3. Providing support for ongoing CRADA-related research in the development of candidate therapeutic compounds:
   (a) financial support to facilitate scientific goals;
   (b) technical or financial support for further design of candidate therapeutic compounds; and
   (c) financial and logistical support for clinical trials Phases I-III.
4. Providing and implementing plans to independently secure future continuing supplies of candidate therapeutic compounds to assure continued preclinical and clinical development.
5. Providing plans and supporting clinical development leading to FDA approval of candidate therapeutic compounds.
6. Producing, packaging, marketing, and distributing successful therapeutic compounds.
7. Using the proposed technology for other novel biopharmaceutical and/or veterinary applications.
8. 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, development and commercialization 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 ability to perform clinical testing or trials, and obtain IND, NDA and FDA approval for a new drug or treatment modality.

4. The willingness to commit best effort and demonstrated resources to the research, development and commercialization of this technology.

5. The demonstration of expertise in the commercial development, production, marketing and sales of products related to this area of technology.

6. The level of financial support the CRADA Collaborator will provide for CRADA-related Government activities.

7. The willingness to cooperate with the National Cancer Institute in the timely publication of research results.

8. 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.

9. The willingness to accept the legal provisions and language of the CRADA with only minor modifications, if any. These provisions govern the equitable distribution of patent rights to CRADA inventions. Generally, the rights of ownership are retained by the organization which is the employer of the inventor, with (1) the grant of a research license to the Government when the CRADA Collaborator's employee is the sole inventor, or (2) the grant of an option to negotiate for an exclusive or nonexclusive license to the CRADA Collaborator when the Government employee is the sole inventor.

Dated July 28, 1995.

Thomas D. Mays,

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

[FR Doc. 95–19733 Filed 8–9–95; 8:45 am]

BILLING CODE 4140–01–P

National Institute of Mental Health; 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 meeting of the National Institute of Mental Health Special Emphasis Panel:

Agenda Purpose: To review and evaluate grant applications.

Committee Name: National Institute of Mental Health Special Emphasis Panel.

Date: August 14, 1995.

Time: 1:30 p.m.

Place: Parklawn Building, Room 9C–18, 5600 Fishers Lane, Rockville, MD 20857.

Contact Person: Phyllis L. Zusman, Parklawn Building, Room 9C–18, 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301–443–1340.

The meeting will be closed in accordance with the provisions set forth in secs. 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.

This notice is being published less than fifteen days prior to the meeting due to the urgent need to meet timing limitations imposed by the grant review cycle.

(Catalog of Federal Domestic Assistance Program Numbers: 93.242, Mental Health Research Grants; 93.281, Mental Research Scientist Development Award and Research Scientist Development Award for Clinicians; 93.282, Mental Health Research Service Awards for Research Training.

Dated: August 4, 1995.

Margery G. Grubb,

Senior Committee Management Specialist, NIH.

[FR Doc. 95–19732 Filed 8–9–95; 8:45 am]

BILLING CODE 4140–01–M

Prospective Grant of Exclusive License: Tumor Infiltrating Lymphocytes as a Treatment Modality for Human Cancer

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: This is notice in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i) that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive world-wide license to practice the inventions embodied in U.S. Patent 5,126,132 and corresponding foreign patent applications entitled, ''Tumor Infiltrating Lymphocytes as a Treatment Modality for Human Cancer'' to Applied Immune Systems, Inc. of Santa Clara, California. The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless within sixty (60) days from the date of this published notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Conventional chemotherapy is relatively ineffective in the treatment of patients with metastatic cancer. An effective therapy of patients with malignancy is needed. New cancer therapy modalities utilizing the augmentation of a cancer patient's immune system (immunotherapy) have attracted much scientific interest. The present invention covers a method of providing immunotherapy to cancer patients using a combination of tumor infiltrating lymphocytes (TIL) and interleukin-2. Tumors that are removed from cancer patients are used for the isolation of lymphocytes (tumor infiltrating lymphocytes). Single cell suspensions are prepared which consist largely of tumor cells but with occasional lymphocytes. These lymphocytes are cultured in presence of IL–2 which expands their numbers and activates them to destroy the tumor cells. Patients with cancer are then