

gastrectomy, most will die from recurrent disease. Recently, there has been increasing interest in the use of neoadjuvant or primary chemotherapy, frequently using fluoropyrimidine-based combination chemotherapy, in an attempt to increase respectability and improve survival of patients with locally advanced gastric cancer. Neoadjuvant chemotherapeutic treatment provides an early opportunity to assess individual patient response using the in situ primary tumor. Overall response rates in studies using neoadjuvant 5-fluorouracil ("5-FU") based regimens in locally advanced gastric cancer range from 25–45%. Therefore, at least half of all patients treated in this setting are being subjected to unnecessary toxicity and delay in operation with no therapeutic benefit. Strategies that would accurately predict tumor responsiveness to 5-FU therapy would provide an opportunity to selectively treat patients most likely to benefit from treatment and avoid unnecessary toxicity in those who would not.

The '034 invention is directed to methods for determining whether a chemotherapeutic treatment is appropriate for patients afflicted with gastrointestinal cancers, comprising:

- a. Obtaining a solid tumor tissue sample from the patient;
- b. Measuring a thymidylate synthase expression level in the tissue sample; and
- c. Comparing the thymidylate synthase expression level with a group of standard tumor tissue samples, the standards having known thymidylate synthase expression levels and known responses to the chemotherapeutic treatment, to determine if the chemotherapeutic treatment is appropriate for the patient.

The above mentioned Invention is available, including any available foreign intellectual property rights, for licensing.

Dated: July 2, 1999.

**Jack Spiegel,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Program Support Center

#### Privacy Act of 1974; New System of Records

**AGENCY:** Program Support Center (PSC), HHS.

**ACTION:** Notification of a new system of records.

**SUMMARY:** In accordance with the requirements of the Privacy Act, the PSC is publishing a notice of a new system of records, 09-40-0013, "PSC Parking Program and PSC Transhare Program Records, HHS/PSC/AOS." We are also proposing routine uses for this new system.

**DATES:** The PSC invites interested parties to submit comments on the proposed internal and routine uses on or before August 18, 1999. The PSC has sent a Report of a New System to the Congress and to the Office of Management and Budget (OMB) on July 2, 1999. The new system of records will be effective 40 days from the date submitted to OMB unless PSC receives comments which would result in a contrary determination.

**ADDRESSES:** Address comments to the Privacy Act Officer, Program Support Center, 5600 Fishers Lane, Room 17A-08, Rockville, Maryland 20857. We will make comments received available for public inspection at the above address during normal business hours, 8:30 a.m.-5 p.m.

**FOR FURTHER INFORMATION CONTACT:** Irene West, Room 17A-08, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443-2045. This is not a toll-free number.

**SUPPLEMENTARY INFORMATION:** The Program Support Center (PSC) proposes to establish a new system of records: 09-40-0013, "PSC Parking Program and PSC Transhare Program Records, HHS/PSC/AOS." This system of records will be used by PSC staff to: (1) Administer the parking program at the Parklawn Building complex; (2) manage the PSC Transhare Program, including receipt and processing of employee applications, and coordination of the fare media distribution to employees; and (3) monitor the use of funds used to support the PSC Transhare Program.

The system will contain records that contain information such as participant's name; pay plan; grade level; employing organization; building and room; duty hours and location; name of supervisor; home address; office telephone number; assigned parking space number; vehicle

information, i.e., tag number and State; make and model of car; physician's statement in support of handicapped parking assignments and query to supervisors in support of handicapped parking assignments, where applicable; Transhare commuter card number; commute mode to work; and type of fare media used.

The amount of information recorded on each individual will be only that which is necessary to accomplish the purpose of the system. Each record is established from an application form that has been submitted to the Parking and Information Office, Building Management Branch, Division of Property Management, Administrative Operations Service, PSC, by the applicant.

**Authorities:** The Federal Property and Administrative Services Act of 1949, as amended; and, Pub. L. 101-509 section 629, as amended, (5 U.S.C. 7905, "Programs to encourage commuting by means other than single-occupancy motor vehicles").

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

The routine uses proposed for this system are compatible with the stated purposes of the system, i.e., to administer and manage the PSC Parking and Transhare Programs and to monitor the use of funds used to support the PSC Transhare Program.

The PSC will disclose relevant information to third parties outside the Department as follows: Routine use 1: PSC may disclose information from this system of records to city, county, State, and Federal law enforcement agencies should PSC become aware of evidence of a potential violation of civil or criminal law. Routine use 2: Disclosure may be made to a congressional office from the record of an individual upon the written request of the record subject to obtain assistance from his/her congressional representative. Individuals sometimes request the help of a Member of Congress in resolving some issue relating to a matter before HHS. The Member of Congress then writes HHS and HHS must be able to give sufficient information to be responsive to the inquiry. Routine use 3: Disclosure may be made to the Department of Justice, or to a court or other tribunal, in case of litigation where HHS determines that such disclosure is relevant and necessary and would help in the effective representation of the governmental party, provided, however, that in each case HHS determines that such disclosure is compatible with the purpose for which the records were

collected. Routine use 4: Disclosure may be made to a contractor for the purpose of collating, analyzing, aggregating or otherwise refining records in this system. HHS occasionally contracts out certain of its functions when this would contribute to effective and efficient operations. HHS must be able to give a contractor whatever information is necessary for the contractor to fulfill its duties. Routine use 5: Disclosure may be made to officials of labor organizations when relevant and necessary to their duties of exclusive representation concerning practices and matters affecting working conditions. Routine use 6: Disclosure may be made to organizations deemed qualified by the Secretary to carry out quality assessments or utilization review.

#### SAFEGUARDS:

The PSC has instituted extensive safeguards to protect both the automated and non-automated records. The PSC Systems Security Officer has certified that the safeguards for the system are commensurate with the sensitivity and criticality of the records. The system notice describes: (1) The safeguards that are in effect to ensure that only authorized users have access to the records; (2) the physical security measures used to protect the records; (3) the procedural safeguards to ensure data integrity and prevent unauthorized access and disclosure; and (4) security guidelines for contractors, as applicable.

The system notice is written in the present rather than future tense to avoid the unnecessary expenditure of public funds to republish the notice after the new system becomes effective.

Dated: July 2, 1999.

**Lynda M. Regan,**

*Director, Program Support Center.*

**09-40-0013**

#### SYSTEM NAME:

PSC Parking Program and PSC Transshare Program Records, HHS/PSC/AOS.

#### SECURITY CLASSIFICATION:

None.

#### SYSTEM LOCATION:

Division of Property Management, Administrative Operations Service, Program Support Center, Room 5B-07, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

#### CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Current HHS employees and others who use Parklawn Building parking facilities; HHS employees who apply for

and participate in the PSC Transshare Program.

#### CATEGORIES OF RECORDS IN THE SYSTEM:

This system contains records relating to the administration of the parking permit system and the PSC Transshare Program for the Parklawn Building complex. The records include information such as name; pay plan; grade level; employing organization; building and room; duty hours and location; name of supervisor; home address; office telephone number; assigned parking space number; vehicle information, i.e., tag number and State; make and model of car; physician's statement in support of handicapped parking assignments and query to supervisors in support of handicapped parking assignments, where applicable; Transshare commuter card number, commute mode to work; and type of fare media used.

#### AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The Federal Property and Administrative Services Act of 1949, as amended; and, Pub. L. 101-509 section 629, as amended, (5 U.S.C. 7905, "Programs to encourage commuting by means other than single-occupancy motor vehicles").

#### PURPOSE(S):

These records are used to:

1. Administer the parking program at the Parklawn Building complex.
2. Manage the PSC Transshare Program, including receipt and processing of employee applications, and coordination of the fare media distribution to employees.
3. Monitor the use of funds used to support the PSC Transshare Program.

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

These records or information from these records may be used:

1. To disclose pertinent information to appropriate city, county, State and Federal law enforcement agencies responsible for investigating, prosecuting, enforcing, or implementing statutes, rules, regulations or orders, when HHS becomes aware of evidence of a potential violation of civil or criminal law.
2. To disclose information to a congressional office from the record of an individual in response to a verified inquiry from that congressional office made at the written request of that individual.
3. To disclose information to the Department of Justice, a court or other tribunal, when: (a) HHS, or any component thereof; or (b) any HHS

employee in his or her official capacity; or (c) any HHS employee in his or her individual capacity where the Department of Justice (or HHS where it is authorized to do so) has agreed to represent the employee; or (d) The United States or any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation or has interest in such litigation, and HHS determines that the use of such records by the Department of Justice, the court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however, that in each case HHS determines that such disclosure is compatible with the purpose for which the records are collected.

4. When HHS contemplates contracting with a private firm for the purpose of collating, analyzing, aggregating, or otherwise refining records in this system, relevant records will be disclosed to such a contractor. The contractor will be required to maintain Privacy Act safeguards with respect to such records. These safeguards are explained in the section entitled "Safeguards."

5. To disclose information to officials of labor organizations recognized under 5 U.S.C. Chapter 71 when relevant and necessary to their duties of exclusive representation, concerning personnel policies, practices, and matters affecting working conditions.

6. Disclosure may be made to organizations deemed qualified by the Secretary to carry out quality assessments or utilization review.

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

##### STORAGE:

These records are maintained in file folders, cabinets, on disks and in an automated data base.

##### RETRIEVABILITY:

These records are retrieved by the name, parking space number, permit number, address, vehicle information and PSC Transshare commuter card number of the individuals on whom they are maintained.

##### SAFEGUARDS:

1. *Authorized Users:* Data on computer files is accessed by authorized users who are PSC employees and who are responsible for implementing the program.

2. *Physical Safeguards:* Rooms where records are stored are locked when not in use. During regular business hours,

rooms are unlocked but are controlled by on-site personnel.

### 3. *Procedural and Technical*

**Safeguards:** A password is required to access the terminal, and a data set name controls the release of data to only authorized users. All users of personal information in connection with the performance of their jobs (see Authorized Users above) protect information from public view and from unauthorized personnel entering an unsupervised office.

4. **Contractor Guidelines.** A contractor who is given records under routine use 4 must maintain the records in a secured area, allow only those individuals immediately involved in the processing of the records to have access to them, prevent unauthorized persons from gaining access to the records, and return the records to the System Manager immediately upon completion of the work specified in the contract. Contractor compliance is assured through inclusion of Privacy Act requirements in contract clauses, and through monitoring by contract and project officers. Contractors who maintain records are instructed to make no disclosure of the records except as authorized by the System Manager and as stated in the contract.

### RETENTION AND DISPOSAL:

Parking records are maintained for varying periods of time, in accordance with NARA General Records Schedule 11 (parking permits). Disposal of manual records is by shredding; electronic data is erased.

PSC Transhare records are retained for a maximum of two years following the last month of an employee's participation in the PSC Transhare Program. Paper copies are destroyed by shredding. Computer files are destroyed by deleting the record from the file.

### SYSTEM MANAGER(S) AND ADDRESS:

Office Manager, Parking and Information Office, Building Management Branch, Division of Property Management, Administrative Operations Service, PSC, Room 5B-07, 5600 Fishers Lane, Rockville, MD 20857.

### NOTIFICATION PROCEDURES:

Same as Access Procedures. The requester is required to specify reasonably the contents of the records being sought.

### RECORD ACCESS PROCEDURES:

To determine whether information about themselves is contained in this system, the subject individual should contact the System Manager at the above

address. 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. Individuals must provide the following information for their records to be located and identified: (a) Full name, (b) parking space number (if appropriate); (c) vehicle license number (if appropriate) and (d) for the PSC Transhare Program, the requester must provide the commuter card number and the dates of participation in the Program. The requester must also understand that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense subject to a fine. An individual who is the subject of records maintained in this records system may also request an accounting of disclosures that have been made of his or her records.

Requests by telephone: Since positive identification of the caller cannot be established, telephone requests are not honored.

### CONTESTING RECORD PROCEDURES:

Contact the System Manager specified above and reasonably identify the record, specify the information to be contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant.

### RECORD SOURCE CATEGORIES:

Records are developed from information supplied by applicants and, for handicapped parking assignments, by physicians and supervisors.

### SYSTEM(S) EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Public Health Service

#### Nation Toxicology Program; Meeting

National Toxicology Program Public Meeting to receive comment on the review procedures and listing criteria used in the preparation of the DHHS Report on Carcinogens (RoC); September 15, 1999, Ronald Reagan Building, The International Trade Center, 1300 Pennsylvania Avenue, NW., Horizon Room, Washington, DC, beginning at 9 a.m.

The National Toxicology Program announces a public meeting for the purpose of reviewing nominations for listing in or delisting from the RoC and the current listing criteria used for evaluation of the nominations to the RoC. The purpose of this public meeting is to obtain input and to provide all interested parties an opportunity to express their views about the review process and/or the evaluation criteria and to comment on the views expressed by others.

The meeting will begin at 9 a.m. and will conclude at 5 p.m. or at the conclusion of the public comment and discussion, if sooner. On-site registration will begin at 8:30 a.m. Details regarding registration follow. Attendance at the meeting is limited only by the space available.

### Background

The DHHS Report on Carcinogens (RoC) is a public information document prepared for the U.S. Congress by the National Toxicology Program in response to Section 301(b)(4) of the Public Health Service Act, as amended. The intent of the document is to provide a listing of those agents, substances or exposure circumstances which are either "known" or "reasonably anticipated" to cause cancer in humans, and to which a significant number of people in the United States are exposed. The first edition of the report (then known as the Annual Report on Carcinogens) was published in 1980, and similar criteria and review processes were used to consider nominated substances for listing through preparation of the 7th edition published in 1994. In 1994 Dr. Ken Olden, Director of NTP and NIEHS established an ad hoc working group of the NTP Board of Scientific Counselors and charged them to review and make recommendations on two issues: the adequacy of the existing criteria and the incorporation of mechanistic data as part of the criteria for listing substances in future Reports. In addition Dr. Olden directed that the process used to review nominations for listing in or delisting from the Report be revised to allow more public input throughout the process and to add external review to broaden the scope of scientific review. As a consequence, in 1994 and 1995 the criteria were examined by a panel whose membership included academia, industry, labor, public/environmental organizations, state and local health departments and government who met in public session in public meetings. Recommendations were made for revising the listing criteria and the nomination review process which were