

Contact Person: Tracy Riley or Angie Whitacre, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7001, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12534. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss new drug application (NDA) 20-961, Vitravene® (fomivirsen sodium intravitreal injection, ISIS Pharmaceuticals), for treatment of cytomegalovirus (CMV) retinitis in patients with acquired immune deficiency syndrome (AIDS).

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by July 17, 1998. Oral presentations from the public will be scheduled between approximately 8 a.m. and 8:30 a.m., and between approximately 1 p.m. and 1:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 17, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 12, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98-16851 Filed 6-24-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Privacy Act of 1974; Altered System of Records

AGENCY: National Institutes of Health, HHS.

ACTION: Notification of an altered system of records.

SUMMARY: In accordance with the requirements of the Privacy Act, the National Institutes of Health (NIH) is publishing a notice of proposal to alter an existing system of records 09-25-0036, "Extramural Awards and

Chartered Advisory Committees: IMPAC (Grant/Contract/Cooperative Agreement Information/Chartered Advisory Committee Information), HHS/NIH/OER and HHS/NIH/CMO." The system is altered by including contractor past performance information as a new category of records; adding consultants and contractors as individuals covered by the system; and including a new routine use which allows NIH to share information it collects on contractor past performance information with other Federal agencies.

DATES: The NIH invites interested parties to submit comments on the proposed internal and routine uses on or before July 27, 1998. The NIH sent a Report of the Altered System to the Congress and to the Office of Management and Budget (OMB) on June 19, 1998. The alteration of this system of records will be effective 40 days from the date submitted to the OMB, unless NIH receives comments which would result in a contrary determination.

ADDRESSES: Please submit comments to: NIH Privacy Act Officer, 6011 Executive Boulevard, Room 601, MSC 7669, Rockville, MD 20852, 301-496-2832. (This is not a toll free number.)

Comments received will be available for inspection at this same address from 9 a.m. to 3 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: NIH Privacy Act Officer, 6011 Executive Boulevard, Room 601, MSC 7669, Rockville, MD 20852, 301-496-2832. (This is not a toll free number.)

SUPPLEMENTARY INFORMATION: The National Institutes of Health (NIH) proposes to alter an existing system of records 09-25-0036, "Extramural Awards and Chartered Advisory Committees: IMPAC (Grant/Contract/Cooperative Agreement Information/Chartered Advisory Committee Information), HHS/NIH/DRG and HHS/NIH/CMO." The system is altered by including contractor past performance information as a new category of records; adding consultants and contractors as individuals covered by the system; including a new routine use which allows NIH to share information it collects on contractor past performance information with other Federal agencies; and editorial changes to accommodate normal updating changes.

The purposes of this system of records are to (1) support centralized grant programs of the Public Health Service by providing services in the areas of grant application assignment and referral, initial review, council review, award processing and grant accounting;

maintain communication with former fellows and trainees who have incurred a payback obligation through the National Research Service Award Program; maintain current and historical information pertaining to the establishment of chartered advisory committees of the National Institutes of Health and the appointment or designation of their members; and maintain current and historical information pertaining to contracts awarded by the National Institutes of Health, and performance evaluations on NIH contracts and contracts awarded by other Federal agencies that participate in the NIH Contractor Performance System.

This system will comprise records that contain names, applications, grant or contract ID number, contractor tax ID number, awards, trainee appointments, current and historical information pertaining to chartered advisory committees, and past performance information pertaining to contractors.

The records in this system will be maintained in a secure manner compatible with their content and use. NIH and contractor staff will be required to adhere to the provisions of the Privacy Act and the HHS Privacy Act regulations. The System Managers will control access to the data. Authorized users will be granted access only to those records within their specific area of responsibility. Only authorized users whose official duties require the use of such information will have regular access to the records in this system. Authorized users are NIH extramural and committee management staff, NIH contract management staff, and Federal acquisition personnel. One-time and special access by other employees is granted on a need-to-know basis as specifically authorized by the System Manager. Records may be stored on hard copy, discs and magnetic tapes, and in other machine-readable format, regardless of physical form or characteristics. Manual and computerized records will be maintained in accordance with the standards of Chapter 45-13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf:45-13, the Department's Automated Information System Security Program Handbook, and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

Access to source data files is strictly controlled by files staff. Records may be removed from files only at the request of the System Manager or other

authorized employee. Access to computer files is controlled by the use of registered accounts, registered initials, keywords, and similar limited access systems. Access to the contractor performance files is restricted through the use of secure socket layer encryption and through an IBM password protection system. Physical access to work areas is restricted to employees or authorized contractors with a valid "need-to-know."

The routine uses proposed for this system are compatible with the stated purposes of the system. The first routine use allows disclosure to the National Technical Information Service (NTIS), Department of Commerce, for dissemination of scientific and fiscal information on funded awards. The second routine use allows disclosure to the cognizant audit agency for auditing. The third routine use allows disclosure to a Member of Congress or to a Congressional staff member in response to an inquiry of the Congressional office made at the written request of the constituent about whom the record is maintained. The fourth routine use allows disclosure to qualified experts not within the definition of Department employees as prescribed in Department regulations for opinions as a part of the application review process. The fifth routine use allows disclosure to a Federal agency, in response to its request, in connection with the issuance of a license, grant or other benefit by the requesting agency, to the extent that the record is relevant and necessary to the requesting agency's decision in the matter. The sixth routine use allows disclosure of contractor past performance information to a Federal agency upon request and allows routine access to contractor past performance information to Federal agencies that subscribe to the NIH Contractor Performance System. The seventh routine use allows disclosure for a research purpose as authorized by the Department or required by law. The eighth routine use allows disclosure to a private contractor or Federal agency for the purpose of collating, analyzing, aggregating or otherwise refining records in this system. The ninth routine use allows disclosure to a grantee or contract institution in connection with performance or administration under the conditions of the particular award or contract. The tenth routine use allows disclosure to the Department of Justice, or to a court or other adjudicative body, from this system of records when HHS determines that the records are relevant and necessary to the proceeding and would

help in the effective representation of the governmental party.

We have also made editorial changes throughout the System Notice to enhance clarity and specificity and to accommodate normal updating changes.

The following notice is written in the present, rather than future tense, in order to avoid the unnecessary expenditure of public funds to republish the notice after the system has become effective.

Dated: June 5, 1998.

Anthony L. Itteilag,

Deputy Director for Management.

SYSTEM NAME:

Extramural Awards and Chartered Advisory Committees: IMPAC (Grant/Contract/Cooperative Agreement Information/Chartered Advisory Committee Information), HHS/NIH/OER and HHS/NIH/CMO.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Rockledge Centre II, 6701 Rockledge Drive, Bethesda, MD 20817
Building 12, NIH Computer Center, 9000 Rockville Pike, Bethesda, MD 20892
Building 31, Room 3B-59, 9000 Rockville Pike, Bethesda, MD 20892.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Principal investigators; program directors; program and projects staff and others named in the application; National Research Service Awards (NRSA) trainees and fellows; research career awardees; chartered advisory committee members; contractor personnel; subcontractor personnel; and consultants.

CATEGORIES OF RECORDS IN THE SYSTEM:

Funding applications, awards, associated records, trainee appointments, current and historical information pertaining to chartered advisory committees, and past performance information pertaining to contractors.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301; 42 U.S.C. 217a, 241, 282(b)(6), 284a, and 288. 48 CFR Subpart 15.3 and Subpart 42.15.

PURPOSE(S) OF THE SYSTEM:

(1) To support centralized grant programs of the Public Health Service. Services are provided in the areas of grant application assignment and referral, initial review, council review, award processing and grant accounting.

The database is used to provide complete, accurate, and up-to-date reports to all levels of management.

(2) To maintain communication with former fellows and trainees who have incurred a payback obligation through the National Research Service Award Program.

(3) To maintain current and historical information pertaining to the establishment of chartered advisory committees of the National Institutes of Health and the appointment or designation of their members.

(4) To maintain current and historical information pertaining to contracts awarded by the National Institutes of Health, and performance evaluations on NIH contracts and contracts awarded by other Federal agencies that participate in the NIH Contractor Performance System.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to the National Technical Information Service (NTIS), Department of Commerce, for dissemination of scientific and fiscal information on funded awards (abstract of research projects and relevant administrative and financial data).

2. Disclosure may be made to the cognizant audit agency for auditing.

3. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

4. Disclosure may be made to qualified experts not within the definition of Department employees as prescribed in Department regulations for opinions as a part of the application review process.

5. Disclosure may be made to a Federal agency, in response to its request, in connection with the issuance of a license, grant or other benefit by the requesting agency, to the extent that the record is relevant and necessary to the requesting agency's decision in the matter.

6. Disclosure of past performance information pertaining to contractors may be made to a Federal agency upon request. In addition, routine access to past performance information on contractors will be provided to Federal agencies that subscribe to the NIH Contractor Performance System.

7. A record may be disclosed for a research purpose, when the Department: (A) Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; (B) has determined that the

research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) justifies the risk to the privacy of the individual that additional exposure of the record might bring; (C) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining that information, and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written authorization of the Department, (c) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law; and (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

8. Disclosure may be made to a private contractor or Federal agency for the purpose of collating, analyzing, aggregating or otherwise refining records in this system. The contractor or Federal agency will be required to maintain Privacy Act safeguards with respect to these records.

9. Disclosure may be made to a grantee or contract institution in connection with performance or administration under the conditions of the particular award or contract.

10. Disclosure may be made to the Department of Justice, or to a court or other adjudicative body, from this system of records when (a) HHS, or any component thereof; of (b) any HHS officer or employee in his or her official capacity; or (c) any HHS officer or employee in his or her individual capacity when the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the officer or employee; or (d) the United States or any agency thereof where HHS determines that the proceeding is likely to affect HHS or any of its components, is a party to proceeding or has any interest in the proceeding, and HHS determines that the records are relevant and necessary to the proceeding and

would held in the effective representation of the governmental party.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored on hard copy, discs and magnetic tapes, and in other machine-readable format, regardless of physical form or characteristics.

RETRIEVABILITY:

Records are retrieved by name, application, grant or contract ID number, and contractor tax ID number.

SAFEGUARDS:

1. *Authorized Users:* Employees who maintain records in this system are instructed to grant regular access only to NIH extramural and committee management staff, NIH contract management staff, and Federal acquisition personnel. Other one-time and special access by other employees is granted on a need-to-know basis as specifically authorized by the System Manager.

2. *Physical Safeguards:* Physical access to Office of Extramural Research (OER) work areas is restricted to OER employees. Physical access to Office of Contracts Management (OCM) work areas is restricted to OCM employees. Physical access to Committee Management Office (CMO) work areas is restricted to CMO employees. Access to the contractor performance files is restricted through the use of secure socket layer encryption and through an IBM password protection system. Only authorized government contracting personnel are permitted access. Access is monitored and controlled by permitted access. Access is monitored and controlled by OCM.

3. *Procedural Safeguards:* Access to source data files is strictly controlled by files staff. Records may be removed from files only at the request of the System Manager or other authorized employee. Access to computer files is controlled by the use of registered accounts, registered initials, keywords, and similar limited access systems.

These practices are in compliance with the standards of chapter 45-13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary chapter PHS hf: 45-13, and Part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing

Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records," item 4000-A-2, which allows records to be destroyed when no longer needed for administrative purposes. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGERS AND ADDRESSES:

For extramural awards:

Director, Extramural Information Systems, OD/OER/OPERA, Rockledge II, Room 2172, Bethesda, MD 20892

For chartered Federal advisory committees of the National Institutes of Health:

NIH Committee Management Officer, Building 31, Room 3B-59, 31 Center Drive, Bethesda, MD 20892

For contracts:

Office of Contracts Management, 6100 Executive Boulevard, Room 6D01, Rockville, MD 20892

NOTIFICATION PROCEDURE:

To determine if a record exists, write to the System Manager listed above. The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Privacy Act, subject to a five thousand dollar fine.

RECORD ACCESS PROCEDURE:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the official under notification procedures above, and reasonably identify the record and specify the information to be contested, and state the corrective action sought and the reasons for the correction, with supporting justification. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Applicant institution, individual, individual's educational institution and references, and participating Federal acquisition personnel.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 98-16914 Filed 6-24-98; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Substance Abuse and Mental Health Services Administration****Grant Award to the Department of Community Medicine and Health Care, University of Connecticut**

AGENCY: Center for Substance Abuse Treatment (CSAT), Substance Abuse and Mental Health Services Administration (SAMHSA), HHS.

ACTION: Availability of grant funds for the Department of Community Medicine and Health Care, University of Connecticut.

SUMMARY: This notice is to inform the public that CSAT is making available approximately \$200,000 for an award in FY 1998 to the University of Connecticut Department of Community Medicine and Health Care to develop knowledge concerning the effectiveness of primary care referral and behavioral health treatment for alcohol dependence in managed care. Eligibility for this program is limited to the Department of Community Medicine and Health Care, University of Connecticut. Using Robert Wood Johnson funding, the University of Connecticut has already implemented an experimental design research program on the cost effectiveness of alcohol screening and brief intervention in six managed care settings. This cross-site study in managed care settings is unique in its design and scope. However, none of the study settings are testing the cost effectiveness of Motivational Enhancement Therapy (MET) vs. standard alcoholism treatment. SAMHSA/CSAT, by means of this relatively small investment in this existing University of Connecticut program, will be able to capitalize on this unique opportunity to test the cost effectiveness on different models of alcoholism treatment for primary care vs. non primary care referred patients in managed care settings within the context of the existing Robert Wood Johnson funded study protocol. It is for these reasons, and in order to obtain the benefits of the additional information for the affected provider communities, that only the University of Connecticut is invited to apply. The application will be considered for funding on the basis of its overall technical merit as

determined through the peer and CSAT National Advisory Council review processes.

Funding from CSAT will support supplemental evaluation activities in three Robert Wood Johnson supported screening and brief intervention (SBI) study sites. These sites will extend their current evaluation studies, to include the following: (1) implement data information systems to track patients who are referred by the primary care practices into treatment; (2) evaluate the cost effectiveness of primary care physician vs. primary care intervention specialist referrals for alcohol dependence and (3) evaluate the cost effectiveness of MET vs. standard treatment for alcohol dependent patients.

Authority: The award will be made under the authority of Section 501(d)(5) of the Public Health Service Act, as amended (42 U.S.C. 290aa). The Catalog of Federal Domestic Assistance (CFDA) number for this program is 93.230.

Contact: Dr. Mady Chalk, Director, Office of Managed Care, Center for Substance Abuse Treatment, SAMHSA, Rockwall II, 7th floor, 5600 Fishers Lane, Rockville, MD 20857, (301) 443-8796.

Dated: June 19, 1998.

Richard Kopanda,
Executive Officer, SAMHSA.

[FR Doc. 98-16932 Filed 6-24-98; 8:45 am]

BILLING CODE 4162-20-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Substance Abuse and Mental Health Services Administration (SAMHSA) Notice of Meetings**

Pursuant to Pub. L. 92-463, notice is hereby given of the following meetings of the SAMHSA Special Emphasis Panel I in July 1998.

Summaries of the meetings and rosters of the members may be obtained from: Ms. Dee Herman, Committee Management Liaison, SAMHSA, Office of Policy and Program Coordination, Division of Extramural Activities, Policy, and Review, 5600 Fishers Lane, Room 17-89, Rockville, Maryland 20857. Telephone: 301-443-7390.

Substantive program information may be obtained from the individuals named as Contact for the meetings listed below.

The meetings will include the review, discussion and evaluation of individual grant applications. These discussions could reveal personal information concerning individuals associated with the applications. Accordingly, these meetings are concerned with matters

exempt from mandatory disclosure in Title 5 U.S.C. 552b(c)(6) and 5 U.S.C. App.2, § 10(d).

Committee Name: SAMHSA Special Emphasis Panel I (SEP I).

Meeting Date: July 22, 1998.

Place: Hyatt Regency at Crystal City, 2799 Jefferson Davis Highway, Arlington, VA 22202.

Closed: July 22, 1998, 8:30 a.m.-10:00 a.m.

Panel: Center for Mental Health Services Minority Fellowship Program SM98-008.

Committee Name: SAMHSA Special Emphasis Panel I (SEP I).

Meeting Date: July 22, 1998.

Place: Hyatt Regency at Crystal City, 2799 Jefferson Davis Highway, Arlington, VA 22202.

Closed: July 22, 1998, 10:30 a.m.-12:00 p.m.

Panel: Center for Mental Health Services Cooperative Agreement for a Technical Assistance Center SM 98-011.

Contact: Kenneth D. Howard, 17-89, Parklawn Building, Telephone: 301-443-9919 and FAX: 301-443-3437.

Committee Name: SAMHSA Special Emphasis Panel I (SEP I).

Meeting Dates: July 27-30, 1998, 9:00 a.m.-5:00 p.m., July 31, 1998, 9:00 a.m.-adjournment

Place: Hyatt Regency at Crystal City, 2799 Jefferson Davis Highway, Arlington, VA 22202.

Closed: July 27-30, 1998, 9:00 a.m.-5:00 p.m., July 31, 1998, 9:00 a.m.-adjournment.

Panel: Statewide Consumer and Consumer Supporter Networking Grants SM 98-013.

Contact: Clark K. Lum, Room 17-89, Parklawn Building, Telephone 301-443-9919, FAX: 301-443-3437.

Dated: June 22, 1998.

Jeri Lipov,

Committee Management Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 98-16978 Filed 6-24-98; 8:45 am]

BILLING CODE 4162-20-P

DEPARTMENT OF THE INTERIOR**Fish and Wildlife Service****Notice of Receipt of Applications for Permit**

The following applicants have applied for a permit to conduct certain activities with endangered species. This notice is provided pursuant to Section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531, et seq.):