

simple way to measure dust mite allergens on a regular basis. The primary objective of this study is to determine if use of in-home test kits results in decreased dust mite allergen levels in home of children sensitive or allergic to dust mites. A secondary objective is to determine if use of in-home test kits result in additidual and behavioral changes related to implementing and maintaining dust mite reduction strategies. This study is a randomized intervention trial designed to test the efficacy of an in-home test kit in influencing behaviors to reduce dust mite allergen levels. Households will be recruited through flyers and will be screened for eligibility through a recruitment call line and a home visit to determine baseline dust mite levels in the household. Study participants will

be randomly assigned to a treatment or control group. The treatment group will receive educational materials and an in-home test kit at set intervals, while the control group will receive educational materials alone. Vacuumed dust samples will be collected and delivered to the NIEHS laboratory for ELISA-based measurements of the dust mite allergens Der f2 and Der p 2. A questionnaire will be used to collect information on home characteristics and on dust mite reduction attitudes and behaviors. Data will be collected at baseline, 6 months and 12 months. The results from this study will be used by NIEHS to plan future primary and secondary asthma prevention trials. *Frequency of Response:* After the two stages of eligibility screening, data will be collected at baseline, 6-months, and 12-

months. *Type of Respondents:* Parents of children with dust-mite allergies. The annual reporting burden is as follows: *Estimated Number of Respondents:* See table below; *Estimated Number of Responses per Respondent:* See table below; *Average Burden Hours Per Response:* 0.25 hour for initial screening, 0.5 hour for dust mite eligibility screening, 1.5 hours for each baseline visit, and 1 hour for each follow-up home visit (6- and 12-month); and *Estimated Total Annual Burden Hours Requested:* 690.5. The annualized cost to respondents is estimated at: \$13,810 (assuming \$20 hourly wage × 690.5 hours). There are no Capital Costs, Operating Costs and/or Maintenance Costs to report.

CALCULATION FOR DATA BURDEN OF DUST MITE ALLERGEN REDUCTION STUDY

Type of data collection	Number of respondents	Hours per response	Total hours
Eligibility Screening	450	0.25	112.5
Dust Mite Level Eligibility Screening	280	0.5	140.0
Baseline Visit	144	1.5	216.0
6-month follow-up	122	1.0	122.0
12-month follow-up	100	1.0	100.0
Total hours			690.5

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, DC 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. Darryl Zeldin, NIEHS, Laboratory of Pulmonary Pathobiology, P.O. Box 12233, Research Triangle Park, NC 27709 or call non-toll-free number (919) 541-1169 or e-mail your request, including your address to dz20a@niehs.nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: January 11, 2006.

Richard A. Freed,
Associate Director for Management, NIEHS,
National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health/National Institute of Environmental Health Sciences

Proposed Collection; Comment Request; Environmental Factors in the Development of Polycystic Ovary Syndrome

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 Institute of Environmental Health Sciences (NIEHS), the National Institutes of Health (NIH) 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: Environmental Factors in the Development of Polycystic Ovary Syndrome. *Type of Information Collection Request:* Revision of OMB No. 0925-0483 and expiration date 3/31/2006. *Need and Use of Information Collection:* The purpose of this study is to identify a cohort of living female twin pairs in which at least one member is

likely to have Polycystic Ovary Syndrome (PCOS) for future study. Potential participants (~3,700) will come from the Mid-Atlantic Twin Registry (MATR) and were chosen based on their answers to several questions (in a preliminary MATR survey) concerning irregular periods and a history of cystic ovaries. The instrument to be used here will be administered by telephone by professional interviewers at the MATR. It contains 17 simple and direct questions and will take about 10 minutes to complete. Its contents deal with the frequency of menstrual periods, a history of polycystic ovaries, obesity, excess facial hair and other evidence of hyperandrogenism. Since this is such a short telephone survey, participants will receive no prior notification. Informed consent will be asked for verbally over the phone at the time of the interview. All participants will be asked about their willingness to participate in future studies if their answers meet certain criteria. The major objectives of future studies using this cohort are to determine more reliable concordance rates for PCOS in monozygotic and dizygotic twins, establish baseline heritability estimates, and develop hypotheses concerning possible pathogenetic and/or environmental factors. The findings from this study will aid in developing:

(1) Genetic tests to identify high risk women; (2) preventative strategies; and (3) more effective therapies for PCOS and related syndromes such as type 2 diabetes, obesity, idiopathic hyperandrogenism, and male pattern baldness. *Frequency of Response:* One time. *Affected Public:* Individuals or households. *Type of Respondents:* Adult women. The annual reporting burden is as follows: *Estimated Number of Respondents:* 3,700; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours Per Response:* 0.167; and *Estimated Total Annual Burden Hours Requested:* 206 per year for 3 years. The annualized cost to respondents is estimated at \$6,179.00. 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.

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 Dr. Patricia C. Chulada, Health Scientist Administrator, Program in Clinical Research, NIEHS, P.O. Box 12233, Research Triangle Park, NC 27709 or call non-toll-free number (919) 541-7736 or e-mail your request, including your address to: chulada@niehs.nih.gov.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: January 11, 2006.

Richard A. Freed,

Associate Director for Management, NIEHS, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Survey of Non-Federal Funding Sources for Cancer CAM Research

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 Cancer Institute (NCI), the

National Institutes of Health (NIH) 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: Survey of Non-Federal Funding Sources for Cancer Complementary and Alternative Medicine (CAM) Research. *Type of Information Collection Request:* NEW.

Need and Use of Information Collection: The goal of this study is to collect information that will allow the NCI Office of Cancer Complementary and Alternative Medicine (OCCAM) to develop a directory of organizations external to the Federal Government that offer funding for cancer CAM research. This study will assist OCCAM in its mission to increase the quality of cancer CAM research supported by the NCI. One of the hurdles that many cancer CAM researchers encounter is the difficulty of obtaining research funding—and in particular, the difficulty of obtaining Federal funding for foundational or exploratory research. Often, researchers must obtain their initial funding through non-Federal sources, so that they can demonstrate proof of concept, which can be a precondition of obtaining Federal funds. The funding directory that is developed through this study will provide cancer CAM researchers with a resource that they can use to identify non-Federal funding sources, and target the funding sources that are most closely aligned with their research objectives.

Frequency of Response: Semiannual.

Affected Public: Nonprofit organizations; Businesses or other for-profit organizations; *Type of Respondents:* Organizations (other than Federal Government) that offer funding for cancer CAM research and have an open grant application process. The annual reporting burden is as follows: *Estimated Number of Respondents:* 200; *Estimated Number of Responses per Respondent:* 2 per year; *Average Burden Hours Per Response:* .25; and *Estimated Total Annual Burden Hours Requested:* 100. The annualized cost to respondents is estimated at: \$2000 (assumes \$20 hourly rate × 100 hours). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent (annual estimate)	Average burden hours per response	Estimated total annual burden hours requested
Nonprofit organizations	150	2	.25	75
Businesses or other for-profit organizations	50	2	.25	25