

additional contact information is also available here and on the OSP website ([www.osp.od.nih.gov](http://www.osp.od.nih.gov)). The NIH Director may rescind the certification of a host-vector system (see Section IV-C-1-b-(2)-(g), *Minor Actions*). If certification is rescinded, NIH will instruct investigators to transfer cloned DNA into a different system or use the clones at a higher level of physical containment level, unless NIH determines that the already constructed clones incorporate adequate biological containment. Certification of a host-vector system does not extend to modifications of either the host or vector component of that system. Such modified systems shall be independently certified by the NIH Director. If modifications are minor, it may only be necessary for the investigator to submit data showing that the modifications have either improved or not impaired the major phenotypic traits on which the containment of the system depends. Substantial modifications to a certified host-vector system requires submission of complete testing data.

#### Appendix I-II-B. Data To Be Submitted for Certification

##### Appendix I-II-B-1. Host-Vector 1 Systems Other than *Escherichia coli* K-12

The following types of data shall be submitted, modified as appropriate for the particular system under consideration: (i) A description of the organism and vector; the strain's natural habitat and growth requirements; its physiological properties, particularly those related to its reproduction, survival, and the mechanisms by which it exchanges genetic information; the range of organisms with which this organism normally exchanges genetic information and the type of information is exchanged; and any relevant information about its pathogenicity or toxicity; (ii) a description of the history of the particular strains and vectors to be used, including data on any mutations which render this organism less able to survive or transmit genetic information; and (iii) a general description of the range of experiments contemplated with emphasis on the need for developing such an Host-Vector 1 system.

##### Appendix I-II-B-2. Host-Vector 2 Systems

Investigators planning to request Host-Vector 2 systems certification may obtain instructions from NIH OSP concerning data to be submitted (see Appendices I-III-N and O, *Footnotes and References of Appendix I*). In general, the following types of data are required: (i) Description of construction steps with indication of source, properties, and manner of introduction of genetic traits; (ii) quantitative data on the stability of genetic traits that contribute to the containment of the system; (iii) data on the survival of the host-vector system under non-permissive laboratory conditions designed to represent the relevant natural environment; (iv) data on transmissibility of the vector and/or a cloned DNA fragment under both permissive and non-permissive conditions; (v) data on all other properties of the system which affect

containment and utility, including information on yields of phage or plasmid molecules, ease of DNA isolation, and ease of transfection or transformation; and (vi) in some cases, the investigator may be asked to submit data on survival and vector transmissibility from experiments in which the host-vector is fed to laboratory animals or one or more human subjects. Such *in vivo* data may be required to confirm the validity of predicting *in vivo* survival on the basis of *in vitro* experiments. Data shall be submitted to the Office of Science Policy, National Institutes of Health, preferably by email to: [NIHGuidelines@od.nih.gov](mailto:NIHGuidelines@od.nih.gov); additional contact information is also available here and on the OSP website ([www.osp.od.nih.gov](http://www.osp.od.nih.gov)). Investigators are encouraged to publish their data on the construction, properties, and testing of proposed Host Vector 2 systems prior to consideration of the system by NIH. Specific instructions concerning the submission of data for proposed *Escherichia coli* K-12 Host-Vector 2 system (EK2) involving either plasmids or bacteriophage in *Escherichia coli* K-12, are available from the Office of Science Policy, National Institutes of Health, preferably by submitting a request for this information to: [NIHGuidelines@od.nih.gov](mailto:NIHGuidelines@od.nih.gov); additional contact information is also available here and on the OSP website ([www.osp.od.nih.gov](http://www.osp.od.nih.gov)).

Appendix L, GENE THERAPY POLICY CONFERENCES (GTPCS), is proposed to be deleted in its entirety.

Appendix M, Points to Consider in the Design and Submission of Protocols for the Transfer of Recombinant or Synthetic Nucleic Acid Molecules into One or More Human Research Participants (Points to Consider), is proposed to be deleted in its entirety.

Dated: August 7, 2018.

**Lawrence A. Tabak,**  
Deputy Director, National Institutes of Health.  
[FR Doc. 2018-17760 Filed 8-16-18; 8:45 am]  
BILLING CODE 4140-01-P

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### National Institutes of Health

##### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings 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:* Center for Scientific Review Special Emphasis Panel; PAR-17-144: Limited Competition: National Primate Research Centers (P51).

*Date:* September 11-14, 2018.

*Time:* 8:00 a.m. to 12:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hotel Vintage Portland, 422 SW Broadway, Portland, OR 97205.

*Contact Person:* Brian H. Scott, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, 301-827-7490, [brianscott@mail.nih.gov](mailto:brianscott@mail.nih.gov).

*Name of Committee:* Brain Disorders and Clinical Neuroscience Integrated Review Group; Pathophysiological Basis of Mental Disorders and Addictions Study Section.

*Date:* September 13-14, 2018.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Renaissance Orlando at SeaWorld, 6677 Sea Harbor Drive, Orlando, FL 32821.

*Contact Person:* Boris P. Sokolov, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5217A, MSC 7846, Bethesda, MD 20892, 301-408-9115, [bsokolov@csr.nih.gov](mailto:bsokolov@csr.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 13, 2018.

**Sylvia L. Neal,**  
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018-17785 Filed 8-16-18; 8:45 am]

BILLING CODE 4140-01-P

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### National Institutes of Health

##### Draft Report on Carcinogens Monograph on Night Shift Work and Light at Night; Availability of Document; Request for Comments; Notice of Peer-Review Meeting

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The National Toxicology Program (NTP) announces a meeting to peer review the Draft Report on Carcinogens Monograph on Night Shift Work and Light at Night. NTP has conducted a literature-based assessment to determine whether night shift work (e.g., working at least three hours between 12 a.m. and 6 a.m.) and light at night are cancer hazards and should