, constitutes a serious and foreseeable risk for the subjects concerned. The members were surprised that this study, as constituted, should have received CCPPRB approval (Advisory Committee on the Protection of the Person in Biomedical Research).

Therefore, after hearing evidence from representatives of the TRT-5 group and of the General Health Directorate, the National AIDS Council, in a letter dated April 5, 2001, requested that the Minister with responsibility for Health should consider suspending the study as soon as possible on the grounds that it involves placing the HIV-positive persons concerned at "serious medical risk".

In a letter dated April 25, the Minister with responsibility for Health confirmed that the general anaesthesia would be replaced with local anaesthesia. Because of this, the research protocol would have to be re-submitted for CCPPRB approval.

The National AIDS Council is satisfied that the study has been suspended. It wishes, nevertheless, to draw the attention of the Minister with responsibility for Health to the problem of highly invasive surgical procedures carried out solely for research purposes and which can only be justified on the basis of a closely conducted evaluation which confirms the scientific interest and validity of the protocol, and of a high level of vigilance as to the information given to those taking part in such research and their consent. The National Council for AIDS will, therefore, pay great attention to this question.

Further to this, the members of the National AIDS Council wish that the ministerial authorities for public health should, as necessary, provide them with the necessary information for understanding experimental protocols. This is because, in view of the ethical and scientific questions raised by such protocols, an institution such as the Council, which in this case is acting at the request of representatives of patients' associations whose concern is the interest of the sufferers, is not able to examine all of the elements which would enable it to arrive at a sound appraisal.

In more general terms, the National AIDS Council considers it essential that consideration should be given to the information provided to subjects involved in clinical research studies covered by the Huriet law, their place and their role in the study, concerning the composition and functioning of CCPPRBs, and the ratification of their decisions by the regulatory authorities. For this

purpose, it has therefore decided to refer these questions to the CCNE (the National Advisory Committee on Ethics in Life Sciences and Health (NACE).