Time: 2 p.m. to 2:30 p.m.
Agenda: To review and evaluate grant applications.
Place: NIH, Rockledge 2, Bethesda, MD 20892. (Telephone Conference Call)
Contact Person: Nancy Shinowara, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4208, MSC 7814, Bethesda, MD 20892–7814, (301) 435–1173, *shinowan@drg.nih.gov.*
This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel.
Date: December 4, 2001.
Time: 3 p.m. to 4 p.m.
Agenda: To review and evaluate grant applications.
Place: NIH, Rockledge 2, Bethesda, MD 20892. (Telephone Conference Call)
Contact Person: Nancy Shinowara, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4208, MSC 7814, Bethesda, MD 20892–7814, (301) 435–1173, *shinowan@drg.nih.gov.*
This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

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

Dated: December 3, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–30524 Filed 12–10–01; 8:45 am]

BILLING CODE 4140–01–M

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 (5 U.S.C. Appendix 2), 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.
Date: December 10, 2001.
Time: 2 p.m. to 4:30 p.m.
Agenda: To review and evaluate grant applications.
Place: NIH, Rockledge 2, Bethesda, MD 20892. (Telephone Conference Call).
Contact Person: Richard Marcus, PhD., Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5168, MSC 7844, Bethesda, MD 20892, 301–435–1245, *richard.marcus@nih.gov.*
This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel.
Date: December 10, 2001.
Time: 2:30 p.m. to 3:30 p.m.
Agenda: To review and evaluate grant applications.
Place: NIH, Rockledge 2, Bethesda, MD 20892. (Telephone Conference Call).
Contact Person: Joy Gibson, DSC, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4172, MSC 7804, Bethesda, MD 20892, 301–435–4522, gibsonj@csr.nih.gov.
This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel.
Date: December 13, 2001.
Time: 8 a.m. to 12 p.m.
Agenda: To review and evaluate grant applications.
Place: NIH, Rockledge 2, Bethesda, MD 20892. (Telephone Conference Call).
Contact Person: Priscilla B. Chen, PhD., Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4104, MSC 7814, Bethesda, MD 20892, (301) 435–1787.
This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel.
Date: January 4, 2002.
Time: 11 a.m. to 12 p.m.
Agenda: To review and evaluate grant applications.
Place: NIH, Rockledge 2, Bethesda, MD 20892. (Telephone Conference Call).
Contact Person: Karen Sirocco, PhD., Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3184, MSC 7848, Bethesda, MD 20892, 301–435–0676, *siroccok@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine, 93.306; 93.333, Clinical Research, 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: December 3, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–30525 Filed 12–10–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of Biotechnology Activities; Recombinant DNA Research: Action Under the NIH Guidelines

AGENCY: National Institutes of Health (NIH), PHS, DHHS.

ACTION: Notice of final action under the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines).

SUMMARY: The NIH is amending Appendix B–I of the NIH Guidelines to establish criteria for designating strains of E. coli as risk group 1 agents.

DATES: This final action is effective December 11, 2001.

FOR FURTHER INFORMATION: Background documentation and additional information can be obtained from the Office of Biotechnology Activities (OBA), 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892–7985, Phone: 301–496–9838, Fax: 301–496–9839. The OBA web site is located at *http://www4.od.nih.gov/oba.*

SUPPLEMENTARY INFORMATION: This final action amends Appendix B–I of the NIH Guidelines. The proposed action was published for comment in the **Federal Register** on August 13, 2001 (66 FR 42555), and considered by the NIH Recombinant DNA Advisory Committee (RAC) at its meeting on September 6–7, 2001.

Background Information and Response to Comments

The background of the August 13, 2001, proposed action was set forth fully in the **Federal Register** notice announcing that action (66 FR 42555–56). During its September 6–7, 2001, meeting, the RAC discussed the proposed action and considered the one public comment that was received prior to the meeting. This commenter suggested that establishing risk criteria for a specific bacterial strain was inappropriate and that the proposed criteria were not general enough and too complex. The commenter felt that the current definition of a risk group 1 agent should be sufficient. This suggestion was discussed by the RAC. It was the RAC's consensus that establishing

criteria specific for E. coli provided useful guidance in response to the specific request from the University of Florida. The RAC recommended acceptance of the proposed criteria for designation of E. coli as a risk group 1 agent by a vote of 7 in favor, 0 opposed, and 1 abstention.

The NIH concurs with the RAC that risk assessment is enhanced by the establishment of these criteria for designating strains of E. coli as risk group 1 agents. As noted in the proposed action, these criteria are not intended to eliminate the need for case-by-case consideration of the potential effects of a biological agent on those who may be exposed to it (Section II–A–2 of the NIH Guidelines) and are subject to reevaluation and change if it is shown that a strain meeting the criteria is associated with disease in healthy human adults.

After the September RAC meeting, an additional comment on the proposed criteria was received. This comment, from the American Biological Safety Association (ABSA), suggested that the phrase ''rough colony morphology'' was not very informative; colony morphology is influenced by environmental factors and is not solely dependent upon genotype. We concur with that comment; thus, mention of ''rough'' colony morphology has been deleted from the criteria. ABSA also suggested that the second criterion should be expanded upon to state that the bacteria do not carry ''* * *any functional or complete genes encoding these factors'' as opposed to ''* * *any genes encoding these factors.'' We did not concur with this comment due to the fact that the strains of E. coli that have been studied demonstrate the presence or entire absence of factor-encoding genes. Strains carrying genes that have been rendered non-functional by laboratory manipulations (e.g., partial deletions or missense mutations) should not automatically be designated as risk group 1 agents.

Accordingly, the only change in this final action from the proposed action is deletion of the reference to ''rough colony morphology.''

Amendments to the NIH Guidelines

Appendix B–I. Risk Group (RG1) Agents of the NIH Guidelines is amended to read:

RG1 agents are not associated with disease in healthy adult humans. Examples of RG1 agents include asporogenic Bacillus subtilis or Bacillus licheniformis (see Appendix C–IV–A, Bacillus subtilis or Bacillus licheniformis Host-Vector Systems, Exceptions); adeno-associated virus (AAV) types 1 through 4; and recombinant AAV constructs, in which the transgene does not encode either a potentially tumorigenic gene product or a toxin molecule and are produced in the absence of a helper virus. A strain of Escherichia coli (see Appendix C–II–A, Escherichia coli K–12 Host Vector Systems, Exceptions) is an RG1 agent if it (1) does not possess a complete lipopolysaccharide (i.e., lacks the O antigen); and (2) does not carry any active virulence factor (e.g., toxins) or colonization factors and does not carry any genes encoding these factors.

Those agents not listed in Risk Groups (RGs) 2, 3 and 4 are not automatically or implicitly classified in RG1; a risk assessment must be conducted based on the known and potential properties of the agents and their relationship to agents that are listed.

OMB's ''Mandatory Information Requirements for Federal Assistance Program Announcements'' (45 FR 39592) requires a statement concerning the official government programs contained in the Catalog of Federal Domestic Assistance. Normally, NIH lists in its announcements the number and title of affected individual programs for the guidance of the public. Because the guidance in this notice covers virtually every NIH and Federal research program in which recombinant DNA techniques could be used, it has been determined not to be cost effective or in the public interest to attempt to list these programs. Such a list would likely require several additional pages. In addition, NIH could not be certain that every Federal program would be included as many Federal agencies, as well as private organizations, both national and international, have elected to follow the NIH Guidelines. In lieu of the individual program listing, NIH invites readers to direct questions to the information address above about whether individual programs listed in the Catalog of Federal Domestic Assistance are affected.

Dated: November 21, 2001.

Ruth L. Kirschstein,

Acting Director, National Institutes of Health.

[FR Doc. 01–30513 Filed 12–10–01; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of Biotechnology Activities; Recombinant DNA Research: Proposed Actions Under the NIH Guidelines

AGENCY: National Institutes of Health (NIH), PHS, DHHS.

ACTION: Notice of final action under the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines).

SUMMARY: The NIH is amending the provisions of the NIH Guidelines relating to the Recombinant DNA Advisory Committee (RAC) by authorizing a minimum of 15 voting members and establishing the charter of the committee as the controlling document for the membership and procedures of the RAC.

DATES: This Final Action is effective as of January 10, 2002.

FOR FURTHER INFORMATION: Documentation and additional information can be obtained from the Office of Biotechnology Activities, National Institutes of Health, MSC 7985, 6705 Rockledge Drive, Suite 750, Bethesda, Maryland 20892, Phone 301–496–9838, FAX 301–496–9839. The NIH OBA Web site is located at *http://www4.od.nih.gov/oba/.*

SUPPLEMENTARY INFORMATION:

Background

The RAC serves a unique role in promoting awareness and understanding of the scientific, medical, safety, and ethical issues associated with human gene transfer research. This occurs through review and public discussion of protocols, as well as through specific recommendations for improving trials that are conveyed to investigators and their institutions. To fulfill these functions and address all dimensions of human gene transfer research as fully as possible, the RAC has historically been constituted in a manner that allows for diverse perspectives and necessary expertise in relevant disciplines.

Section IV–C–2 of the NIH Guidelines has provided that the RAC consist of 15 voting members including the Chair, appointed by the DHHS Secretary or designee, at least 8 of whom must be authorities knowledgeable in the fields of molecular genetics, molecular biology, recombinant DNA research, or other scientific fields. At least 4 members of RAC, according to this section, shall be persons knowledgeable