

NIH Proposes Revisions to Section III-E-1 of the *NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)* - In March 2009, the NIH Office of Biotechnology Activities ([OBA](#)) published a proposal to revise the [NIH Guidelines](#) to address biosafety for research with synthetic nucleic acids. This proposal also included proposed changes to several other sections of the *NIH Guidelines*, including [Section III-E-1](#), which addresses containment for work with partial viral genomes in tissue culture. Experiments covered by Section III-E-1 may proceed concurrently with [Institutional Biosafety Committee](#) registration.

In response to the [comments](#) received on the Federal Register notice and further consultations with the NIH Recombinant DNA Advisory Committee, OBA has developed a substantially [revised proposal](#) for Section III-E-1. This proposal would allow containment to be lowered provided the ability of the virus to replicate has been irreversibly impaired by a complete deletion in one or more capsid, envelope or polymerase genes required for viral replication. A quantitative criterion based on the amount of the genome present would also be maintained.

The full version of the revised proposal may be found in the April 22, 2010 [Federal Register](#).

In light of these substantive changes, OBA is seeking comment on this revised proposal. Comments may be submitted to OBA via email at oba@od.nih.gov, mailed to: 6705 Rockledge Drive, Suite 750, Bethesda, Maryland 20892-7985 or faxed to (301) 496-9839. All comments on the proposed revisions must be submitted by June 1, 2010. All written comments received will be available for public inspection weekdays between the hours of 8:30 a.m. and 5:00 p.m. in the NIH OBA office at the address above.

If you have questions, or require additional information about these proposed revisions, please feel free to contact OBA at 301-496-9838 or oba@od.nih.gov.