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**REPORT FOLLOWED BY AN
OPINION**

ETHICS OF RESEARCH AND CARE

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1996 MAY 23TH

REPORT FOLLOWED BY AN OPINION ON THE
POSSIBILITY OF RECRUITING WOMEN OF CHILD-
BEARING AGE AS VOLUNTEERS FOR ANRS
VACCINATION TRIALS

REPORT

See French version

OPINION

Asked for its views by those involved in conducting the programme of vaccine trials conducted by the *Agence Nationale de Recherche sur le Sida* / National AIDS Research Agency (ANRS), the National AIDS Council resolved on its own initiative to address the issue of the possibility of recruiting women of childbearing age as volunteers for such trials.

Since 1991, ANRS has been conducting tests focused on the immunization of men using HIV proteins (phase I trials) with the aim, still far-off, of developing a vaccine. Volunteers able to receive immunization products as part of the research are selected according to an extremely rigorous method combining clinical (somatic and psychological), biological and ethical criteria in due compliance with our national legislation and traditions.

In this context, women of less than 40 years of age have not yet been selected. The question is whether women of childbearing age can now be permitted to take part in the research : first, in order to study localized immunity, since they will be priority recipients of a possible later vaccine; and, second, at a scientific level, because immunization of the genital mucous membrane may be an important focus for development of means of defence.

Over and above an evaluation, as governed by the provisions contained in the Huriet statute, of the expected benefits for the wider community, compared with the risks run by individuals, this issue raises the question of how women are perceived in the scientific domain in the AIDS era.

1. In principle, there is no impediment to women of childbearing age participating in immunization trials leading to a vaccine.
2. Given the impossibility of eliminating all somatic and psychological risks for any volunteer (male or female) or for the child to be born, it is recommended :
 - to ensure that as much information as possible has been gathered on local vaccine immunization by experimentation on animals ;
 - to ensure that as much information as possible has been gathered by studying women who are already volunteers and chosen for vaccine trials in progress ;
 - to begin by recruiting those women for whom pregnancy is particularly unlikely ;

- to limit the recruitment of women of childbearing age to research protocols specifically directed at the study of the female reproductive system.