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.

[FR Doc. 2024–07082 Filed 4–4–24; 8:45 am]

BILLING CODE 4140–01–P

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.*

(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.

[FR Doc. 2024–07277 Filed 4–4–24; 8:45 am]

BILLING CODE 4140–01–P

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

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 Diabetes and Digestive and Kidney Diseases Initial Review Group; Fellowships in Kidney, Urology, and Hematology DDK–G Fellowships in Kidney, Urology, and Hematology.

Date: June 12, 2024.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW, Washington, DC 20015 (In-Person).

Contact Person: Xiaodu Guo, M.D., Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7023, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–4719, *guox@extra.niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: April 2, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–07279 Filed 4–4–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

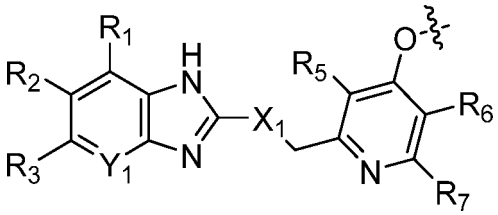
ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. to achieve expeditious commercialization of results of federally-funded research and development.

FOR FURTHER INFORMATION CONTACT: Licensing information may be obtained by contacting Michael Shmilovich, Esq, MS, CLP; 301–435–5019; *michael.shmilovich@nih.gov,* at the National Heart, Lung, and Blood, Office of Technology Transfer and Development Office of Technology Transfer, 31 Center Drive Room 4A29, MSC2479, Bethesda, MD 20892–2479. A signed Confidential Disclosure Agreement may be required to receive any unpublished information.

SUPPLEMENTARY INFORMATION: This notice is in accordance with 35 U.S.C. 209 and 37 CFR part 404. Technology description follows. Prazole-Based Antiviral Therapeutics:

Available for licensing and commercial development is a patent estate that covers prazole based compounds and their methods of use as antiviral therapeutics. Prazoles are benzimidazole derivatives generally marketed as stomach-acid reducers, owing to their ability to inhibit the H+/K+ ATPases (proton pumps) of the parietal cells in the stomach epithelium. Prazoles can inhibit the egress of several viral targets: HIV–1, HSV–1 and –2, MAYV, and EBV by interfering with the ESCRT complex in the formation of exosomes. In that respect, the target for inhibition of these viruses is Tumor susceptibility gene 101 (Tsg101), a member of the ESCRT–I complex. The N-terminal ubiquitin E2 variant (UEV) domain of Tsg101 has both ubiquitin and P[T/S]AP motif binding sites, where the prazole binds to C73 in the middle of the ubiquitin-binding site, sterically inhibiting the Ub-Tsg101 interaction. By way of example, and not limitation, a prazole compound according to this invention can take on the follow core structure:



Where L is optionally present and is a C_1-C_6 alkyl group, a C_1-C_6 alkoxy group, a -$(CH_2CH_2O)_n$- group where n is an integer from 1 to 6, a phenyl group, or a benzyl group, each of which is optionally substituted. B is a substituted or unsubstituted aromatic or heteroaromatic substituent, and where

X_1 is S(=O) or S;

Y_1 is N or CR_4; and

each of R_1-R_7 is independently selected from hydrogen, C_1-C_6 alkyl, C_1-C_6 alkoxy, perfluoro C_1-C_6 alkyl, perfluoro C_1-C_6 alkoxy, halo, -CN, -OH, -$COOR_8$, substituted or unsubstituted aromatic, or substituted or unsubstituted heteroaromatic, and

each R_8 independently is hydrogen, C_1-C_6 alkyl, phenyl, or benzyl.

Potential Commercial Applications:

- antivirals
- therapeutics
- ESCRT complex formation
- prazole
- antifungal

Development Stage:

- Early stage

Inventors: Nico Tjandra (NHLBI), Carol Carter (Stonybrook), Rolf E. Swenson (NHLBI), David Nyenhuis (NHLBI), Natarajan Raju (NHLBI), Chandra Mushti, (NHLBI), and Venkata Sabbasani (NHLBI).

Intellectual Property: HHS Reference No. E–239–2023–0; U.S. Provisional Patent Application No. 63/545,080 filed October 20, 2023.

Publication: D. A. Nyenhuis, S. Watanabe, R. Bernstein, R. E. Swenson, N. Raju, V. R. Sabbasani, C. Mushti, D.-Y. Lee, C. Carter, N. Tjandra, ''Structural Relationships to Efficacy for Prazole-Derived Antivirals.'' *Adv. Sci.* 2024, 2308312. *https://doi.org/10.1002/advs.202308312.*

Licensing Contact: Michael Shmilovich, Esq, MS, CLP; 301–435–5019; *michael.shmilovich@nih.gov.*

Dated: April 2, 2024.

Michael A. Shmilovich,

Senior Licensing and Patenting Manager, National Heart, Lung, and Blood Institute, Office of Technology Transfer and Development.

[FR Doc. 2024–07278 Filed 4–4–24; 8:45 am]

BILLING CODE 4140–01–P