

Section III–D–3. Experiments Involving the Use of Infectious DNA or RNA Viruses or Defective DNA or RNA Viruses in the Presence of a Helper System in Tissue Culture Systems

*Caution:* The potential for reversion or generation of replication competent virus should be considered when generating or using defective viruses or vectors in the presence of helper systems (e.g., helper viruses, packaging cell lines, transient transfection systems, replicon systems). Special care should be used in the evaluation of containment levels for experiments which are likely to either enhance the pathogenicity (e.g., insertion of a host oncogene) or to extend the host range (e.g., introduction of novel control elements) of viral vectors under conditions that permit a productive infection. In such cases, serious consideration should be given to increasing physical containment by at least one level.

*Note:* Recombinant or synthetic nucleic acid molecules or nucleic acid molecules derived therefrom, which contain less than two-thirds of the genome of any eukaryotic virus (all viruses from a single Family (see Section V–J, *Footnotes and References of Sections I–IV*) being considered identical (see Section V–K, *Footnotes and References of Sections I–IV*)), are considered defective and may be used in the absence of helper systems under the conditions specified in Section III–E–1, *Experiments Involving the Formation of Recombinant or Synthetic Molecules Containing No More than Two-Thirds of the Genome of any Eukaryotic Virus*.

*Section III–D–3–a.* Experiments involving the use of infectious or defective Risk Group 2 viruses (see Appendix B–II, *Risk Group 2 Agents*) in the presence of a helper system may be conducted at BL2.

*Section III–D–3–b.* Experiments involving the use of infectious or defective Risk Group 3 viruses (see Appendix B–III–D, *Risk Group 3 (RG3)—Viruses and Prions*) in the presence of a helper system may be conducted at BL3.

*Section III–D–3–c.* Experiments involving the use of infectious or defective Risk Group 4 viruses (see Appendix B–IV–D, *Risk Group 4 (RG4)—Viral Agents*) in the presence of a helper system may be conducted at BL4.

*Section III–D–3–d.* Experiments involving the use of infectious or defective restricted poxviruses (see Sections V–A and V–L, *Footnotes and References of Sections I–IV*) in the

presence of a helper system shall be determined on a case-by-case basis following NIH OSP review. A U.S. Department of Agriculture permit is required for work with plant or animal pathogens (see Section V–G, *Footnotes and References of Sections I–IV*).

*Section III–D–3–e.* Experiments involving the use of infectious or defective viruses in the presence of a helper system which are not covered in Sections III–D–3–a through III–D–3–d may be conducted at BL1.

Section III–E–1 will be amended as follows:

Section III–E–1. Experiments Involving the Formation of Recombinant or Synthetic Nucleic Acid Molecules Containing No More Than Two-Thirds of the Genome of Any Eukaryotic Virus

Recombinant or synthetic nucleic acid molecules containing no more than two-thirds of the genome of any eukaryotic virus (all viruses from a single Family being considered identical [see Section V–J, *Footnotes and References of Sections I–IV*]) may be propagated and maintained in cells in tissue culture using BL1 containment. For such experiments, it must be demonstrated that the cells lack a helper system for the specific Families of defective viruses being used. If a helper system is present, procedures specified under Section III–D–3, *Experiments Involving the Use of Infectious Animal or Plant DNA or RNA Viruses or Defective Animal or Plant DNA or RNA Viruses in the Presence of Helper Systems in Tissue Culture Systems*, should be used. The DNA may contain fragments of the genome of viruses from more than one Family but each fragment shall be less than two-thirds of a genome.

Appendix B–II–D will be amended as follows:

**Appendix B–II–D. Risk Group 2 (RG2)—Viruses**

Flaviviruses—Group B Arboviruses  
—Saint Louis Encephalitis Virus (SLEV)  
—West Nile virus (WNV)

**Appendix B–IV–D Risk Group 4 (RG4)—Viruses**

Filoviruses  
—Ebola viruses  
—Marburg viruses  
Hemorrhagic fever viruses as yet undefined

Dated: March 25, 2024.

**Lawrence A. Tabak,**

*Principal Deputy Director, National Institutes of Health.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting**

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Clinical Trial Planning Grants (R34 Clinical Trial Not Allowed).

*Date:* May 1, 2024.

*Time:* 2:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G22, Rockville, MD 20852 (Virtual Meeting).

*Contact Person:* Michael M. Opata, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G22, Rockville, MD 20852, 240–627–3319, [michael.opata@nih.gov](mailto:michael.opata@nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: April 2, 2024.

**Lauren A. Fleck,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting**

Pursuant to section 1009 of the Federal Advisory Committee Act, as