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Ladies and Gentlemen,

The American Biological Safety Association (ABSA) is an international group of biological safety professionals and is known as one of the world's foremost resources on biological safety practices. ABSA has reviewed the redrafted proposed revisions to the "NIH Guidelines for Research with Recombinant DNA (NIH Guidelines)" which are part of the overall effort to consider work with synthetic DNA. These revisions were announced in the Federal Register on April 22, 2010,

We agree with the redrafted, proposed revisions to Section III-E-1 of the NIH Guidelines. We encourage the Office of Biotechnology Activities (OBA) to prepare and share a guidance document addressing how to apply this section to all known categories and risk groups of viral vectors, including adenovirus and adeno-associated viral vectors. The redrafted proposed revisions of this section only address lentivirus vectors and Risk Group (RG) 3 and RG 4 vectors. Additionally, the guidance document should include references or information on how to test the cell lines for helper functions, as well as examples and an explanation on how to use the vector sequence information to determine if the replication defective vector can be rescued via homologous recombination.

The availability of the suggested guidance document will provide additional information to biosafety officers and IBCs charged with reviewing a broad diversity of experiments, thus facilitating more consistent and complete reviews by those groups.

We appreciate this comment opportunity for these proposed revisions.

Sincerely,

Benjamin Fontes, MPH, CBSP  
President  
American Biological Safety Association