Public Health Service

National Institutes of Health; Proposed Data Collection; Comment Request; Validation of a New Food Frequency Questionnaire

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the National Institutes of Health (NIH), National Cancer Institute (NCI) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: Validation of a New Frequency Questionnaire.

Type of Information Collection Request: New.

Need and use of Information Collection: The agency conducts and funds studies examining the relationship between diet and chronic diseases. This information collection is needed to validate and further refine a new diet history questionnaire to be used in studies of diet and disease. The new questionnaire will be validated against reference data from four non-consecutive 24-hour dietary recalls among a national sample of persons 20–70 years of age. The validity of the new questionnaire will be compared to two widely-used food frequency questionnaires. As a further validation, biological nutrition measures from blood specimens will be obtained from a 20% sub-sample of participants.

Frequency of response: One-time study.

Affected public: Individuals or households.

Types of Respondents: U.S. adults 20–70 years of age. The annual reporting burden is as follows:

Data collection form	Estimated number of respondents	Estimated number of responses per respondent	Avg. burden hours per response	Estimated total hour burden	Estimated total annual burden hours requested
Screener	2700	1	0.167	450.9	300.6
Recalls interview #1	1620	1	0.75	1215.0	810.0
Recall interview #2	1563	1	0.5	781.5	521.0
Recall interview #3	1507	1	0.5	753.5	502.3
Recall interview #4	1451	1	0.5	725.5	483.7
New Questionnaire	1225	1	0.75	918.8	612.5
Food Questionnaire 1	612	1	0.5	306.0	204.0
Food Questionnaire 2	612	1	0.668	408.8	272.5
Opinion form	1225	1	0.167	204.6	136.4
Blood substudy	240	2	0.25	120.0	80.0
Total	2700	.....	.....	5884.6	3923.0

REQUEST FOR COMMENTS: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proposed performance of the functions of the agency, including whether the information shall have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Amy F. Subar, Ph.D., Project Officer, National Cancer Institute, EPN, 313, 6130 Executive Blvd MSC 7344, Bethesda, MD 20892–7344, or call non-toll-free number (301) 496–8500, or FAX your request to (301) 435–3710, or E-mail your request, including your address, to subara@dcpceps.nci.nih.gov.

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received on or before February 24, 1997.

Dated: December 13, 1996.

Nancie L. Bliss,

OMB Project Clearance Liaison.

[FR Doc. 96–32582 Filed 12–23–96; 8:45 am]

BILLING CODE 4140–01–M

National Institutes of Health

Submission for OMB Review; Comment Request; Evaluation of NIH Implementation of Section 491 of the Public Health Service Act, Mandating a Program of Protection for Research Subjects

SUMMARY: Under the provisions of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH), Office of the Director (OD) 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 published in the Federal Register on October 10, 1996, page 53228–53229 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

The National Institutes of Health 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 October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection

Title: Evaluation of NIH Implementation of Section 491 of the Public Health Service Act, Mandating a Program of Protection for Research Subjects.

Type of Information Collection Request: Extension of OMB No. 0925–0404, expiration 12/31/96.

Need and Use of Information Collection: This study will assess the performance of the system of human subjects protections. It will provide up-to-date comprehensive and systematic information on the effectiveness and efficiency of procedural protections by measuring outcome, output, process, and resources of the current system to

develop possible recommendations. The study will use survey, interview, and record extraction methodologies. Development of the survey instruments and methodology has involved representatives of the affected public over the past 2 years.

Frequency of Response: One-time.

Affected Public: Individuals or households; Not-for-Profit Institutions; State, Local, or Tribal Government.

Type of Respondents: University officials, staff, and faculty.

The annual reporting burden is as follows:

Estimated Number of Respondents: 2,358.

Estimated Number of Responses per Respondent: 1.

Average Burden per Response: 0.485 hours.

Estimated Total Annual Burden Hours Requested: 1,145. The annualized cost to respondents is estimated at: $55,125. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Request for Comments

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points. (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

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, D.C. 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Charles R. MacKay, Project Clearance Officer, Office of Policy for Extramural Research Administration, Office of Extramural Research, Office of the Director, NIH, Rockledge II, 6701 Rockledge Drive, MSC 7730, Room 2196, Bethesda, MD 20892–7730, or call nontoll-free number (301) 435–0978 or E-Mail your request, including your address to: cm13f@nih.gov.

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received on or before January 23, 1997.

Dated: December 17, 1996.

Geoffrey E. Grant,

Director, Office of Policy for Extramural Research Administration.

[FR Doc. 96–32583 Filed 12–23–96; 8:45 am]

BILLING CODE 4140–01–M

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health.

ACTION: Notice.

The invention listed below is owned by an agency of the U.S. Government and is available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for U.S. companies and may also be available for licensing.

ADDRESSES: Licensing information and a copy of the U.S. patent application patent referenced below may be obtained by contacting David Sadowski at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804 (telephone 301/496–7735 ext 288; fax 301/402–0220). A signed Confidential Disclosure Agreement will be required to receive a copy of the patent application.

Container for Drying Biological Samples, Method of Making Such Container, and Method of Using Same

Kidd, G.L. (NEI)
Filed 20 Sep 96 (claiming priority date of 22 Sep 95)
Serial No. 08/717,114

Problem Addressed By This Invention: Many compounds, such as drugs, growth factors, etc., must be kept sterile and must be aliquotted for storage. Usually, these aliquots are best stored lyophilized. Yet, researchers have never had a way to keep aliquots sterile through the lyophilization process. Consequently, each aliquot has had to be filter-sterilized when reconstituted for use. This process has the disadvantages of consuming excessive filters, syringes, sterile, receptacles, and time and results in serious loss of precious sample due to absorption by the filters (especially with small aliquots less than 1 ml). Alternatively, researchers have had to forego lyophilization and store their solutions in the less-stable frozen form.

Solution Offered By This Invention: Sterile-lyophilization tubes having a 0.22 micron filter built into the cap. This unique feature allows a sterile solution to remain sterile throughout lyophilization, even after the vacuum is released and air reenters the tube. Thus, a starting solution is simply filter-sterilized while in a relatively large volume, using a single filter and therefore suffering minimal loss and consuming little time. It is then aliquotted into sterile-lyophilization tubes and lyophilized. The tubes can then be transferred directly to the freezer, if desired. The compound is reconstituted when needed, and may then be used immediately without further filtration.

Potential Applications Of This Invention: All researchers worldwide who utilize sterile, labile compounds will have an interest in this product, including governmental, university, institutional, and drug company laboratories. Most notably in need are investigators involved in drug-testing, which is normally done either in cell cultures, laboratory animals, or humans, and which requires sterility of many aliquots of many drugs. Additionally, this product will have a large market relating to basic research utilizing microbial, plant, or animal cell or organ cultures, to which sterile compounds such as growth factors are commonly added. Research in drugs, growth factors, etc., is expanding ever more rapidly, and generally requires a cell culture system in which to study such compounds. Most of these compounds are quite expensive. Loss of potency during storage and loss of material during filtration are widespread problems which may be overcome with this invention. Therefore, there exists a tremendous need, and immense market for, this sterile-lyophilization vessel.

Stage of Development: Development is complete and invention has been successfully tested. Prototypes are available.

Dated: November 26, 1996.

Barbara M. McGarey,

Deputy Director, Office of Technology Transfer.

[FR Doc. 96–32580 Filed 12–23–96; 8:45 am]

BILLING CODE 4140–01–M