communicated shortly thereafter to all respondents with whom initial confidential discussions will have established sufficient mutual interest.

SUPPLEMENTARY INFORMATION:

Technology Available

DHHS scientists are developing a variety of novel targeted drugs defined as a conjugated molecule consisting of a specific binding moiety, such as a monoclonal antibody, a receptor ligand or a similar construct, and a natural product or synthetic cytotoxic moiety which may include, but not be limited to the broad category of toxins and drugs. The specific binding and cytotoxic moieties would be joined by appropriate linker molecules. The NCI can provide a variety of natural product cytotoxic drugs either in the unaltered state or chemically-modified (to facilitate conjugation) as starting substances for the creation of new targeted drug agents. In addition, a limited number of monoclonal antibodies which can be used in this drug development effort are available from the NCI. The NCI can also provide the chemical expertise to modify agents, as well as the resources to test newly constructed agents in an *in vitro* cell line screen. Publications outlining these developments are available on request, and descriptions of other (unpublished) advances can be obtained from Dr. Stackhouse via a Confidential Disclosure Agreement.

DHHS now seeks collaborative arrangements for the creation, optimization, evaluation and possible clinical exploitation of these agents. A Cooperative Research and Development Agreement (CRADA) will be established to provide for distribution of intellectual property rights developed under the Agreement. The successful CRADA collaborator will provide expertise and experience in the preparation of targeted drugs, and will prepare one or more targeted drug candidates using starting substances provided jointly by the NCI and the CRADA collaborator. For targeted drug candidates selected for clinical trials, the Collaborator will also provide the necessary resources and expertise to perform tests to determine the drug candidate's physicochemical makeup, biological activity, stability and other characteristics necessary for filing an Investigational New Drug (IND) application with the FDA. The NCI will provide starting substances as well as consultation and expertise on drug preparation and development. Also, the NCI may elect to provide resources for preclinical and/or clinical evaluation, subject to future review and approval. CRADA aims will include rapid publication of research results as well as timely clinical evaluation and exploitation of any commercial opportunities.

The role of the National Cancer Institute in this CRADA will include, but not be limited to:

1. Providing intellectual, scientific, and technical expertise and experience to the research project.
2. Providing the Collaborator with samples of the subject compounds to create, optimize, test and develop targeted drugs for clinical studies .
3. Planning research studies and interpreting research results.
4. Additional support for preclinical and/or clinical development of the targeted drug candidate(s) derived from this CRADA. Commitment of substantial resources would require specific review and approval by the Decision Network Committee of the NCI's Division of Cancer Treatment, Diagnosis, and Centers (DCTDC). These resources may include:

(A) *In vitro* testing in the DCTDC cell line screen.

(B) Assistance with design and conduct of preclinical *in vivo* efficacy experiments.

(C) Toxicology experiments.

(D) Provision of additional starting materials for use by the Collaborator in preparing final targeted drug product.

(E) IND filing and sponsorship of clinical trials.

5. Publishing research results.

The role of the CRADA Collaborator may include, but not be limited to:

1. Providing significant intellectual, scientific, and technical expertise or experience to the research project.
2. Planning research studies and interpreting research results.
3. Providing samples of the subject compounds to create, optimize, test and develop targeted drugs for clinical studies.
4. Providing technical and/or financial support to facilitate scientific goals and for further design of applications of the technology outlined in the agreement.
5. Production, by current Good Manufacturing Practices (cGMP), purification, vialing, product release, and post-release testing of targeted drug candidates for clinical trials.
6. Publishing research results.

Selection criteria for choosing the CRADA Collaborator may include, but not be limited to:

1. The ability to collaborate with NCI on further research and development of this technology. This ability can be demonstrated through experience and expertise in this or related areas of technology indicating the ability to contribute intellectually to ongoing research and development.
2. The demonstration of adequate resources to perform the research and development of this technology (e.g. facilities, personnel and expertise) and accomplish objectives according to an appropriate timetable to be outlined in the CRADA Collaborator's proposal.
3. The willingness to commit best effort and demonstrated resources to the research and development of this technology, as outlined in the CRADA Collaborator's proposal.
4. The demonstration of expertise in the commercial development and production of products related to this area of technology.
5. The level of financial support the CRADA Collaborator will provide for CRADA-related Government activities.
6. The willingness to cooperate with the National Cancer Institute in the timely publication of research results.
7. The agreement to be bound by the appropriate DHHS regulations relating to human subjects, and all PHS policies relating to the use and care of laboratory animals.
8. The willingness to accept the legal provisions and language of the CRADA with only minor modifications, if any. These provisions govern the distribution of patent rights to CRADA inventions. Generally, the rights of ownership are retained by the organization that is the employer of the inventor, with (1) the grant of a license for research and other Government purposes to the Government when the CRADA Collaborator's employee is the sole inventor, or (2) the grant of an option to elect an exclusive or nonexclusive license to the CRADA Collaborator when the Government employee is the sole inventor.

Dated: August 25, 1997.

Kathleen Sybert,

Acting Director, Office of Technology Development, National Cancer Institute, National Institutes of Health.

[FR Doc. 97–23901 Filed 9–9–97; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

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

National Cancer Institute Special Emphasis Panel (SEP) meeting:

Name of SEP: Science Enrichment Program.

Date: September 29–30, 1997.

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

Place: National Cancer Institute, Executive Plaza North, Conference Room J, 6130 Executive Boulevard, Bethesda, MD 20892.

Contact Person: Wilna Woods, Ph.D., Scientific Review Administrator, National Cancer Institute, NIH, Executive Plaza North, Room 622B, 6130 Executive Boulevard, MSC 7410, Bethesda, MD 20892–7410, Telephone: 301/496–7903.

Purpose/Agenda: To evaluate and review responses to Requests for Proposals.

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

(Catalog of Federal Domestic Assistance Program Numbers: 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cnacer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control)

Dated: September 4, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–23894 Filed 9–9–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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 Heart, Lung, and Blood Special Emphasis Panel (SEP) meetings:

Name of SEP: Cooperative Agreement on Asthma Clinical Research Network.

Date: October 1, 1997.

Time: 8:00 a.m.

Place: Holiday Inn Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, Maryland 20815.

Contact Person: Anne P. Clark, Ph.D, Two Rockledge Center, Room 7186, 6701 Rockledge Drive, Bethesda, MD 20892–7924, (301) 435–0280.

Purpose/Agenda: To review and evaluate cooperative agreement applications.

Name of SEP: Review of Institutional National Research Service Awards (T32s), Short-term Training Students in Health Professional Schools Awards (T35s), Independent Scientist Awards (K02s), and Mentored Clinical Scientist Development Awards (K08s).

Date: October 13–14, 1997.

Time: 8:00 a.m.

Place: Hyatt Regency, One Bethesda Metro, Bethesda, Maryland 20814.

Contact Person: S. Charles Selden, Ph.D., Two Rockledge Center, Room 7196, 6701 Rockledge Drive, Bethesda, MD 20892–7924, (301) 435–0288.

Purpose/Agenda: To review and evaluate grant applications.

These meetings will be closed in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Programs Nos. 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; and 93.839, Blood Diseases and Resources Research, National Institutes of Health)

Dated: September 4, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–23895 Filed 9–9–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Meeting of the National Heart, Lung, and Blood Advisory Council

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the National Heart, Lung, and Blood Advisory Council, October 23–24, 1997, National Institutes of Health, 9000 Rockville Pike, Building 31, Conference Room 10, Bethesda, Maryland.

The Council meeting will be open to the public on October 23 from 8:30 a.m. to approximately 3:00 p.m. for discussion of program policies and issues. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C., section 10(d) of Public Law 92–463, the meeting will be closed to the public from approximately 3:00 p.m. on October 23 to adjournment on October 24, for the review, discussion, and evaluation of individual grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact the Executive Secretary in advance of the meeting.

Dr. Ronald G. Geller, Executive Secretary, National Heart, Lung, and Blood Advisory Council, Rockledge Building (RKL2), Room 7100, National Institutes of Health, Bethesda, Maryland 20892, (301) 435–0260, will furnish substantive program information.

(Catalog of Federal Domestic Assistance Program Nos. 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; and 93.839, Blood Diseases and Resources Research, National Institutes of Health)

Dated: September 4, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–23897 Filed 9–9–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; 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 of the National Institute of Mental Health Initial Review Group:

Agenda/Purpose: To review and evaluate grant applications.

Committee Name: Epidemiology and Genetics Review Committee.

Date: October 6–October 7, 1997.

Time: 8:30 a.m.

Place: Bethesda Marriott Hotel, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Shirley Williams, Parklawn, Room 9C–18, 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301, 443–1367.

Committee Name: Mental Disorders of Aging Review Committee.

Date: October 9–October 10, 1997.

Time: 8:30 a.m.

Place: Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Richard Johnson, Parklawn, Room 901–18, 5600 Fishers Lane, Rockville, MD 20852. Telephone: 301, 443–1367.

Committee Name: Clinical Psychopathology Review Committee.

Date: October 9–October 10, 1997.