Vaccine Trials under the *NIH Guidelines for Research Involving Recombinant DNA Molecules*

Appendix M-VI-A of the *NIH Guidelines for Recombinant DNA Molecules (NIH Guidelines)* exempts certain types of vaccine trials from the requirements of Appendix M-I. Specifically, this exemption applies to "human studies in which:

- induction or enhancement of an immune response to a vector-encoded microbial immunogen is the major goal,
- such an immune response has been demonstrated in model systems, and
- the persistence of the vector-encoded immunogen is not expected.

Trials with these characteristics do not have to be registered with NIH OBA or undergo RAC review, but can be submitted on a voluntary basis, particularly if the investigator believes that a trial presents scientific, safety, or ethical concerns that would benefit from RAC review and public discussion. Investigators who submit trials voluntarily will be expected to comply with all aspects of the protocol review and reporting requirements. OBA encourages investigators and institutional review bodies to contact us (oba@od.nih.gov) for assistance in determining whether this exemption applies to particular trials.

It is important to note that Appendix M-VI-A does <u>not</u> exempt these vaccine trials from other requirements specified in the *NIH Guidelines*, including biosafety review. Thus, vaccine trials, like other human gene transfer trials subject to the *NIH Guidelines*, must be reviewed and approved by an Institutional Biosafety Committee (IBC) before research participants can be enrolled. More information about IBCs can be found on the IBC page of OBA's Web site:

http://www4.od.nih.gov/oba/IBC/IBCindexpg.htm

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