

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.*  
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## **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

in applicable law, standards of professional conduct and practice, public attitudes, the environment, public health, occupational health, or related fields. Representatives from designated Federal agencies serve as non-voting members.

In recent years, not only has the number of gene transfer trials dramatically increased, but these trials now encompass a much more expansive array of clinical applications than was previously possible. Current trials address, for example, cancer, inborn errors of metabolism, cardiovascular diseases, autoimmune disorders, and neurologic diseases. In addition, trials employ a growing variety of viral vectors, including vaccinia, fowl pox, canary pox, herpes simplex virus, adeno-associated virus, adenovirus, and retroviruses. Thus, an increasingly broad range of expertise is needed on the RAC to adequately assess the issues raised by the progressively more diverse gene transfer trials being proposed and submitted to the NIH. Given the dynamism of the field, flexibility in how this expertise is achieved is key to the effective and efficient functioning of the RAC.

In recognition of the rapidly evolving field of human gene transfer, the NIH is now amending Section IV-C-2 of the NIH Guidelines to authorize a *minimum* of 15 voting members with no maximum number of voting members specified. The maximum number of voting members will be established through the charter for the RAC, which will now be the controlling document for the membership and procedures of the Committee in the event of any conflict with the NIH Guidelines. This will enable NIH to respond promptly to the need for additional expertise on the RAC through appropriate amendments to the charter. The present requirement that at least 8 of the voting members be knowledgeable in the fields of molecular genetics, molecular biology, recombinant DNA research or other scientific fields, is changed to "at least a majority of the voting members," and clinical gene transfer research is added as an example of a relevant scientific field. Finally, the listing of specific types of knowledge for members other than those knowledgeable in relevant scientific fields is broadened by adding laboratory safety and protection of human subjects and by changing "applicable law" to "law," and "standards of professional conduct and practice" to "ethics."

#### Public Comments

These changes were published as a proposal in the August 24, 2001,

**Federal Register** (66 FR 44638) with a 30-day period for comment public. Two sets of comments were received in response, one from a biosafety officer at a large academic institution, the other from private company engaged in gene transfer research. Both commenters expressed the view that it was unnecessary to allow for more than 15 voting members, suggesting instead that additional expertise could be obtained through the use of ad hoc experts. Neither commenter addressed the proposal to make the RAC charter the controlling document for the membership and procedures of the RAC.

#### Response to Public Commentary

Ad hoc members are only intermittently involved in the RAC process, and while they do serve an important function, they do not benefit from the longitudinal perspective that officially appointed RAC members bring to the review and discussion of human gene transfer protocols by virtue of their ongoing participation. Furthermore, because ad hoc experts do not vote, the NIH believes that they do not have as direct a voice in the final recommendations concerning these protocols as do voting members. The ability to vote ensures that the perspectives of RAC members are fully reflected in the outcome of RAC discussions. For these reasons, the use of ad hoc members is not an optimal means of durably enhancing the range of expertise and intellectual continuity on the RAC.

Thus, no changes are being made in the proposed amendments in response to these two sets of comments. Two changes have been made in the proposed amendments in order to clarify their intent, however. The statement that the charter of the RAC would establish the expertise of voting members has been deleted. That statement implied incorrectly that the RAC charter would be more specific than the NIH Guidelines in specifying the expertise of RAC members. The charter will repeat the provisions of the NIH Guidelines on the expertise of RAC members. The reference to a "majority of the voting members" in the third sentence of the second paragraph of Section IV-C-2 has been changed to "At least a majority of the voting members \* \* \*" Consistent with the current provision, this change clarifies that more than a majority may be knowledgeable in scientific fields, so long as at least four members are knowledgeable in the other fields listed. On November 1, the RAC met by teleconference and voted unanimously

to recommend implementation of the proposal.

#### Amendments to the NIH Guidelines

Section IV-C-2 of the NIH Guidelines is amended to state:

##### *Section IV-C-2. Recombinant DNA Advisory Committee (RAC)*

The RAC is responsible for carrying out the functions specified in the NIH Guidelines, as well as others specified in its charter or assigned by the Secretary of Health and Human Services or the NIH Director. The RAC membership and procedures, in addition to those set forth in the NIH Guidelines, are specified in the charter for the RAC which is filed as provided in the General Services Administration Federal Advisory Committee Management regulations, 41 CFR part 101-6, and is available on the OBA web site, <http://www4.od.nih.gov/oba/rac/RACCharter.htm>. In the event of a conflict between the NIH Guidelines and the charter, the charter shall control.

The RAC will consist of not less than 15 voting members, including the Chair, appointed under the procedures of the NIH and the Department of Health and Human Services. The maximum number of voting members will be established in the charter of the RAC. At least a majority of the voting members must be knowledgeable in relevant scientific fields, e.g., molecular genetics, molecular biology, recombinant DNA research, including clinical gene transfer research. At least 4 members of the RAC must be knowledgeable in fields such as public health, laboratory safety, occupational health, protection of human subjects of research, the environment, ethics, law, public attitudes or related fields. Representatives of the Federal agencies listed in the charter shall serve as non-voting members. Nominations for RAC members may be submitted to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9838 (fax).

All meetings of the RAC shall be announced in the **Federal Register**, including tentative agenda items, 15 days before the meeting. Final agendas, if modified, shall be available at least 72 hours before the meeting. No item defined as a Major Action under Section IV-C-1-b-(1) may be added to an agenda following **Federal Register** publication.

OMB's "Mandatory Information Requirement 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 proposed 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. 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.*

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## DEPARTMENT OF THE INTERIOR

### Office of the Secretary

### Bureau of Indian Affairs

### Office of Special Trustee for American Indians

### Office of Indian Trust Transition

### Tribal Consultation on Indian Trust Asset Management

**AGENCIES:** Office of the Secretary, Bureau of Indian Affairs, Office of the Special Trustee for American Indians, Office of Indian Trust Transition, Interior.

**ACTION:** Notice of tribal consultation meetings.

**SUMMARY:** The Office of the Secretary, along with the Bureau of Indian Affairs, the Office of Special Trustee for American Indians, and Office of Indian Trust Transition, will conduct meetings on Indian trust asset management. The purpose of the meetings is to discuss a proposed reorganization of the Department's trust responsibility functions to improve the management of Indian trust assets. Any tribe, band, nation or individual is encouraged to

attend the meetings and to submit written comments.

**DATES:** The dates and city locations of the consultation meetings are as follows:

- December 13, 2001—Albuquerque, New Mexico
- December 20, 2001—Minneapolis, Minnesota
- January 3, 2002—Oklahoma City, Oklahoma
- January 10, 2002—Rapid City, South Dakota
- January 17, 2002—San Diego, California
- January 23, 2002—Anchorage, Alaska
- February 1, 2002—Washington, DC (Arlington, Virginia)

**ADDRESSES:** The addresses for the consultation meetings, which will all begin promptly at 9:00 a.m., are as follows:

- Albuquerque, New Mexico—The Hyatt Regency, 330 Tijeras Street NW
- Minneapolis, Minnesota—The Double Tree Hotel, 7901 24th Ave. South
- Oklahoma City, Oklahoma—Westin Hotel, 1 North Broadway
- Rapid City, South Dakota—Holiday Inn Rushmore Plaza, 505 N. 5th Street
- San Diego, California—Hanaiei Red Lion Hotel, 2270 Hotel Circle North
- Anchorage, Alaska—Hilton Anchorage, 500 West 3rd Street
- Washington, DC—Hyatt Regency Crystal City, 2799 Jefferson Davis Highway, Arlington, Virginia

**FOR FURTHER INFORMATION CONTACT:** Wayne R. Smith, Deputy Assistant Secretary—Indian Affairs, 1849 C Street NW., MS 4140 MIB, Washington, DC 20240 (202/208-7163).

**SUPPLEMENTARY INFORMATION:** The purpose of the meetings is to involve affected and interested parties in the process of organizing the Department's trust asset management responsibility functions. The Department has determined that there is a need for dramatic change in the management of Indian trust assets. This need has been made apparent in several ways. An independent consultant has analyzed important components of the Department's trust reform activities and made several recommendations, including the recommendation that the Department consolidate trust functions under a single entity. Concerns have also been raised in the *Cobell v. Norton* case, which is currently pending in the Federal District Court for the District of Columbia. Internal review has also supported reorganization. Additionally, a recent report commissioned by the Department of the Interior has

supported reorganization. This report, developed by the EDS Corporation, is being made available online at [www.doi.gov](http://www.doi.gov) for public review. A new office in the Department, the Office of Indian Trust Transition, has been created to plan and support reorganization. While preliminary actions have been taken by the Department, the plan for reorganization is still in the early stages of development. Prior notice of the first two consultation meetings scheduled in Albuquerque, New Mexico and Minneapolis, Minnesota, were published in the **Federal Register** on December 5, 2001 (66 FR 63306).

Written comments may be submitted at any of the above listed meeting locations or may be mailed to the address indicated under the heading **FOR FURTHER INFORMATION CONTACT**. Interested persons may examine written comments during regular business hours (7:45 a.m. to 4:15 p.m. EST) in the Office of the Assistant Secretary—Indian Affairs, Washington, DC, Monday through Friday, except for Federal holidays. Commenters who wish to remain anonymous must clearly state this preference at the beginning of their written comments. The Department will honor requests for anonymity to the extent allowable by law.

These meetings support administrative policy on tribal consultation by encouraging maximum direct participation of representatives of tribal governments, tribal organizations and other interested persons in important Departmental processes.

Dated: December 7, 2001.

**J. Steven Griles,**

*Deputy Secretary.*

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## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

[WY-920-02-1320-EL, WYW146744]

### North Jacobs Ranch Tract, Wyoming; Competitive Coal Lease Sale

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of competitive coal lease sale.

**SUMMARY:** Notice is hereby given that certain coal resources in the North Jacobs Ranch Tract described below in Campbell County, WY, will be offered for competitive lease by sealed bid in accordance with the provisions of the