DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mandatory Guidelines for Federal Workplace Drug Testing Programs

AGENCY: Substance Abuse and Mental Health Services Administration (SAMHSA), Department of Health and Human Services.

ACTION: HHS Approval of Entities That Certify Medical Review Officers (MRO).

SUMMARY: The current version of the Department of Health and Human Services (HHS) Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines), effective on October 1, 2010, addresses the role and qualifications of Medical Review Officers (MROs) and HHS approval of entities that certify MROs. Subpart M—Medical Review Officer (MRO), Section 13.1(b) of the Mandatory Guidelines, “Who may serve as an MRO?” states as follows: “Nationally recognized entities that certify MROs or subspecialty boards for physicians performing a review of Federal employee drug test results that seek approval by the Secretary must submit their qualifications and a sample examination. Based on an annual objective review of the qualifications and content of the examination, the Secretary shall annually publish a list in the Federal Register of those entities and boards that have been approved.” HHS has completed its review of entities that certify MROs, in accordance with requests submitted by such entities to HHS.

The HHS Secretary approves the following MRO certifying entities that offer MRO certification through examination:

American Association of Medical Review Officers (AAMRO), P.O. Box 12873, Research Triangle Park, NC 27709; Phone: (800) 489–1839; Fax: (919) 490–1010; Email: cferrell@aamro.com; Web site: http://www.aamro.com/.

Medical Review Officer Certification Council (MROCC), 836 Arlington Heights Road, #327, Elk Grove Village, IL 60007; Phone: (847) 631–0599; Fax: (847) 483–1282; Email: mrocc@mrocc.org; Web site: http://www.mrocc.org./

DATES: HHS approval is effective May 26, 2015.

FOR FURTHER INFORMATION CONTACT: Jennifer Fan, Pharm.D., J.D., Division of Substance Abuse Prevention (CSAP), Substance Abuse and Mental Health Services Administration (SAMHS), 1 Choke Cherry Road, Room 7–1038, Rockville, MD 20857; Telephone: (240) 276–1759; Email: jennifer.fan@samhsa.hhs.gov

Dated: May 15, 2015.

Sylvia M. Burwell, Secretary.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

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

Name of Committee: National Institute of General Medical Sciences Initial Review Group; Training and Workforce Development Subcommittee—C.

Date: June 8, 2015.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Monaco Alexandria, 480 King Street, Alexandria, VA 22314.

Contact Person: Mona R. Trempe, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An.12A, Bethesda, MD 20892–4874, 301–594–3998, trempemo@mail.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: May 19, 2015.

Melanie J. Gray, Program Analyst, Office of Federal Advisory Committee Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Development of Autologous Tumor Infiltrating Lymphocyte Adoptive Cells for the Treatment of Lung, Breast, Bladder, and HPV-Positive Cancers

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to the current licensee, Lion Biotechnologies, Inc., which is located in Woodland Hills, California to practice the inventions embodied in the following patent applications and applications claiming priority to these applications:

The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to the use of the Licensed Patent Rights to develop, manufacture, distribute, sell and use unselected whole autologous tumor infiltrating lymphocyte (TIL) adoptive cell therapy products for the treatment of lung, breast, bladder, and HPV-positive cancers. Specifically excluded from this license are methods of generating or using selected subpopulations of TIL and the use of T cell receptors isolated from TIL.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before June 25, 2015 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: Whitney A. Hastings, Ph.D., Senior 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; Email: hastingw@mail.nih.gov.

SUPPLEMENTARY INFORMATION: Isolating cells from the tumor infiltrating lymphocytes (TIL) of a patient tumor sample provides a suitable initial lymphocyte culture for further in vitro manipulations. NIH scientists have discovered that taking the isolated cells through one cycle of rapid expansion (including exposure to IL–2), rather than multiple cycles, yields lymphocyte cultures with higher affinity and longer persistence in patients. In addition, they have found that through the use of gas permeable (GP) flasks, they could obtain large quantities of highly reactive TIL from patient tumor samples for anticancer immunotherapy. If an adoptive T cell transfer immunotherapy is to gain regulatory approval and successfully treat a wide array of patients, it will need to be rapid, reliable, and technically simple. One of the most critical factors to this approach is the generation of effective lymphocyte cultures that will rapidly and repeatedly attack the target cells when infused into patients.

The prospective exclusive license may be granted unless within thirty (30) 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 Part 404.

Complete 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.

Dated: May 19, 2015.
Richard U. Rodriguez,
Acting Director, Office of Technology Transfer, National Institutes of Health.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request From the Interagency Committee on Human Nutrition Research (ICHNR) for Comments on the Draft National Nutrition Research Roadmap 2015–2020: Advancing Nutrition Research To Improve and Sustain Health

SUMMARY: The Draft National Nutrition Research Roadmap (NNRR) identifies research priorities for human nutrition and describes the role of ICHNR departments and agencies in addressing those priorities over the next five to ten years. ICHNR seeks input about identified research and resource gaps and opportunities and the short- and long-term initiatives proposed to address them. To review the NNRR, please visit https://prevention.nih.gov/nnrr.

DATES: To ensure consideration, your responses must be received by 11:59 p.m. Eastern Standard Time on June 25, 2015.

ADDRESSES: Responses to this Notice must be submitted via email to NNRRfeedback@nih.gov or postal mail to the National Institutes of Health, Division of Nutrition Research Coordination, Two Democracy Plaza, Room 635, 6707 Democracy Boulevard—MSC 5461, Bethesda, Maryland 20892–5461.

FOR FURTHER INFORMATION CONTACT: Dr. Sheila Fleischhacker, Senior Public Health & Science Policy Advisor, National Institutes of Health, Division of Nutrition Research Coordination, Two Democracy Plaza, Room 635, 6707 Democracy Boulevard—MSC 5461, Bethesda, Maryland 20892–5461. Telephone: 301–594–7440, Fax: 301–480–3768, Email: NNRRfeedback@nih.gov.

SUPPLEMENTARY INFORMATION: Background

Improved nutrition could be one of the most cost-effective approaches to address many of the societal, environmental, and economic challenges facing the nation today, including the morbidity, mortality, and economic burden associated with chronic diseases and disorders. That is, nutrition plays an integral role in human growth and development, in the maintenance of good health and functionality, and in the prevention and treatment of infectious, acute and chronic diseases, as well as genetic disorders such as inborn errors of...