

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 on Deafness and Other Communication Disorders Special Emphasis Panel; VSL Fellowship Review.

Date: June 9, 2014.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Kausik Ray, Ph.D., Scientific Review Officer, National Institute on Deafness and Other Communication Disorders, National Institutes of Health Rockville, MD 20850, 301-402-3587, rayk@nidcd.nih.gov.

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; Chemosensory Fellowship Review.

Date: June 11, 2014.

Time: 12:00 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Sheo Singh, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, 6001 Executive Blvd., Room 8351, Bethesda, MD 20892, 301-496-8683, singhs@nidcd.nih.gov.

Name of Committee: Communication Disorders Review Committee.

Date: June 12-13, 2014.

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

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

Contact Person: Shiguang Yang, DVM, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NIDCD, NIH, 6001 Executive Blvd., Room 8349, Bethesda, MD 20892, 301-435-1425, yangshi@nidcd.nih.gov.

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; Hearing and Balance Fellowship Review.

Date: June 18, 2014.

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

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Eliane Lazar-Wesley, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural

Activities, 6001 Executive Boulevard, Room 8339, MSC 9670, Bethesda, MD 20892-8401, 301-496-8683, el6r@nih.gov.

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; P50 Review.

Date: July 17, 2014.

Time: 11:00 a.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Sheo Singh, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, 6001 Executive Blvd., Room 8351, Bethesda, MD 20892, 301-496-8683, singhs@nidcd.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: May 7, 2014.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014-10891 Filed 5-12-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of 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 meeting of the Council of Councils.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

A portion of 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: Council of Councils.
Open: June 20, 2014.

Time: 8:15 a.m. to 11:15 a.m.

Agenda: Council Business Matters and Updates; Aquatic/Zebrafish Model Resources; NIH Update.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 6, Bethesda, MD 20892.

Closed: June 20, 2014.

Time: 12:00 p.m. to 1:00 p.m.

Agenda: Review of grant applications.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 6, Bethesda, MD 20892.

Open: June 20, 2014.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: Updates on Cleared Concepts Being Developed into Common Fund Programs, New Common Fund Concept Clearances, Early Independence Award Process Evaluation and Discussion, Update on Common Fund Planning and Management Evaluation Report.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 6, Bethesda, MD 20892.

Contact Person: Franziska Grieder, DVM, Ph.D., Executive Secretary, Director, Office of Research Infrastructure Programs, Division of Program Coordination, Planning, and Strategic Initiatives, Office of the Director, NIH, 6701 Democracy Boulevard, Room 948, Bethesda, MD 20892, GriederF@mail.nih.gov, 301-435-0744.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement 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 Council of Council's home page at <http://dpcpsi.nih.gov/council/where> an agenda will be posted before the meeting date.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: May 7, 2014.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014-10909 Filed 5-12-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Information: The National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods Requests the Nomination of Reference Chemicals

SUMMARY: The National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) requests the nomination of reference chemicals, with supporting data, to be used to validate *in vitro* metabolizing systems with the potential to interact with estrogen receptors (ERs) or androgen receptors (ARs). Specifically, a list of chemicals is needed to characterize the usefulness and limitations of *in vitro* metabolizing systems for use in conjunction with ER and AR transactivation tests.

DATES: The deadline for receipt of information is June 2, 2014.

ADDRESSES: Nominated reference chemicals and associated data should be submitted electronically in Microsoft® Excel or Word formats to niceatm@niehs.nih.gov. A Microsoft® Excel template for data submission is available at <http://ntp.niehs.nih.gov/go/41493>.

FOR FURTHER INFORMATION CONTACT: Dr. Warren S. Casey, Director, NICEATM; email: warren.casey@nih.gov; telephone: (919) 316-4729.

SUPPLEMENTARY INFORMATION:

Background

Endocrine-active substances (EAS) are chemicals that interfere with normal endocrine hormone function by mimicking, blocking, or increasing their actions, thereby possibly causing adverse health effects. United States legislation (e.g., 7 U.S.C. 136, 110 Stat 1613) requires that chemicals be tested for their ability to disrupt the hormonal systems of mammals; prospective international legislative proposals may have similar requirements. Chemicals found to test positive *in vitro* as EAS may be *in vivo* endocrine disruptors. The lack of *in vitro* tools that mimic *in vivo* metabolism is the main obstacle to implementation of *in vitro* tools for EAS toxicity testing. Improved

understanding of metabolic capabilities and limitations of *in vitro* toxicity testing is critical to:

- Ensure that no potentially active metabolites are missed
- Allow better interpretation of results
- Accurately predict species-specific characteristics of absorption, metabolism, and excretion

While there is a growing body of international *in vitro* test guidelines addressing EAS mechanisms and modes of action, there are few or no standardized methods to incorporate metabolic and toxicokinetic aspects into these EAS *in vitro* tests to date. *In vitro* assays for EAS should incorporate metabolic enzyme systems to better address the relevance of EAS tests to *in vivo* adverse outcome pathways.

The Organization for Economic Co-operation and Development (OECD) Validation Management Group-Non-Animal (VMG-NA) expert working group develops internationally accepted non-animal test guidelines to support various international regulatory needs for the hazard identification of potential EAS. These test guidelines describe methods and approaches capable of identifying potential EAS without the use of animals. Consistent with its purpose of evaluating alternative methods for testing chemicals and chemical products, NICEATM participates in the VMG-NA.

Test guidelines for *in vitro* assays for ER activity have been evaluated and accepted by international regulatory authorities; test guidelines for *in vitro* AR activity assays are currently in development. However, none of these *in vitro* EAS assays account for whole animal metabolism. Further development of specific tests is needed to optimize the use of *in vitro* metabolism with EAS assays. Identification of appropriate reference chemicals to check the metabolic capacity of any proposed test method is key to continued assay development. For this purpose, the VMG-NA is developing a robust list of chemicals that, when metabolized, act as ER or AR agonist or antagonists.

Request for Information

On behalf of the VMG-NA, NICEATM requests nominations of chemicals that can be used to characterize and validate *in vitro* metabolizing systems for use in conjunction with *in vitro* tests for ER and AR transactivation. Responses are requested from all interested parties, including the research community, health professionals, educators, policy makers, industry, and the public. Considerations for selection of

appropriate chemicals include the ability of a chemical to act as an ER or AR agonist or antagonist and:

- Potential for metabolism to make a chemical either more potent (bioactivation) or less potent (detoxification)
- Likelihood of metabolism occurring in relevant routes of exposure and target organs
- Likelihood of metabolism occurring over a range of doses: Information on the ratio of the half maximal effective or inhibitory concentration (EC50 or IC50, respectively) of parent to daughter metabolites will be useful and there is a particular need for information pertaining to substances where biotransformation yields a very small or very large ratio of EC50/IC50 of parent to daughter metabolites
- Stability, preferably with real-time curves and consequent exposure significance of likely metabolites
- Diversity of likely and predominant biotransformative pathways
- Diversity of chemical types, use classes, and consequent applicability domains

The reference chemicals will be used to check the metabolic capacity of the *in vitro* model, including characterization of the general metabolic capacity of the cell lines. To ensure relevant use in a regulatory context, it will be necessary, where possible, to make correlations to:

(a) Relevant *in vivo* metabolic modeling (accounting for absorption, distribution, metabolism, and excretion, etc.) of plasma/blood metabolites in vertebrate animals (e.g., rat, fish, human).

(b) Data from the uterotrophic, Hershberger, and/or other relevant assays with a demonstrated high confidence in prediction of bioactivation of estrogenic or androgenic agonist and antagonist pathways, such that the true systemic *in vivo* metabolic response is addressed as accurately as possible.

When reporting the *in vitro* dose response for potential reference chemicals, the concentrations of solvent and/or carrier proteins used in the assay buffers to solubilize the reference chemicals should be described to facilitate an understanding of potential differences among new *in vitro* assays with regard to free concentrations of parent chemical and metabolites versus nominal dosages within each testing system.

Nominated reference chemicals and associated data should be submitted electronically in Microsoft® Excel or Word formats to niceatm@niehs.nih.gov. Data submitted can include, but need