

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

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 meetings.

The meetings 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: Center for Scientific Review Special Emphasis Panel; Diabetic Neuropathy.

Date: August 29, 2006.

Time: 5:30 p.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: William C. Benzing, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5206, MSC 7846, Bethesda, MD 20892, (301) 435-1254, benzingw@csr.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.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Confocal Microscopy Shared Instrumentation Panel.

Date: September 18-19, 2006.

Time: 8:30 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Beacon Hotel and Corporate Quarters, 1615 Rhode Island Avenue, NW., Washington, DC 20036.

Contact Person: Laura M. Roman, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2138, MSC 7720, Bethesda, MD 20892, 301-435-0715, romanl@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Bacterial Pathogenesis.

Date: September 20, 2006.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Fouad A. El-Zaatari, PhD, Scientific Review Administrator, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3206, MSC 7808, Bethesda, MD 20814-9692, (301) 435-1149, elzaataf@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program Project Review: Cryo-Electron Microscopy.

Date: September 25, 2006.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Sally Ann Amero, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4190, MSC 7849, Bethesda, MD 20892, 301-435-1159, ameros@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-83.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 21, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06-7175 Filed 8-25-06; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: System and Methods for Detecting and Characterizing Macromolecular Interactions in Solution

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 (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive license to practice the inventions embodied in PCT (application number pending) filed July 28, 2006 from U.S. provisional application 60/703,814 (E-167-2005/0-US-01), entitled "System and Methods for Detecting and Characterizing Macromolecular Interactions in Solution" (Inventors: Drs. Allen Minton and Arun Attri) to Wyatt Technology Corporation (hereafter Wyatt), having a place of business in Goleta, California. The patent rights in these inventions have been assigned to the United States of America.

DATES: Only written comments and/or application for a license, which are received by the NIH Office of Technology Transfer on or before October 27, 2006 will be considered.

ADDRESSES: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Chekesha Clingman, Ph.D., Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; e-mail: clingmac@mail.nih.gov; telephone: (301) 435-5018; facsimile: (301) 402-0220.

SUPPLEMENTARY INFORMATION: The present invention relates to systems and methods for sensitive detection and characterization of macromolecular interactions in homogenous or heterogeneous solutions of macromolecules, such as proteins, DNA, RNA, biopolymers, organic and inorganic polymers, macromolecular pharmaceutical compounds and others. The methods employed by this system do not require the need for labeling or chemical modification of any test substance, and it is more rapid than any conventional methods. The system includes a dispenser to dispense a solution containing the macromolecule, and one or more detectors to measure a light scattering and concentration associated with the macromolecule in solution. For instance, the first detector can be a light scattering detector (such as a static light-scattering detector). The second detector (such as a UV-Vis detector) can be added in to measure light absorbance and hence concentration. The detectors can be arranged in parallel, to receive identical flow of solution from the dispenser, so that at any given time point, both detectors collect data on flow of identical concentrations.

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 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.

The field of use may be limited to the development of a system and method for detecting and characterizing macromolecular interactions in solution.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments

and objections submitted in response 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: August 21, 2006.

Steven M. Ferguson,
 Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.
 [FR Doc. E6-14190 Filed 8-25-06; 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.

Proposed Project: Opioid Drugs in Maintenance and Detoxification Treatment of Opioid Dependence—42 CFR part 8 (OMB No. 0930-0206)—Revision

This regulation establishes a certification program managed by SAMHSA’s Center for Substance Abuse Treatment (CSAT). The regulation requires that Opioid Treatment Programs (OTPs) be certified. “Certification” is the process by which SAMHSA determines that an OTP is qualified to provide opioid treatment under the Federal opioid treatment standards established by the Secretary of Health and Human Services. To become certified, an OTP must be accredited by a SAMHSA-approved accreditation body. The regulation also provides standards for such services as individualized treatment planning, increased medical supervision, and assessment of patient outcomes. This submission seeks continued approval of the information collection requirements in the regulation and of the forms used in implementing the regulation.

SAMHSA currently has approval for the Application for Certification to Use Opioid Drugs in a Treatment Program Under 42 CFR 8.11 (Form SMA-162); the Application for Approval as Accreditation Body Under 42 CFR 8.3(b) (Form SMA-163); and the Exception Request and Record of Justification Under 42 CFR 8.12 (Form SMA-168), which may be used on a voluntary basis by physicians when there is a patient

care situation in which the physician must make a treatment decision that differs from the treatment regimen required by the regulation. Form SMA-162 is used as the initial application to request certification of an OTP, to request renewal of certification and to change existing information regarding the program’s location, sponsor and medical director. This form collects information such as address, program name, contact information, sponsor name and address and medical director name and address. Attachments are required to complete this form regarding the OTPs accrediting status, organizational structure, and operating procedures. Form SMA-163 is used as an application to become a SAMHSA approved accrediting body. This form collects accrediting body name, address and contact information. Attachments are required to complete this form regarding the accrediting body’s operating procedures and standards and their staff’s education and experience. Form SMA-168 is a simplified, standardized form to facilitate the documentation, request, and approval process for exceptions. This form collects patient admission date, dosage amount, patient status, attendance schedule per week, dates of exception and justification.

The tables that follow summarize the annual reporting burden associated with the regulation, including burden associated with the forms.

ESTIMATED ANNUAL REPORTING REQUIREMENT BURDEN FOR ACCREDITATION BODIES

42 CFR citation	Purpose	Number of respondents	Responses/respondent	Hours/response	Total hours
8.3(b)(1-11)	Initial approval (SMA-163)	1	1	6.0	6
8.3(c)	Renewal of approval (SMA-163)	2	1	1.0	2
8.3(e)	Relinquishment notification	1	1	0.5	0.5
8.3(f)(2)	Non-renewal notification to accredited OTPs.	1	90	0.1	9
8.4(b)(1)(ii)	Notification to SAMHSA for seriously noncompliant OTPs.	2	2	1.0	4
8.4(b)(1)(iii)	Notification to OTP for serious non-compliance.	2	10	1.0	20
8.4(d)(1)	General documents and information to SAMHSA upon request.	6	5	0.5	15
8.4(d)(2)	Accreditation survey to SAMHSA upon request.	6	75	0.02	9
8.4(d)(3)	List of surveys, surveyors to SAMHSA upon request.	6	6	0.2	7.2
8.4(d)(4)	Report of less than full accreditation to SAMHSA.	6	5	0.5	15
8.4(d)(5)	Summaries of Inspections	6	50	0.5	150
8.4(e)	Notifications of Complaints	6	6	0.5	18
8.6(a)(2) and (b)(3)	Revocation notification to Accredited OTPs.	1	185	0.3	55.5
8.6(b)	Submission of 90-day corrective plan to SAMHSA.	1	1	10	10.0
8.6(b)(1)	Notification to accredited OTPs of Probationary Status.	1	185	0.3	55.0