Rockville Pike, Rockville, MD 20852–1448, 301–827–0379.

**SUPPLEMENTARY INFORMATION:** FDA regulations in part 312 (21 CFR part 312) provide procedures that govern the use of investigational new drugs and biologics in human subjects. If FDA determines that a proposed or ongoing study may pose significant risks for human subjects or is otherwise seriously deficient, as discussed in the investigational new drug regulations, it may order a clinical hold on the study. The clinical hold is one of FDA's primary mechanisms for protecting subjects who are involved in investigational new drug or biologic trials. Section 312.42 describes the grounds for ordering a clinical hold.

A clinical hold is an order that FDA issues to a sponsor to delay a proposed investigation or to suspend an ongoing investigation. The clinical hold may be ordered on one or more of the investigations covered by an investigational new drug application (IND). When a proposed study is placed on clinical hold, subjects may not be given the investigational drug or biologic as part of that study. When an ongoing study is placed on clinical hold, no new subjects may be recruited to the study and placed on the investigational drug or biologic, and patients already in the study should stop receiving therapy involving the investigational drug or biologic unless FDA specifically permits it.

When FDA concludes that there is a deficiency in a proposed or ongoing clinical trial that may be grounds for ordering a clinical hold, ordinarily FDA will attempt to resolve the matter through informal discussions with the sponsor. If that attempt is unsuccessful, a clinical hold may be ordered by or on behalf of the director of the division that is responsible for the review of the IND.

FDA regulations in § 312.48 provide dispute resolution mechanisms through which sponsors may request reconsideration of clinical hold orders. The regulations encourage the sponsor to attempt to resolve disputes directly with the review staff responsible for the review of the IND. If necessary, the sponsor may request a meeting with the review staff and management to discuss the clinical hold.

CBER began a process to evaluate the consistency and fairness of practices in ordering clinical holds by instituting an oversight committee to review clinical holds (see 61 FR 1031 at 1033, January 11, 1996). CBER held its first clinical hold oversight committee meeting on May 17, 1995, and plans to conduct further quality assurance oversight of the IND process. The review procedure of the committee is designed to afford an opportunity for a sponsor who does not wish to seek formal reconsideration of a pending clinical hold to have that clinical hold considered ''anonymously.'' The committee consists of senior managers of CBER, a senior official from the Center for Drug Evaluation and Research, and the FDA Chief Mediator and Ombudsman.

Clinical holds to be reviewed will be chosen randomly. In addition, the committee will review clinical holds proposed for review by biological product sponsors. In general, a biological product sponsor should consider requesting the review when it disagrees with FDA's scientific or procedural basis for the decision.

Requests for committee review of a clinical hold should be submitted to the FDA Chief Mediator and Ombudsman, who is responsible for selecting clinical holds for review. The committee and CBER staff, with the exception of the FDA Chief Mediator and Ombudsman, are never advised, either in the review process or thereafter, which of the clinical holds were randomly chosen and which were submitted by sponsors. The committee will evaluate the selected clinical holds for scientific content and consistency with FDA regulations and CBER policy.

The meetings of the oversight committee are closed to the public because committee discussions deal with confidential commercial information. Summaries of the committee deliberations, excluding confidential commercial information, may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. If the status of a clinical hold changes following the committee's review, the appropriate division will notify the sponsor.

For each meeting, FDA invites biological product companies to submit to the FDA Chief Mediator and Ombudsman the name and IND number of any investigational biological product trial that was placed on clinical hold during the past 12 months that they want the committee to review. Submissions should be made by July 1, 1997, for the August meeting, and by October 1, 1997, for the November meeting to Amanda Bryce Norton, FDA Chief Mediator and Ombudsman (address above).

Dated: May 28, 1997.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 97–14684 Filed 6–4–97; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Submission for OMB Review; Comment Request, Alcoholism Prevalence and Gene/Environment Interactions in Native American Tribes (a 10 Tribe Study)

**SUMMARY:** Under the provisions of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the National Institute on Alcohol Abuse and Alcoholism (NIAAA), National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously in the **Federal Register** on July 1, 1996, and allowed 60 days for public comment. There were no requests for additional information about this data collection activity, no public comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

The NIH may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after June 30, 1999, unless it displays a currently valid OMB control number.

**Proposed Collection**

*Title:* Alcoholism Prevalence and Gene/Environment Interactions in Native American Tribes (a 10 tribe study). *Type of Information Collection request:* New. *Need and Use of Information Collection:* The information proposed for collection in this study will be used by the NIAAA to define the prevalence in alcoholism and associated problems in tribes in which the rates of alcoholism have been reported to be widely divergent. Additional information will be collected on severe trauma and stress, alcohol availability and socioeconomic factors to identify how these variables interact with hereditary factors in the development of alcoholism and related problems.

*Frequency of Response:* On Occasion. *Affected Public:* Individuals. *Type of Respondents:* Native American adults. *Estimated Number of Respondents:* 1000. *Estimated Number of Responses per Respondent:* 1. *Average Burden*

*Hours per Response:* 6. *And Estimated total Annual Burden Hours Requested:* 6000. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

The annual burden estimates are as follows:

| Type and number of respondents | Responses per respondent | Total responses | Hours | Total hours |
|---|---|---|---|---|
| Clients—1000 | 1 | 1000 | 6.0 | 6000 |

Total Number of Respondents—3000 (1000 per year)

Total Number of Responses—3000 (1000 per year)

Totals Hours—18000 (6000 per year)

**Request For Comments**

Comments are invited on: (a) Whether the proposed collection is necessary, including whether the information has practical use; (b) ways to enhance the clarity, quality, and use of the information to be collected; (c) the accuracy of the agency estimate of burden of the proposed collection; and (d) ways to minimize the collection burden of the respondents. Send written comments to Ms. Ronni Nelson, Laboratory of Neurogenetics, Division of Intramural Clinical and Biological Research, NIAAA, NIH, DANAC4 (Flow Labs), 12501 Washington Ave., Rockville, Maryland 20852.

**Direct Comments to OMB**

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time should be directed to the Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH.

**FOR FURTHER INFORMATION:** To request more information on the proposed project or to obtain a copy of the data collection plans, contact Ms. Ronni Nelson, Laboratory of Nuerogenetics, Division of Division of Intramural Clinical and Biological Research (DICBR), NIAAA, DANAC4 (Flow Labs), 12501 Washington Ave., Rockville, Maryland 20852, or call non-toll-free number (301) 443–5781.

**COMMENTS DUE DATE:** Comments regarding this information collection are best assured of having their full effect if received on or before July 7, 1997.

Dated: May 21, 1997.

**Martin K. Trusty,**

*Executive Officer, NIAAA.*

[FR Doc. 97–14714 Filed 6–4–97; 8:45 am]

BILLING CODE 4140–01–M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Cancer Institute; Call for Nominations for the National Cancer Institute Director's Consumer Liaison Group

The National Cancer Institute (NCI), the Federal Government's primary agency for cancer research, is launching a new initiative—the Director's Consumer Liaison Group (DCLG). Notice is hereby given that the NCI is accepting nominations for membership on the DCLG. This group will help the NCI to increase the representation of the cancer advocacy community on Institute advisory committees, and increase their involvement in program and policy development. The DCLG will consist of fifteen (15) consumer-advocates who are involved in cancer advocacy. The NCI will bring together these advocates from diverse communities, creating a two-way street that enables them to interact directly with the scientific community at the NCI on a wide range of programs and issues. The DCLG will also help the NCI to widen the pool of qualified consumer-advocates who can be called upon to serve on NCI advisory committees and other groups. Specifically the DCLG will meet several times a year to:

- Help develop and establish processes, mechanisms, and criteria for identifying appropriate consumer-advocates to serve on a variety of program and policy advisory committees responsible for advancing the mission of the NCI.
- Serve as a primary forum for discussing issues and concerns and exchanging viewpoints that are important to the broad development of the NCI programmatic and research priorities.
- Establish and maintain strong collaborations between the NCI and the cancer advocacy community to reach common goals.

The DCLG will provide advice and make recommendations to the Advisory Committee to the Director, NCI. Members of the first DCLG will serve one, two, or three year terms. In subsequent years, members will serve three year terms.

*Eligibility Requirements for Individual Members.* To serve on the DCLG, a member must meet the following minimum eligibility requirements:

- Be involved in the cancer experience as a cancer survivor, a person affected by the suffering and consequences of cancer, or a professional or volunteer who works with survivors or those affected.
- Represent a constituency (formally or informally) with which she or he communicates regularly on cancer issues and be able to serve as a conduit for information both to and from his/her constituency.

Another essential requirement is a commitment to participating in the DCLG. This will not be used in the initial screening of nominees, but will be assessed as part of a more in-depth evaluation of qualified candidates.

*Criteria for Evaluating Individual Candidates.* Nominees who meet the minimum eligibility requirements will be further assessed based on the following criteria:

- Cancer advocacy experience.
- Ability to communicate effectively.
- Ability to represent broad issues, think ''globally.''
- Ability to contribute to an effective group process (e.g., cooperative, constructive, flexible, innovative).
- Leadership ability. (While members of the DCLG are not required to hold a formal leadership position within a cancer advocacy organization, they must have leadership skills.)

*Characteristics of the DCLG.* In addition to the criteria for individual candidates, the following characteristics of the DCLG as a group are intended to ensure that it reflects the breadth and diversity of the consumer advocacy community:

- Multicultural diversity.
- A broad mix of cancer sites.
- Representation of the medically underserved.
- Men and women.
- A range of organizations (local/regional and national).
- Age diversity.
- Geographic diversity (rural/urban mix).