

Dated: March 17, 2010.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Evaluation of the State Early Childhood Comprehensive Systems Grant (ECCS) Program: New

HRSA's Maternal and Child Health Bureau (MCHB) is conducting an assessment of MCHB's State Early Childhood Comprehensive Systems Grant (ECCS) Program. The purpose of the ECCS Program is to assist States and

Territories in their efforts to build and implement statewide Early Childhood Comprehensive Systems that support families and communities in their development of children that are healthy and ready to learn at school entry. These systems must be multi-agency and be comprised of the key public and private agencies that provide services and resources to support families and communities in providing for the healthy physical, social, and emotional development of all young children. Grantees are also charged with addressing seven key elements of early childhood comprehensive systems: (1) Governance, (2) financing, (3) communications, (4) family leadership development, (5) provider/practitioner support, (6) standards, and (7) monitoring/accountability. ECCS funding is offered to 52 States and Jurisdictions.

An evaluation will be conducted to: (1) Identify and analyze the strategies that grantees and partners are using to build comprehensive early childhood systems, (2) measure the level of progress grantees have made in meeting both the overarching Federal goals and objectives for ECCS grantees and those of their statewide plans, and (3) assess the effectiveness of grantees' early childhood systems development activities. The information from the evaluation will supplement and enhance MCHB's current data collection efforts by providing a quantifiable, standardized, systematic mechanism for collecting information across the funded implementation grantees. The results

will also provide MCHB with timely feedback on the achievements of the ECCS Program and identify potential areas for improvement which will inform program planning and operational decisions.

Data collection tools for which OMB approval is being requested include Web-based surveys, telephone interviews, and a Web-based indicator reporting system. Web-based surveys are intended to collect information from all grantees regarding the structure and functioning of the State Team, the nature of activities, and perceptions of progress made in achieving outcomes. One survey will be directed at ECCS Coordinators while a second similar, but shorter survey will be directed at selected State Team members (5 State Team members from each State). The telephone interviews will be conducted with ECCS Coordinators to collect more detailed information on how early childhood services have been integrated, challenges and successes of implementation, and how the activities are designed to improve the lives of children and families. ECCS Coordinators will also be asked to enter information on three early child and family outcome indicators and provide a theory of change, or rationale, on how a specific ECCS activity or set of related activities will produce a measurable change in each outcome indicator.

Respondents: ECCS Coordinators and State Team members from the 52 grantees will be the primary respondents for the instruments. The estimated response burden is as follows:

ESTIMATE ANNUALIZED BURDEN TABLE

Forms	Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Web-based Survey	ECCS Coordinators	52	1	0.75	39
Web-based Survey	State Team Members	260	1	0.3	78
Telephone Interview	ECCS Coordinators	52	1	1.75	91
Indicator Reporting System	ECCS Coordinators	52	1	1.5	78
Total	416	286

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by e-mail to OIRA submission@omb.eop.gov or by fax to 202-395-6974. Please direct all correspondence to the "attention of the desk officer for HRSA."

Dated: March 15, 2010.

Sahira Rafiullah,

Director, Division of Policy and Information and Coordination.

[FR Doc. 2010-6437 Filed 3-23-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Revision to Proposed Collection; Comment Request; the National Children's Study, Vanguard (Pilot) Study

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 Child Health and Human Development (NICHD), 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: The National Children's Study, Vanguard (Pilot) Study

Type of Information Collection

Request: Revision

Need and Use of Information

Collection: The purpose of the proposed methodological study is to evaluate the feasibility, acceptability, and cost of three separate recruitment strategies for enrollment of pregnant women into a prospective, national longitudinal study of child health and development. This study is one component of a larger group of studies being conducted during the Vanguard Phase of the National Children's Study (NCS). In combination, these studies will be used to inform the design of the Main Study of the National Children's Study.

Background: The National Children's Study is a prospective, national longitudinal study of the interaction between environment, genetics on child health and development. The Study defines "environment" broadly, taking a number of natural and man-made environmental, biological, genetic, and psychosocial factors into account. By studying children through their different phases of growth and development, researchers will be better able to understand the role these factors have on health and disease. Findings from the Study will be made available as the research progresses, making potential benefits known to the public as soon as possible. The National Children's Study is led by a consortium of federal partners: the U.S. Department of Health and Human Services (including the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the National Institute of Environmental Health Sciences of the National Institutes of Health and the Centers for Disease Control and Prevention), and the U.S. Environmental Protection Agency.

To conduct the detailed preparation needed for a study of this size and complexity, the NCS was designed to include a preliminary pilot study known as the Vanguard Study. The purpose of the Vanguard Study is to assess the feasibility, acceptability, and cost of the recruitment strategy, study procedures, and outcome assessments that are to be used in the NCS Main

Study. The Vanguard Study begins prior to the NCS Main Study and will run in parallel with the Main Study. At every phase of the NCS, the multiple methodological studies conducted during the Vanguard phase will inform the implementation and analysis plan for the Main Study.

The Vanguard Study was designed to enroll approximately 1,750 pregnant women through seven study locations after 12 months of data collection. Two of the locations began recruitment in January 2009 and the remaining 5 in April 2009. As of March 2010, however, approximately 700 pregnant women have been enrolled, leading to questions about the assumptions underlying the Vanguard Study recruitment model.

Under this proposed plan, additional sites will be added to the Vanguard Study, both to increase enrollment in the Vanguard Study and to evaluate the feasibility, acceptability and cost of three separate recruitment strategies for enrollment of pregnant women into the NCS. The seven currently enrolled sites use a household enumeration and screening strategy to identify eligible women for recruitment into the study. Although household enumeration is often considered the gold standard for reducing sampling bias, in that all dwelling units are canvassed for eligibility, for the NCS Vanguard Study this method has not yielded the target number of births projected from initial models. Although current enumeration rates (~85%) and current consent rates (~60%) are comparable to other birth cohort studies, they yielded fewer pregnant women and births than originally estimated. Study planners are thus investigating alternate methods to increase enrollment rates and ultimately the number of women and children enrolled in the study.

Research Goal: The guiding research goal for this methodological study is identification of recruitment strategies and components of recruitment strategies that are most effective to identify, recruit and enroll sufficient numbers of eligible participants into a population based cohort study.

Methods: We propose to add as many as 30 additional sites to the Vanguard Cohort in order to ensure an adequate cohort size. The additional sites will be chosen from among those already identified for the Main Study of the NCS. These selected Study Centers represent a range of demographic and other characteristics that will be important for the NCS' evaluation of recruitment strategies, including racial and ethnic backgrounds, languages spoken, socioeconomic status, education level, population density and

urbanicity, and geographic region of the United States, but they do not constitute a statistically representative sample. Across these additional sites, we will compare three alternate recruitment strategies. Each of the alternative strategies is designed to identify and recruit age- and geographically-eligible women to participate in the study, while retaining the probability basis of the sample. Women targeted for enrollment include both pregnant women and women who are not pregnant but who might become pregnant in the future. Women must be part of the probability sample; that is, they must reside in a preselected study segment. The provider-based recruitment method relies on health care providers for assistance in participant identification and recruitment. The enhanced household recruitment method builds on the lessons learned in the existing Vanguard Study by enhancing enumeration techniques and a more streamlined recruitment process. The two-tiered recruitment method relies on larger secondary sampling units to increase the number of geographically-eligible women in a given area. We describe anticipated features of each strategy below.

We will evaluate the feasibility (technical performance), acceptability (respondent tolerance and impact on study infrastructure), and cost (operations, time, and effort) of each strategy using pre-determined measures. We will compare these findings and use them as a basis to inform the strategies, or combinations of strategies, that might be used in the Main Study of the NCS.

Provider-Based Recruitment Strategy: The goal of this strategy is to introduce the NCS through the existing health care system, by providing pregnant and other age-eligible women with information about the NCS via health care providers in a familiar and trusted environment. A group of Vanguard Study sites will develop lists of health care providers who serve women in the geographically-eligible segments. These providers will receive information about the NCS and would be invited to participate collaboratively in efforts to identify potentially eligible women and to inform them about the study. It is expected that a variety of strategies to inform and engage potential participants will be used once women express interest, depending on the specific setting. For example in more rural communities, where one provider sees most of the patients, NCS staff may decide to co-locate in the providers office to provide information and recruit participants into the study. In more

urban areas, where there are multiple providers, the provider may decide to simply provide information about the study to their patients and a phone number or additional contact information for patients to contact the study center. Study staff (not providers) will be available to eligible women to answer questions about the study. The Study staff will check the geographic eligibility of potential study participants; segment boundaries will not be communicated to non-Study staff. To maintain the household-based probability sampling frame, NCS staff will only actually recruit women identified in the health care provider settings that live in the identified sample segments. Using estimates from the original Vanguard Study proposal, less enumeration efforts and efficiencies gained from field experience, we estimate this recruitment strategy will require 27,800 respondent burden hours over the first two years of data collection. (For reference, the original Vanguard Study proposed expending 37,042 respondent burden hours for the same data collection period.)

The provider-based recruitment strategy draws on the advantages of utilizing a trusted source for initial introduction to the study, an approach used effectively in many other studies. Additionally, as compared to other recruitment strategies, this approach enhances identification of pregnant women by centering recruitment activities at places of prenatal care and other locations that pregnant women visit for health care. As such, this approach is likely to be more cost effective than other less targeted efforts. Like the other recruitment strategies considered, it retains a household-based probability sampling design. However, one disadvantage of this approach is that it focuses on identification of women receiving prenatal care. In 2005, it was estimated that 3.5% of pregnant women in the U.S. had no prenatal care or began prenatal care in the third trimester. One way to address the potential under representation of women who do not seek early prenatal care is to develop lists of providers encompassing a wide range of health care facilities, including emergency care and public health clinics, and then to systematically evaluate coverage (or under-coverage) as children are born into the Study. The NCS also allows recruitment through the end of the hospital stay associated with labor, delivery and birth, thus it would be possible to invite women who do not receive prenatal care to join the study during the perinatal period. Another

potential limitation is that characteristics of the provider, provider staff, or setting may result in selection bias regarding the presentation of information about the NCS to potentially eligible women. This potential bias will be assessed as the strategy is implemented. Furthermore, with the geographic sampling approach we will have the ability to compare actual recruitment to the targeted population through analyses of birth certificate data.

Enhanced Household Enumeration Strategy: The enhanced household enumeration recruitment model would improve our ability to identify pregnant women by using enumerators trained in best practices to assist in the most labor-intensive and among the most important aspects of the study. The enhanced household enumeration recruitment model would primarily utilize these staff directly as enumerators, but could also use the best of the enumerators to train new enumerators at study centers, or a combination of the two. Techniques for contacting participants will need to continue to be refined over time to ensure the study reaches hard-to-reach individuals. Using estimates from the original Vanguard Study proposal, less efficiencies in enumeration efforts and other aspects of field work based on field experience, we estimate this recruitment strategy will require 32,230 respondent burden hours over the first two years of data collection. (For reference, the original Vanguard Study proposed expending 37,042 respondent burden hours for the same data collection period.)

The enhanced household recruitment model is considered by many to make use of the gold standard for recruiting an unbiased sample, thereby increasing the generalizability of the resulting data. It relies on established enrollment methods used in other large-scale observation studies, and is most compatible with the existing probability-based sample, since it is not susceptible to external lists that may have coverage issues. However, household enumeration, even when maximally efficient, is time, labor, and cost intensive. Some households are difficult to contact. Additionally, given the fairly high observed enumeration and consent rates in the original Vanguard Center effort, this method may not yield a sufficient increase in enrollment rates over the current method. The method also is dependent upon recruiting and retaining an adequate number of expert enumerators to scale up for the target population of the Main Study.

Two-Tiered Recruitment Strategy: The two-tiered recruitment strategy has several goals. Like the provider-based recruitment strategy and the enhanced household recruitment strategy, the two-tiered recruitment strategy aims to increase enrollment in the Study. The two-tier strategy would do this using two means. First, the two-tiered strategy would increase the number of identified pregnant women by increasing the area determining geographic eligibility into the Vanguard study. Second, the two-tiered strategy would facilitate participation in the Study by administering a lower intensity data collection effort initially; after a period of time during which rapport may be developed, we would then invite a subsample of participants to join a higher intensity data collection (that is, the current full protocol). In this way, we would attempt to increase the enrollment of women who might be initially reluctant join the full study protocol.

The major goals of the two-tier strategy also include generating data to gauge the desired size of the secondary sampling units necessary to yield enrollment targets, and developing information needed to better estimate bias between women who chose to participate in the low intensity data collection and the high intensity data collection. These analyses will significantly benefit Study recruitment planning, regardless of which of the alternate recruitment strategies are found to be most efficient.

In the two-tier approach, the primary sampling units (that is, counties or groups of counties) would remain the same as in the original sampling frame, but the geographic areas selected for the secondary sampling units would be larger (for example, larger clusters of census blocks) than those used for the original Vanguard Study locations. From these comparatively larger secondary sampling units, tertiary sampling units would be selected. These tertiary sampling units would comprise smaller clusters of census blocks and would be similar in size to the secondary sampling units employed in the original Vanguard Study and in the provider-based and enhanced household based recruitment strategies.

In the two-tiered recruitment strategy, age-eligible women residing in the secondary sampling units and in the tertiary sampling units would be asked to participate in a low intensity data collection effort. This effort would be collected by mail or other self-administered means. After a period of time during which rapport may be established between the participant and

the data collector, age-eligible women residing in the tertiary sampling units would also be invited to participate in the high intensity data collection, which is the current Vanguard Study protocol. If a woman eligible to participate in the high intensity collection effort declines, she may continue participating in the low intensity effort.

Based on data collected to date, and assuming no household enumeration or provider-referrals, we anticipate that the secondary sampling units would need to be three times larger than the original Vanguard Study secondary sampling units to identify the required number of pregnant women within the Study's timeframe. Accordingly, assuming age-sex eligible targets three times larger than those in the original Vanguard Study proposal, an approximate 80% participation rate to the initial screener, an approximate 65% consent rate to minimal, self-administered data collection at approximately 30 minutes each 6 month period, less enumeration effort and efficiencies in other aspects of field work based on field experience, we estimate the low intensity tier recruitment strategy will require 78,222 respondent burden hours over the first two years of data collection. For the high intensity tier strategy, assuming respondent burden estimates from the original Vanguard Study proposal, less enumeration efforts and efficiencies gained from field experience, we estimate this recruitment strategy will require 27,800 respondent burden hours over the first two years of data collection. Combined, this recruitment strategy would require approximately 106,022 respondent burden hours over a two year period. (For reference, the original Vanguard Study proposed expending 37,042 respondent burden hours for the same data collection period.)

There are several goals of this recruitment strategy that recommend it despite comparatively higher estimated respondent burden. The two-tier strategy allows the opportunity to engage women participating in the low intensity data collection effort and build trust before participants are asked to consider joining the high intensity effort. This aspect may increase the likelihood of participation in the high intensity data collection (that is, the full protocol) as compared to the other alternate recruitment strategies. This strategy also fits within the existing probability-based sampling frame for the Main Study. Women that decide to leave the high intensity data collection may remain within the study in a structured context in the low intensity setting. Additionally, the two-tier

strategy offers a means to gauge the size of geographic areas that might be necessary for reaching alternative enrollment targets and to systematically compare bias in enrollment between high and low intensity groups—analyses that will benefit the design of the Main NCS study regardless of which recruitment strategies are ultimately chosen.

Frequency of Response: See above descriptions.

Affected Public: Pregnant women and their children

The annualized cost to respondents over the two year data collection period for all three recruitment strategies combined is estimated at \$1,660,520 (based on \$10 per hour). 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 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. Sarah L. Glavin, Deputy Director, Office of Science Policy, Analysis and Communication, National Institute of Child Health and Human Development, 31 Center Drive Room 2A18, Bethesda, Maryland 20892, or call non-toll free number (301) 496-1877 or e-mail your request, including your address, to glavins@mail.nih.gov.

Comments 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: March 18, 2010.

Sarah L. Glavin,

Deputy Director, Office of Science Policy, Analysis and Communications, National Institute of Child Health and Human Development, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are 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 companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7057; fax: 301/402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Novel Regulatory B Cells for Treatment of Cancer and Autoimmune Disease

Description of Invention: The manner by which cancers evade the immune response is not well-understood. What is known is that the manner is an active process that regulates immune responses employing at least two types of suppressive cells, myeloid-derived suppressive cells and regulatory T cells (Tregs), a key subset of CD4⁺ T cells that controls peripheral tolerance to self- and allo-antigens. Tregs are considered to play a key role in the escape of cancer cells from anti-tumor effector T cells.

Cancer cells have been found to directly activate resting B cells to form suppressive regulatory B cells (tBregs) and utilize them to evade immune surveillance and mediate metastasis. tBregs directly inhibit CD4⁺ and CD8⁺ T cell activity in a cell contact-dependent