Time: 1 p.m. to 3 p.m.

Agenda: Review and evaluate the final draft for the Environmental Factors in Cancer 2008/2009 Annual Report.

Place: National Cancer Institute, Office of the Director, National Institutes of Health, 6116 Executive Blvd., Suite 220, Bethesda, MD 20892 (Teleconference).

Contact Person: Abby Sandler, PhD., Executive Secretary, Chief, Institute Review Office, Office of the Director, National Cancer Institute, NIH, 6116 Executive Blvd., Suite 220, MSC 8349, Bethesda, MD 20892–8349, 301/451–9399, *sandlera@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the comments to the Contact Person listed on this notice. The comments should include the name, address, telephone number and, when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *http://deainfo.nci.nih.gov/advisory/pcp/pcp.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 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, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: February 19, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–4048 Filed 2–24–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Co-Exclusive License: Use Fully Human and/or Humanized Monoclonal Antibodies Against IGF-I and/or IGF-II for the Treatment of Human Cancers

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

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 a co-exclusive patent license to practice the inventions embodied in U.S. Patent Application No. 12/296,328 entitled, ''Human IGF-I-Specific and IGF-I and IGF-II Cross-Reactive Human Monoclonal Antibodies'' and all foreign counterparts [HHS Ref. No. E–336–2005/0] to Trubion Pharmaceuticals, Inc., which is located in Seattle, Washington. The patent rights in this invention have been assigned to the United States of America.

The prospective co-exclusive license territory may be worldwide and the field of use may be limited to the use of the antibodies and their method of use in the Licensed Patent Rights for the treatment of human cancers.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before April 27, 2009 will be considered. This notice updates the **Federal Register** Notice published in 73 FR 32719, June 10, 2008.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated co-exclusive license should be directed to: Whitney A. Hastings, M.S., Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804. Telephone: (301) 451–7337; Facsimile: (301) 402–0220; E-mail: *hastingw@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: The type 1 insulin-like growth factor (IGF) receptor (IGF1R) is over-expressed by many tumors and mediates proliferation, motility, and protection from apoptosis. Agents that inhibit IGF1R expression or function can potentially block tumor growth and metastasis. Its major ligands, IGF-I and IGF-II, are over-expressed by multiple tumor types. Previous studies indicate that inhibition of IGF-I and/or IGF-II binding to its cognizant receptor negatively modulates signal transduction through the IGF pathway and concomitant cell growth. Therefore, use of humanized or fully human antibodies against IGFs represents a valid approach to inhibit tumor growth.

The above identified patent applications discloses three (3) novel fully human monoclonal antibodies designated m705, m706, and m708, which are specific for insulin-like growth factor (IGF)-I. Two (2) of the three (3) antibodies, m705 and m706 are specific for IGF-I and do not cross react with IGF-II and insulin while, m708 cross reacts with IGF-II.

These antibodies can be used to prevent binding of IGF-I to its concomitant receptor IGFIR, consequently, modulating diseases such as cancer. Additional embodiments describe methods for treating various human diseases associated with aberrant cell growth and motility including breast, prostate, and leukemia carcinomas. Thus, these novel antibodies may provide a therapeutic intervention for multiple carcinomas without the negative side effects associated with insulin inhibition.

The prospective co-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 co-exclusive license may be granted unless within sixty (60) days from the date of this published notice, the 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.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated co-exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: February 17, 2009.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. E9–4045 Filed 2–24–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Diagnostic Tests for Predicting the Emergence of Suicidal Ideation Subsequent to Anti-Depressant Treatment

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

ACTION: Notice.

SUMMARY: This notice, in accordance with 35 U.S.C. 209(c)(l) and 37 CFR 404.7(a)(l)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the inventions embodied in U.S. Patent Application 60/854,978 [HHS Ref. E–157–2006/0–US–01], PCT Patent Application PCT/US2007/082683 [HHS Ref. E–157–2006/1–PCT–01], U.S. Patent Application 11/925,334 [HHS Ref. E–157–2006/1–US–02], all entitled ''Methods to Identify Patients at Risk of Developing Adverse Events During Treatment With Antidepressant Medication'', and all continuing

applications and foreign counterparts, to NeuroMark, Inc., which has offices in Boulder, CO. The patent rights in these inventions have been assigned to and/or exclusively licensed to the Government of the United States of America.

The prospective exclusive license territory may be worldwide, licensees will need to address the medical usefulness of multi-gene test formats should data be developed to support such approaches and the term of the agreement may be commensurate with commercial incentives and public health needs. The field of use may be limited to:

FDA approved diagnostic test kits for predicting the emergence of suicidal ideation subsequent to anti-depressant treatment and for screening patients to identify those patients more likely to exhibit an increased risk of treatment-emergent suicidal ideation by assaying for the presence of a genotype in the patients which is associated with an increased risk of treatment-emergent suicidal ideation.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before April 27, 2009 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Norbert Pontzer, Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–5502; Facsimile: (301) 402–0220; E-mail: *pontzern@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: Suicidal ideation is an uncommon symptom than can emerge during antidepressant treatment. The Food and Drug Administration (FDA) requires a black box warning of worsening depression and/or emergence of suicidality (i.e., development of suicidal thoughts or behavior) for both adult and pediatric patients taking antidepressant medications. While use of antidepressants fell after to the black box warning, studies suggest that pediatric suicides may actually be rising. This has led to concerns that the black box warning led to a decrease in treatment and resulted in an overall increase in suicides. The Sequenced Treatment Alternatives for Depression (STAR*D) trial at NIH found that versions of genes coding for components of the brain's chemical messenger system may be linked to suicidal thinking associated with antidepressant use. If links between genes and suicidal thinking are validated under a license, depressed individuals at higher risk for suicide could benefit from closer monitoring, alternative treatments, or specialty care while allowing more aggressive treatment in individuals without the increased risk.

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, the 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.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

February 18, 2009.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. E9–4053 Filed 2–24–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: Strategic Prevention Framework State Incentive Grant (SPF SIG) Program (OMB No. 0930–0279) Revision

SAMHSA's Center for Substance Abuse Prevention (CSAP) is responsible for the evaluation instruments of the Strategic Prevention Framework State Incentive Grant (SPF SIG) Program. The program is a major national initiative designed to: (1) Prevent the onset and reduce the progression of substance abuse, including childhood and underage drinking; (2) reduce substance abuse related problems in communities; and (3) build prevention capacity and infrastructure at the State/territory/tribe and community levels.

Five steps comprise the SPF:

Step 1: Profile population needs, resources, and readiness to address needs and gaps.

Step 2: Mobilize and/or build capacity to address needs.

Step 3: Develop a comprehensive strategic plan.

Step 4: Implement evidence-based prevention programs, policies, and practices.

Step 5: Monitor, evaluate, sustain, and improve or replace those that fail.

An evaluation team is currently implementing a multi-method, quasi-experimental evaluation of the first two SPF SIG cohorts receiving grants in FY 2004 and FY 2005. This notice invites comment on grantee-level, community-level, and participant-level data collection instruments designed for the cross-site evaluation of 16 Cohort 3 grantees receiving grants in FY 2006 and 20 Cohort 4 grantees. Since the ultimate goal is to fund all eligible jurisdictions, there are no control groups at the grantee level. The primary evaluation objective is to determine the impact of SPF SIG on the SAMHSA National Outcomes Measures (NOMs). Data collected at the grantee, community, and participant levels using the three instruments will be combined in an analysis that investigates the relationship, if any, between the SPF process and substance use outcomes at individual and community levels. The instruments will be included in an OMB review package submitted immediately after the expiration of the comment period and are the main focus of this announcement.

Grantee-Level Data Collection

Two instruments were developed for assessing grantee-level effects. Both instruments are guides for interviews that will be conducted by the grantees' evaluators twice over the life of the SPF SIG award. These instruments are modified versions of those used in the SPF SIG Cohort 1 and 2 Cross-Site Evaluation Study (OMB No. 09300279). The total burden of the original instruments has been reduced by deleting several questions and replacing the majority of open-ended questions with multiple-choice-response questions. The *Strategic Prevention Framework Implementation Interview Protocol* will be used to assess the relationship between SPF