DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Clinical Center; 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 a meeting of the Board of Scientific Counselors of the Warren Grant Magnuson Clinical Center.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for with the review, discussion, and evaluation of individual intramural programs and projects conducted by the Clinical Center, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: The Board of Scientific Counselors of the Warren Grant Magnuson Clinical Center.

Date: December 13–14, 2000.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Clinical Center Medical Board Room, 2C116, 9000 Rockville Pike, Bethesda, MD 20892.

Contact Person: David K. Henderson, MD, Deputy Director for Clinical Care, Office of the Director, Clinical Center, National Institutes of Health, Building 10, Room, 2C146, Bethesda, MD 20892, 301/402–0244.

Dated: November 4, 1999.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 99–29638 Filed 11–12–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: ''Diagnostic and Therapeutic Methods of Detecting and Treating Cancers of Reproductive Tissues''

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 the U.S. Patent Application 60/098,993, entitled, ''Diagnostic and Therapeutic Methods of Detecting and Treating Cancers of Reproductive Tissues'' and corresponding foreign patent applications to IDEC Pharmaceuticals, Inc. of San Diego, California. The United States of America is an assignee of the patent rights in these inventions and the contemplated exclusive license may be limited to the use of PAGE–4 plasmid DNA and/or PAGE–4 protein as a vaccine to produce an immune response in humans to eliminate PAGE–4 expressing prostate cancer cells.

DATES: Only written comments and/or applications for a license which are received by NIH on or before January 14, 2000.

ADDRESSES: Requests for copies of the patent applications, inquiries, comments and other materials relating to the contemplated licenses should be directed to: J.R. Dixon, Ph.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804. Telephone: (301) 496–7735 ext. 206; Facsimile: (301) 402–0220, E-Mail: DixonJ@OD.NIH.GOV. A signed Confidentiality Agreement will be required to receive copies of any of the patent applications.

Technology Description

PAGE–4 is a human X-linked gene that is strongly expressed in prostate and prostate cancer, and is also expressed in other male and female reproductive tissue (*e.g.*, testis, fallopian tube, placenta, uterus, and uterine cancer). PAGE–4 shows similarity with the GAGE protein family, but it diverges significantly from members of the family so that it appears to belong to a separate family. This, and the existence of another gene, PAGE–2, that share more homology with PAGE–4 than with members of the GAGE family indicates that the PAGE–4 protein belongs to a separate protein family.

The specific detection of PAGE–4 might be valuable for the diagnosis of prostate and testicular tumors, as well as uterine tumors. There are sufficient differences between PAGE–4 and other members of the PAGE and MAGE proteins to produce specific antibodies. Analyses with such antibodies are needed to confirm by immunohistology the expression specificity that is seen in database and mRNA analyses, and to evaluate whether anti-PAGE 4 immunotherapy could be a promising therapeutic approach. One possibility of eliminating PAGE–4 expressing cells could be to use it as a cancer vaccine. Among the many possible approaches to vaccination, one method is direct vaccination with plasmid DNA. In fact, a laboratory at the NIH has been able to obtain good expression of the PAGE–4 protein with mammalian expression plasmids, and has demonstrated that DNA-immunization with such expression constructs leads to good immune responses. Hence, this method may generate anti-PAGE–4 responses, and allow one to analyze if ''PAGE–4-vaccination'' can eliminate PAGE–4 expressing cells, as a therapeutic approach towards neoplasms of the prostate, testis, and uterus.

Prostate Cancer

Prostate Cancer is a disease affecting approximately 1 million men in the U.S.A., with an annual incidence of around 300,000 and approximately 40,000 deaths per year. Control of primary tumor by surgical resection and/or radiation has proven effective in a number of cases, however, metastatic spread, primarily to the bone, especially at late hormone independent stages of the disease, has been more difficult to control and monitor.

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 and may be limited to the field of use of PAGE–4 plasmid DNA and/or PAGE–4 protein as a vaccine to produce an immune response in humans to eliminate PAGE–4 expressing prostate cancer cells. 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 exclusive license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Applications for a license [*i.e.*, completed ''Application for License to Public Health Service Inventions''] filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections will not be made available for public inspection and, to the extent permitted by law, will not be subject to disclosure under the Freedom of Information Act, 5 U.S.C. 552.

Dated: November 5, 1999.

Jack Spiegel,

Director, Division of Technology Development and Transfer, Office of Technology Transfer.

[FR Doc. 99–29635 Filed 11–12–99; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Federal Drug Testing Custody and Control Form

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice of proposed revision.

SUMMARY: The Department of Health and Human Services (HHS) establishes the standards for Federal workplace drug testing programs under authority of Public Law 100–71 and Executive Order No. 12564. As a result of the Executive Order and Public Law, HHS published the Mandatory Guidelines for Federal Workplace Drug Testing Programs in the **Federal Register** on April 11, 1988 (53 FR 11979), which were revised on June 9, 1994 (59 FR 29908), to establish comprehensive standards for all aspects of the Federal workplace drug testing program. The Mandatory Guidelines require all urine specimens to be collected using chain of custody procedures to document the integrity and security of the specimen from the time of collection until receipt by the laboratory. To ensure uniformity among all Federal agency workplace drug testing programs, the Mandatory Guidelines require agencies to use an Office of Management and Budget (OMB) approved Federal drug testing custody and control form (Federal CCF) for their programs. Additionally, the Department of Transportation (DOT) has required its regulated industries to use the Federal CCF. The current Federal CCF has been approved for use by OMB until July 31, 2000, for all Federal agency and federally regulated drug testing programs which must comply with the HHS Mandatory Guidelines.

The current Federal CCF is a seven-part form that consists of the following copies: Copy 1 (Original—Must Accompany Specimen to Laboratory (White)), Copy 2 (Second Original—Must Accompany Specimen to Laboratory (White)), Copy 3 (Split Specimen—Must Accompany Split Specimen to Laboratory (White)), Copy 4 (Medical Review Officer Copy (Pink)), Copy 5 (Donor Copy (Green)), Copy 6 (Collector Copy (Yellow)), and Copy 7 (Employer Copy (Blue)). The reverse side of copies 1, 2, 3, 4, 5, and 6 have a Paperwork Reduction Act Notice statement, the reverse side of Copy 5 has a Privacy Act Statement (for Federal employees only), and the reverse side of Copy 7 has instructions for completing the CCF. Additionally, the tamper-evident specimen bottle seal(s)/label(s) are attached to the right side of Copy 1.

This notice provides proposed changes to the current Federal CCF. It incorporates changes based on the HHS and DOT experiences during the past several years as well as many of the recommendations developed by industry representatives (*i.e.*, users and suppliers of the Federal CCF) at two working group meetings held in January and March 1999. The Substance Abuse and Mental Health Services Administration (SAMHSA) believes the proposed changes will make the Federal CCF easier to use and will more accurately reflect the collection process and how results are reported by the drug testing laboratories. The proposed form is provided in Appendix A.

DATES: Written comments on the proposed draft should be submitted by January 14, 2000.

ADDRESSES: Written comments should be addressed to Robert L. Stephenson II, M.P.H., Director (Acting), Division of Workplace Programs, CSAP, 5600 Fishers Lane, Rockwall II, Suite 815, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: Walter F. Vogl, Ph.D., Drug Testing Section, Division of Workplace Programs, CSAP, 5600 Fishers Lane, Rockwall II, Suite 815, Rockville, Maryland 20857, tel. (301) 443–6014, fax (301) 443–3031, or email: wvogl@samhsa.gov.

Discussion

SAMHSA is proposing the following major changes to the Federal CCF. The first major change is to make the revised Federal CCF a six-part form by eliminating the split specimen copy (current Copy 3). Since the split specimen copy is used only when the split specimen is tested (*i.e.*, less than approximately 5 percent of split specimens are tested), it would be more efficient to have the second laboratory report the split specimen test result on Copy 1. For those instances when the split specimen is tested, the primary laboratory will need to make a photocopy of Copy 1 of the Federal CCF and send it along with the split specimen to the second laboratory. Although this procedure requires the primary laboratory to make a photocopy, SAMHSA believes saving the costs for printing a separate split specimen copy for each Federal CCF outweighs the costs associated with the few times that Copy 1 will need to be photocopied by the primary laboratory. In addition, eliminating the split specimen copy will help make the information that appears on later pages more legible.

The second major change is locating the specimen bottle seal(s)/label(s) on the bottom of Copy 1 rather than attaching them to the right side of the form. This change will eliminate the need to have special and expensive wide carriage printers and equipment to handle the automatic processing of the Federal CCF and will standardize the storage and handling requirements to match those for other documents. We believe this change will increase the number of suppliers printing the Federal CCF, will reduce the cost to print the Federal CCF, and reduce the cost of the forms for the user.

The third major change involves simplifying the chain of custody step by requiring the collector to only sign the form once. SAMHSA believes the current requirement for the collector to sign the form three times can be replaced by using one signature because the certification statement signed by the collector clearly describes that the collector had possession of the specimen from the time collector received the specimen from the donor until the collector released the specimen for shipment to the laboratory.

The fourth major change is to provide additional choices for the laboratory to report specimen test results. The current form uses ''Test Not Performed'' to report anything other than a negative or positive result. SAMHSA believes it is more appropriate to provide choices on the form that accurately reflect the handling and reporting of specimen test results, such as, invalid result, adulterated, substituted, or rejected for testing.

The fifth major change is to include a new step on Copy 1 to allow the secondary laboratory to document a result for the split specimen (Bottle B). This change ensures that the primary specimen and split specimen laboratory test results are recorded on the same copy that is provided to the Medical Review Officer if the split specimen is tested.

The sixth major change is placing the Medical Review Officer steps for the primary and split specimens on Copy 2. This change permits the MRO to record the determination for both the primary specimen and the split specimen (if tested) on the same copy (Copy 2).

Appendix A presents the required format and appearance for each copy of