Follow-up Study
of Chronic Fatigue Syndrome in Georgia

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Contents

Abstract

A.	**Justification**	
1.	**Circumstances Making the Collection of Information Necessary**	**1**
2.	**Purpose and Use of the Information Collected**	**5**
3	**Use of Information Technology and Burden Reduction**	**6**
4.	**Efforts to Identify Duplication and Use of Similar Information**	**7**
5.	**Impact on Small Businesses or Other Small Entities**	**7**
6.	**Consequences of Collecting the Information Less Frequently**	**7**
7.	**Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**	**7**
8.	**Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency**	**7**
9.	**Explanation of Any Payment or Gift to Respondents**	**8**
10.	**Assurance of Confidentiality Provided to Respondents**	**9**
11.	**Justification for Sensitive Questions**	**10**
12.	**Estimation of Hour Burden Including Annualized Hourly Costs**	**11**
13.	**Estimate of Other Total Annual Cost Burden to Respondents or Recordkeepers**	**12**
14.	**Annualized Cost to the Federal Government**	**12**
15.	**Explanation for Program Changes or Adjustments**	**12**
16.	**Plans for Tabulation and Publication and Project Time Schedule**	**13**
17.	**Reason(s) Display of OMB Expiration Date is Inappropriate**	**13**
18.	**Exceptions to Certification for Paperwork Reduction Act Submissions**	**14**
B.	**Collection of Information Employing Statistical Methods**	
1.	**Respondent Universe and Sampling Methods**	**15**
2.	**Procedures for the Collection of Information**	**17**
3.	**Methods to Maximize Response Rates and Deal with Non-response**	**21**
4.	**Tests of Procedures or Methods to be Undertaken**	**24**
5.	**Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data**	**25**
References		**26**

Attachment 1. **Authorizing Legislation**

Attachment 2. **Congressional Language Regarding CFS: 1992-2004**

Attachment 3. **Survey Instrument**

Attachment 4. **Follow-up Study Protocol**

Attachment 5. **60-Day Federal Register Notice**

Attachment 6. **Advance Letter**

Attachment 7A. **Non-Contact Letter**

Attachment 7B. **Refusal Letter**

A. Justification

1. Circumstances Making the Collection of Information Necessary

a. Authorizing Legislation

The authorizing legislation for the *Follow-up Study of Chronic Fatigue Syndrome in Georgia* (hereafter referred to as the *Follow-up Study*) is contained in the US Code. Section 42 USC 241 of this Code authorizes collection this information (Attachment 1).

b. Congressional Support for CFS Research.

Chronic fatigue syndrome (CFS) is a Congressional priority. Beginning in 1992, Congressional language has stressed legislators' desire for CDC to develop control and prevention measures for CFS. Recent Congressional language (2003-2006) has encouraged CDC to use advanced surveillance methodologies to describe risk factors and clinical parameters of the illness and to search for diagnostic markers. Congressional language has stressed that this information be used to educate health care providers about the diagnosis and treatment of CFS and to better inform the public about the illness (Attachment 2). This protocol addresses these Congressional concerns.

c. Need for Data Collection

CFS is a complex medical and public health problem. CFS is characterized by medically and psychiatrically unexplained disabling fatigue that is not relieved by rest and is accompanied by symptoms of prolonged post-exertional malaise, unrefreshing sleep, impaired concentration and short-term memory, muscle and joint pain, headache, sore throat, and tender lymph nodes [Fukuda *et al*., 1994]. At least one million adults in the U.S. suffer from CFS [Reyes *et al*., 2003; Jason *et al*., 1999; Bierl *et al*., 2004]. Their median duration of illness is 7 years, a quarter of them are unemployed or receiving disability

[Solomon *et al*., 2003], and the average affected family forgoes $20,000 annually in lost earnings and wages (half the median U.S. household income). Overall, CFS costs the U.S. just over $9 billion annually in lost productivity [Reynolds *et al*., 2004].

The Survey of Chronic Fatigue Syndrome and Chronic Unwellness in Georgia (Baseline Survey) *(OMB #0920-0638, expiration date: August 2005*), conducted between 2004 and 2005, provided baseline information on CFS in metropolitan, urban, and rural regions of Georgia (Atlanta, Macon and Warner Robins, and the counties surrounding Macon, respectively). The Baseline Survey used random-digit dialing from a prepared list of telephone numbers to ascertain eligible households for a screening interview within the prescribed geographic stratum. An estimated response rate of 79% was calculated after taking into consideration the estimated number of age-eligible households among the telephone numbers with indeterminate residential status, and households where screening was incomplete. Based on the symptoms and inclusion criteria reported in the screening interview, persons were selected for a detailed telephone interview to assess inclusion and exclusion criteria, and a 75% response rate was achieved. Based on responses to the detailed telephone interview, subjects were selected for a clinical evaluation to further evaluate exclusion criteria and risk factors and a 54% response rate was achieved.

Acknowledging that random-digit dialing methods typically result in a significant number of missed households, thereby limiting the ability to ascertain a representative sample of the population, analyses of *Baseline Survey* data estimated that 2.54% of the adults who participated in this study suffer from CFS. The *Baseline Survey* evaluated the occurrence of CFS in different racial/ethnic populations of metropolitan, urban, and rural Georgia, obtained data concerning access to and utilization of health care and economic impact of CFS, and evaluated associated risk factors.

Analyses of *Baseline Survey* data show that 2.54% of the participants ~~adult population of Georgia~~ suffer~~s~~ from CFS. This figure is 6- to 10-fold higher than previous prevalence estimates and likely reflects improved screening methods and more sensitive and specific diagnostic criteria. CFS prevalence is higher among white~~s~~ participants compared to black participants~~s~~, suggesting that the incidence will be

higher among whites, as well. Overall ~~risk~~prevalence of CFS did not differ between metropolitan, urban, and rural ~~populations~~strata. However, this was only true among women (p = .37). Among men, CFS prevalence varied significantly among geographic strata; 0.42% of men in the metropolitan ~~area~~stratum, 1.82% of males in the urban ~~residents~~stratum, and 2.89% of men in the~~from~~ rural ~~areas~~stratum suffered from CFS. This was reflected in sex-specific ~~risk~~odds ratios; in the metropolitan ~~area~~stratum, the CFS prevalence in women was 11.2 times that in men (p = .009), whereas in the urban and rural ~~populations~~strata the female-to-male ratios of CFS prevalence were 1.7 and 0.8, respectively, and did not represent statistically significant differences. The other major finding to date is that 48% of persons clinically evaluated because CFS-like illness was identified during telephone interviews had exclusionary medical or psychiatric conditions. Most were amenable to treatment if appropriately recognized as having CFS. The *Follow-up Study* has four specific aims.

Aim 1. Clinical, Psychosocial and Environmental Variables that Characterize the Clinical Course of CFS. We designed the *Follow-up Study* to evaluate changes in clinical parameters of CFS over the interval since the *Baseline Survey*. Clinical evaluation of fatigued study participants and randomly selected well controls assesses functional impairment by using the Medical Outcomes Survey 36-item Short Form or SF-36 [Ware & Sherbourne, 1992], fatigue measured by the Multi-dimensional Fatigue Inventory or MFI [Smets *et al*., 1995], and the occurrence and severity of symptoms as measured by the CDC Symptom Inventory [Wagner *et al*., 2005].

The findings that acute stress often precedes and exacerbates CFS in adults, combined with the strong association of childhood stress with CFS, support a stress-diathesis model, in which genetic liabilities interact with stressful experiences in determining individual vulnerability to disease, including CFS. We hypothesize that CFS patients with a lifetime history of stressful experiences will be less likely to recover or improve compared to CFS patients who do not have a lifetime history of stressful

experiences. We collected data on stress history during the *Baseline Survey* with the purpose of confirming this association in the *Follow-up Study*.

Aim 2 – Physiologic Markers that Characterize CFS. Clinical, psychosocial and environmental factors evaluated in Specific Aim-1 are also reflected physiologically as allostatic load. Allostatic load was first described by McEwen and Stellar [McEwen & Stellar, 1993] as the cumulative wear and tear on the body and brain resulting from chronic over-activity or inactivity of the HPA axis in adaptation to environmental challenge, such as acute disease, physical and emotional trauma (i.e., stress). The allostatic load index includes laboratory measurements of metabolic, cardiovascular, inflammatory and HPA-axis factors. We hypothesize that high allostatic load will be significantly associated with worsening clinical course of CFS. We are particularly interested in whether allostatic load index predicts clinical outcome in the acute versus gradual onset cases and whether the illness contributes to the allostatic load index.

Aim 3 - Economic Impact of CFS — Access to/Utilization of Health Care. Congress has directed CDC to accelerate its CFS research plan to identify the economic impact of CFS and accelerate its educational activities for health care providers. The *Follow-up Study* will evaluate direct and indirect costs of persons with CFS relative to well and unwell controls, compare access to/utilization of health care by those who suffer from CFS with well and unwell controls, and measure changes in health care utilization and economic impact over time. Clinical follow-up of subjects with CFS will also allow us to examine the relationship between provision of health care and recovery. Information concerning economic impact of CFS will be used to tailor an intensive regional provider education project, develop public health strategies, and evaluate cost effectiveness of different therapeutic modalities.

Aim 4 – Incidence of CFS in Different Racial/Ethnic Populations of Metropolitan, Urban, and Rural Georgia. An understanding of the occurrence of new incidents of CFS is fundamental to focusing etiologic research, targeting health-care and educational programs, and developing prevention strategies. This will be the first follow-up in a study of five-year CFS incidence. The objective is to estimate the incidence of CFS among those categorized as unwell and well in the *Baseline Survey*.

2. Purpose and Use of the Information Collected

As noted in Section A.1.b, the purpose of the proposed *Follow-up Study* is to evaluate for a second time subjects who participated in the *Baseline Survey* and at that time indicated their willingness to be recontacted. We will utilize the data to implement measures that decrease the morbidity (burden) of CFS in the general public. Specifically, information on clinical course and knowledge regarding variables related to morbidity of CFS (e.g., stress history and allostatic load) will be incorporated into ongoing provider education and public awareness programs. Data concerning specific aspects of stress history and allostatic load will used to further refine molecular epidemiology laboratory studies directed at defining the pathophysiology of CFS. Information on access to and utilization of health care will be used in planning and evaluating a targeted pilot regional intervention program for the 84% of people with CFS who have not been diagnosed and treated. Finally, this is the first of four additional studies to estimate the incidence of CFS.

The *Follow-up Study* uses methodology developed for the *Baseline Survey* (OMB #0920-0638). Like the *Baseline Survey*, the follow-up study entails a detailed telephone interview to obtain data on participant health status during the last twelve-month period. The interview will collect information on fatigue and other symptoms, medical and psychiatric conditions, demographics, psychiatric comorbidity, and other psychosocial factors. The telephone survey is similar to the instrument approved by OMB for baseline data collection. See Attachment 3 for a copy of the survey instrument. Eligible subjects will be asked to participate in clinical evaluations. Clinical protocols and instruments for this follow-up are

similar to the procedures and materials used in the baseline study (OMB #0920-0638). Please see Attachment 4 for the full study protocol. Because clinical studies are exempt from OMB review, the clinical portion of this study is provided to the Office of Management and Budget for information only. In this submission, we request only a review of the telephone survey data collection.

3. Use of Information Technology and Burden Reduction

All telephone interviews will be conducted using computer-assisted telephone interviewing (CATI) technology. CATI is an efficient interviewing mode that reduces respondent burden and improves the quality of the data collected. The CATI system will include logic checks and skip-pattern controls to ensure that respondents receive the appropriate questions and that the interview process goes smoothly. These programmed checks also identify inconsistent responses, allowing the interviewer to resolve discrepancies during the interview.

The sample management portion of the CATI system efficiently handles large samples, as well as samples with numerous strata or clusters. Distribution of telephone numbers to interviewers is very fast. The system allows for flexible scheduling of callbacks to allow respondents to be called at their convenience. It also contains well-tested calling algorithms for delivering cases to interviewers based on the outcomes of previous call attempts that maximize the probability of completing interviews and thereby increase response rates.

Another CATI software module allows supervisors to monitor production and quality, including monitoring of interviews as they transpire. Researchers have easy access to survey responses and data frequencies for each variable. For survey review and preliminary analysis, the CATI system can produce a copy of the questionnaire with survey frequencies posted next to each question.

The CATI system also contains protections against data loss. Completed questionnaire data are stored during the interviewing process; nightly, a full backup of the entire CATI system occurs.

4. Efforts to Identify Duplication and Use of Similar Information

We are aware of no studies to define the clinical course of CFS and identify associated risk factors in representative US metropolitan, urban, and rural communities. Because medical evaluation is necessary to confirm a classification of CFS, this survey of CFS cannot readily be combined with other studies in defined metropolitan, urban, and rural communities. Because of the nature of the information that must be collected, it would not be feasible to combine this with other population studies conducted by CDC.

5. Impact on Small Businesses or Other Small Entities

No small businesses are involved in this study

6. Consequences of Collecting the Information Less Frequently

The proposed data collection is a follow-up to the *Baseline Survey*. The collection of longitudinal data is required to obtain information regarding clinical course, access to and utilization of health care, economic impact and incidence of CFS among persons ascertained from ~~in~~ metropolitan, urban, and rural communities of Georgia.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5.

There are no special circumstances for this information collection. The *Follow-up Study* is in full compliance with the guidelines of 5 CFR 1320.5.

8. Comments on Response to the Federal Register Notice and Efforts to Consult Outside Agency

a. Federal Register Notice and Public Comment

In accordance with the Paperwork Reduction Act of 1995, the Division of Viral and Rickettsial Diseases published a notice in the Federal Register announcing the agency's intention to request an OMB

review of the proposed data collection activities. The notice was published on October 25, 2006 in Volume 71, Number 206, pages 62473 to 62474 and provided a 60-day period for public comment. A copy of this notice is provided in Attachment 5. No public comments were received.

b. Other Consultants

As noted earlier, the methodology and instrumentation for the *Follow-up Study* are the same as the materials used for the *Baseline Survey*. The CDC drew on the expertise of a group of consultants from Abt Associates Inc. for their development. These consultants are listed in Exhibit A.8.1.

Exhibit A.8.1. Consultants from Abt Associates Inc.

Name	Title	Address	Telephone	Year(s) in which consultation took place
Scott Royal, Ph.D.[a]	Project Director	Abt Associates Inc. 4550 Montgomery Avenue Suite 800 North Bethesda, MD 20814 scott_royal@abtassoc.com	(703) 919-0189	2006-2007
David Hoaglin, Ph.D.	Principal Scientist	Abt Associates Inc. 55 Wheeler Street Cambridge, MA 02138 dave_hoaglin@abtassoc.com	(617) 349-2814	2003-2007
Johnny Blair	Survey Methodologist	Abt Associates Inc. 4550 Montgomery Avenue Suite 800 North Bethesda, MD 20814 johnny_blair@abtassoc.com	(301) 634-1825	2003, 2006

9. Explanation of Any Payment or Gift to Respondents

Telephone interview respondents will not receive payment for their participation. Participants who complete the one-day clinical evaluation will be given an incentive of $250.00, which is the same amount provided in the *Baseline Survey of CFS in Georgia.*

10. Assurance of Confidentiality Provided to Respondents

The CDC Privacy Act Officer has reviewed this OMB application and has determined that the Privacy Act is applicable. Participants will be asked sensitive questions regarding: (1) pregnancy history, (2) use or abuse of alcohol and other controlled substances, (3) psychiatric diagnoses, and (4) stress and trauma. While data will be filed by identification number, because the data can be linked to respondent names by the contractor and sensitive information is being collected, the Privacy Act applies.

Data for the proposed study will be collected and protected in accordance with Privacy Act system notice 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems." Data collection will be conducted by Abt Associates, the contractor hired by CDC for this project. Although the first and last names and addresses of all respondents will be collected during interviews to contact respondents for the clinical portion of the study and for follow-up studies of CFS, CDC will not have access to this information. CDC will receive data labeled only by identification (ID) numbers. Abt Associates will maintain the only link between name and ID number. Survey data are maintained at Abt Associates until the electronic data are verified and there is no longer need for reference to hard-copy documents (approximately six months after the end of data collection). At that time, the data will be moved to Abt Associates' off-site storage facility. At the conclusion of the study, the survey data will be destroyed in accordance with the terms of the contract between CDC and Abt Associates.

All Abt Associates project staff, including data collection staff, are carefully instructed on protecting confidentiality. Such instruction is a key component of Abt Associates' project and corporate training. Instructions are based on CDC's standard procedures and on specifics dictated by Abt Associates' physical facilities. All Abt Associates staff with access to confidential information are required to sign Affidavits of Non-Disclosure, a standard requirement for all employees and subcontractor staff who have access to confidential data. These staff will also sign Affidavits of Non-Disclosure that are required by CDC. Violation of the signed agreement is grounds for immediate dismissal. If prosecuted and convicted, violators may be fined up to $250,000 and/or imprisoned up to

five years. Prior to each period of data collection, confidentiality requirements are reviewed with all staff.

Abt Associates Inc. is extremely conscious of the need to protect the confidentiality of data. For over forty years, the company has conducted numerous projects involving sensitive information; consequently, facilities and procedures have been developed to maintain this confidentiality. At all sites, building security forces are on duty twenty-four hours, seven days per week. The Cambridge office has a DOD-approved Secret Security Clearance. In all company offices, access to data processing areas is controlled, with only authorized personnel allowed in the computer rooms and the computer tape libraries. Locked tape files and storage areas are used by all contracts. In addition, individual data banks and files are protected by passwords and other techniques that prohibit access by staff who do not have appropriate clearances. Access to areas where confidential data are maintained is restricted to authorized personnel. All databases are password protected, with only the data administrators having write authority over files.

Each computer platform at Abt Associates Inc. is protected by a log-in system that requires the user to produce both group and individual identification, including personal passwords. This system protects individual files as well as general access to automated hardware and software. Individuals cannot change group affiliation; only a systems administrator can institute such modifications. This system effectively restricts computer access to authorized users.

Auditing programs, in place on each of the platforms, allow system administrators and project directors to monitor the identity and log-in times of all users on the system. Virus scanners are used on all computer networks and PCs to protect against data loss from malicious virus attack.

11. Justification for Sensitive Questions

There are topics in the telephone interview and in the clinical evaluation that are sensitive and private in nature. Questions that are sensitive in nature include:

- A question on pregnancy history.
- Questions regarding use or abuse of alcohol and other controlled substances.

- Questions concerning psychiatric diagnoses.
- Questions concerning stress and trauma.

The first three topics noted above are essential to the purpose of the project, because the information they provide is necessary for identifying individuals who meet the CFS case definition. At present, CFS must be identified by exclusion. A primary criterion to be classified as a CFS case is the absence of preexisting clinical conditions that may produce a similar syndrome. Psychiatric conditions and effects of substance abuse and recent pregnancy may exhibit symptoms similar to the CFS symptom cluster. For example, a confirmed CFS classification requires that certain specific psychiatric disorders have not previously occurred. The questions concerning stress and trauma are important for identifying precipitating factors for fatiguing illness as well as for identifying individuals to invite for future studies of CFS.

In interviews conducted for the *Baseline Survey*, participants willingly answered questions on these topics. No adverse events associated with these questions were reported.

12. Estimation of Hour Burden Including Annualized Hourly Costs

The proposed Follow-up Study entails follow-up interviews by telephone with subjects who participated in the Baseline Survey in three segments of the Georgia population: metropolitan (represented by DeKalb and Fulton Counties), urban (represented by Bibb County, which contains the city of Macon, and the nearby city of Warner Robins, in Houston County), and rural (represented by counties surrounding Macon). For the *Follow-up Study*, respondents will be asked to complete a one-time-only detailed telephone interview. It is anticipated that detailed interviews will be completed with 2,870 respondents who completed baseline interviews and agreed to be contacted for follow-up. The estimated average time needed by a respondent to complete the detailed interview is about 18 minutes. The estimated time needed for completing the detailed interview is derived from our experience on the *Baseline Survey*.

A summary of the respondent burden estimates is included in Exhibit A.12.1, below. The hour-burden estimates include the time needed for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Respondents to this study will be interviewed by telephone, so the majority of their time will be spent answering the survey questions. Respondents will spend almost no time reviewing instructions or gathering, maintaining, or reviewing data. Annualized costs associated with the hour burdens for the collection of information are also included in the table below.

Exhibit A.12.1. Summary of Respondent Burden Estimates And Annualized Costs to Respondents

Respondent	No. of Respondents	No. Responses per Respondent	Average burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Follow-up Study Detailed Interview	2,870	1	18/60 [b]	861	$18.70[a]	$16,100

[a] Based on preliminary data for all occupations in Georgia, Quarter 3 2005. Source: Quarterly Census of Employment and Wages, Bureau of Labor Statistics, US Department of Labor.

[b] The 60-day federal register notice listed the estimated average burden response as 30/60 hours. Since publication of the notice, the questionnaire has been shortened so that it is estimated to take about 18 minutes to complete.

13. Estimate of Other Total Annual Cost Burden to Respondents or Recordkeepers

There are no capital costs, operating costs, or maintenance costs to report.

14. Annualized Cost to the Federal Government

The data for the *Follow-up Study* will be collected during an approximate forty-week period. The estimated contract cost to the government is $320,000 for the telephone survey.

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

A proposed schedule appears in Exhibit A.16.1. Our proposed start date for the study will be two weeks following receipt of OMB clearance; data collection is expected to last approximately ten months.

Exhibit A.16.1. Proposed Project Schedule

Mail advance letters	2 weeks after OMB approval
Telephone data collection begins	4 weeks after OMB approval
Clinical evaluations begin	10 weeks after OMB approval
Telephone data collection ends	6 months after OMB approval
Clinical evaluations end	9 months after OMB approval
Cleaning and processing data	3 – 10 months after OMB approval
Data analysis	9 – 16 months after OMB approval
Publication	16 months after OMB approval

Section B of this submission describes in detail our plans for weighting and estimating incidence of CFS and other fatiguing illnesses. The Congress has directed CDC to complete such analyses. Our specific hypotheses are described in Section A.1 above. CDC's CFS Study Group, with assistance from the contractor, will be responsible for all analyses and publications. All studies undertaken by this group have resulted in publications in peer-reviewed journals.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The expiration date will be displayed on the paper questionnaires for this study. The expiration date will also be provided for telephone survey respondents upon request.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

This submission requests no exceptions to the Certification for Paperwork Reduction Act (5 CFR 1320.9).

B. Collection of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

The proposed *Follow-up Study* entails follow-up interviews by telephone with subjects who participated in the *Baseline Survey* in three segments of the Georgia population: metropolitan (represented by DeKalb and Fulton Counties), urban (represented by Bibb County, which contains the city of Macon, and the nearby city of Warner Robins, in Houston County), and rural (represented by counties surrounding Macon). All subjects agreed to be contacted for a follow-up study.

Exhibit B.1.1 presents the *Follow-up Study* sample assumptions. It begins with the 5,623 subjects who completed baseline interviews. Respondents who had temporary or permanent medical and psychiatric exclusions have been removed from this sample. Respondents who declined to be contacted for future studies also have been removed. CDC expects 3,587 respondents to be eligible for follow-up telephone interviews. An 80 percent response rate is expected—2,870 completed interviews.[1]

[1] In the *Baseline Survey*, telephone interviews were completed with 64.9% of the respondents who were selected. In the *Follow-up Study*, a higher response rate is expected because all eligible respondents completed baseline interviews and agreed to be contacted for follow-up.

Exhibit B.1.1. Sample Assumptions for *Follow-up Study*

Completed baseline telephone interviews	5,623
Medical and psychiatric exclusions (20.7%)	(1,164)
Age exclusion (over age 59 at anticipated start of data collection, only for respondents who did not complete baseline clinical evaluations)	(174)
Declined to be contacted for future studies (16.2% of remaining sample)	(698)
Follow-up Study telephone interview sample (63.8% of baseline telephone interview completes)	3,587
Follow-up Study telephone interview completes (80.0% of sample)	2,870

Exhibit B.1.2 presents demographic information of the 3,587 respondents who are eligible for follow-up telephone interviews.

Exhibit B.1.2. Demographic Characteristics of *Follow-up Study* Sample (n=3,587)

	Number	Percent
Sex		
Male	1,260	35.1
Female	2,327	64.9
Age in years		
18-19	24	0.7
20-24	274	7.6
25-29	353	9.8
30-34	382	10.6
35-39	430	12.0
40-44	540	15.0
45-49	552	15.4
50-54	524	14.6
55-59	464	12.9
60-64	33	0.9
Age undetermined	11	0.3
Race/Ethnicity		
Black	1,133	31.6
White/Other	2,454	68.4
Hispanic/Latino	120	3.3

2. Procedures for Collection of Information

The goal of the present study is to build on the *Baseline Survey* and identify risk factors for and biomarkers of CFS so as to improve identification, clinical evaluation, diagnosis, and management of the illness. Participants are drawn from the population-based surveillance cohort that participated in the *Baseline Survey* and who agreed to participate in future studies. The *Follow-up Study* is a modification of the *Baseline Survey* and utilizes most of the baseline instruments, with some modifications. Information will be incorporated into a national health care provider education program (Contract #200-2002-00793) and into a national public awareness effort (Contract #200-2004-09722). Data will also be used to develop a targeted regional provider education project.

a. Statistical Methodology for Stratification and Sample Selection

As described in Section B.1 above, the proposed *Follow-up Study* entails follow-up interviews by telephone with subjects who participated in the *Baseline Survey* in the metropolitan, urban and rural segments of the Georgia population.

b. Estimation Procedure

Each of the persons who completed detailed interviews during the *Baseline Survey* received a baseline sampling weight, which reflects the probability that the person was selected for a detailed interview. The baseline sampling weights also incorporate adjustments for nonresponse (for example, interviews that could not be conducted and households for which the screening questionnaire was not completed). Each person completing the *Follow-up Study* will be assigned a nonresponse-adjusted weight (their baseline sampling weight with additional adjustments for nonresponse to the *Follow-up Study*). These weights will compensate for nonresponse by applying weighting-class adjustments. Within each cell in a set of cells, the initial interview weight (that is, the baseline sampling weight) of each respondent will be multiplied by the ratio of the total weight for respondents and nonrespondents to the total weight for respondents. These cells will be based on geographic stratum (i.e., metropolitan, urban, rural), fatigue status, race/ethnicity, sex, and age (as in the Georgia *Baseline Survey*).

The data from clinical evaluations of persons whose responses to the telephone interviews classify them as CFS-like or chronically unwell will permit estimation of the incidence of CFS. Each CFS-like or chronically unwell person who has a completed clinical evaluation will receive an additional weight, equal to the person's nonresponse-adjusted interview weight multiplied by a further adjustment for nonresponse on the clinical evaluation. Estimates of incidence of CFS will be weighted percentages of the sample (using these additional weights). Estimates of incidence of CFS-like illness will require only the nonresponse-adjusted interview weights.

c. Level of Accuracy

As its primary objective, the *Follow-up Study* aims to produce estimates of morbidity and clinical course for CFS and CFS-like illness. The expected sample size of 3,587 eligible respondents is expected to provide adequate precision for these estimates and to detect differences that would be important for establishing public health policies. The exact precision of the resulting estimates will depend on the observed changes in morbidity over time, which are unknown. This study also aims to begin to estimate incidence of CFS. The incidence estimates will be developed to calculate the weighted percentage of the interview sample that are newly diagnosed CFS cases~~., either overall or within particular demographic subgroups. As in earlier surveys, the demographic subgroups will be based on sex, age, race, and household income (both singly and in selected combinations).~~ In addition, the sample design will allow estimation of incidence for the metropolitan, urban, and rural strata. ~~For a demographic subgroup, each geographic stratum will yield an incidence estimate.~~ These estimates can be studied separately (though the sample is not designed to yield stratum-specific estimates of high precision for subgroups), and they can be combined to obtain an *overall* estimate (from all three strata).

d. Use of Periodic Data Collection Cycles To Reduce Burden

Follow-up Study respondents will be asked to complete a single telephone interview. Use of periodic data collection cycles would have no effect on respondent burden.

e. Data Collection Protocol

CDC is requesting OMB review of the telephone data collection protocol for the *Follow-up Study*. Detailed interviews will be administered using computer-assisted telephone interviewing (CATI). Prior to calling selected telephone numbers, advance letters will be sent to all respondents. These letters remind respondents of their prior participation in the *Survey of Chronic Fatigue Syndrome and Chronic*

Unwellness in Georgia, notify them of the follow-up survey, explain its purpose and sponsor, and alert respondents to expect an interviewer to call. A copy of the advance letter appears as Attachment 7.

All telephone interviews will be conducted by professional interviewers with special training in administering these survey instruments. The script that the telephone interviewers will use to contact respondents and conduct the interviews is included in the questionnaire (Attachment 3).

Potential respondents who are initially reluctant to cooperate may be sent follow-up letters, emphasizing the importance of their participation in the study and giving them a toll-free telephone number to call to schedule or complete interviews. Two separate follow-up letters were designed for this study. The first letter is directed to respondents whom we have been unable to reach by telephone. The second letter is directed to respondents who are reluctant to complete detailed interviews. These letters are included as Attachments 8A and 8B, respectively.

In-person interviews will be scheduled and completed if target response rates cannot be achieved with telephone interviews. The telephone center supervisor will carefully screen uncontacted respondents to ensure that only appropriate cases are given to the field—respondents for whom we believe we have correct addresses but which we have not been able to reach by telephone. A field interviewer will first try to contact the respondent by telephone, and will then visit the respondent's home and try to persuade the respondent to call the Telephone Center to complete the interview. If the respondent prefers, field interviewers will conduct the interview on the spot.

Quality control measures include monitoring of telephone interviews by supervisory staff using Abt Associates' monitoring system. Abt Associates' Telephone Centers are equipped with separate monitoring rooms that allow unobtrusive monitoring of interviewers. Interviewers will not know when they will be monitored. The monitoring supervisor will listen to the telephone interview while observing the interviewer's data entry on a computer monitor that mirrors the interviewer's screen.

All telephone interviewers will be routinely monitored at selected time intervals. They will be given active coaching and immediate feedback, both positive and negative, on their performance so that success can be rewarded and reinforced, while problems are identified and corrected. The monitoring

system is also used to evaluate performance patterns across interviewers to identify any problematic areas or items in the questionnaire. If individual interviewers need to improve, retraining will focus on the specific problems. If these interviewers fail to improve after remedial training, they will be replaced.

As an additional quality control measure, project staff will review questionnaire item frequencies, as well as interview length, numbers of completed interviews, and similar information, to identify any potential for interviewer falsification; correct skip pattern errors; and detect any other anomalies in the data.

The full study protocol is included as Attachment 4.

3. Methods to Maximize Response Rates and Deal with Non-response

The success of any survey in achieving high response rates depends on the strategy that is used to encourage respondents to participate and on the energy with which this strategy is pursued. CDC and Abt Associates have considerable experience conducting data collection efforts using methods and modes similar to those proposed for the *Follow-up Study*. Experience with the *San Francisco Study, Sedgwick County Studies*, the *National Pilot Survey for Chronic Fatigue Syndrome*, and the *Survey of Chronic Fatigue Syndrome and Chronic Unwellness in Georgia* provides insights into the most effective strategies to maximize response rates for both fatigued and non-fatigued individuals. Based on this experience, the target response rate for the proposed study is 80 percent.

Procedures that will be used to maximize response rates for the *Follow-up Study* reflect best practices in the survey industry.

- Mailing advance letters to selected respondents prior to attempting to contact them by telephone. Advance letters introduce the study to potential respondents and increase cooperation with telephone interviews.
- Using trained, professional telephone interviewers who understand the study and who are skilled at gaining cooperation from respondents.
- Conducting telephone interviews primarily during evening and weekend hours, when respondents are most likely to be at home.
- Allowing respondents to schedule telephone interviews at their convenience.

- Employing specially trained refusal conversion interviewers to contact respondents who are initially reluctant to participate in the study. Before telephoning initially reluctant respondents, refusal conversion interviewers review the history of contacts with specific respondents and, if necessary, consult with supervisors to determine the best refusal conversion strategy.

- Sending refusal conversion letters to respondents who are difficult to reach by telephone or who are initially reluctant to participate. Some respondents are more likely to participate if they receive requests by mail.

- Sending trained interviewers into the field persuade reluctant and hard-to-reach respondents to call the Telephone Center for the Detailed Interview. Field interviewers will have mobile telephones for respondents who have no landline.

a. Procedures for Dealing with Nonresponse

Minimizing non-response is part of each step in the *Follow-up Study*. Procedures are described below.

- Using a call management system that tracks and manages the sample of telephone numbers so that telephone numbers are called at different times on different days, appointments with respondents are kept, and callbacks are made at the appropriate times.

- Maintaining a sufficient staff of interviewers so that respondents are called in an efficient and timely manner—respondents must be called within two weeks of the advance letter mailing; appointments and callbacks must occur at the correct times even during peak calling hours.

- Training interviewers in refusal aversion techniques to prevent initial refusals.

- Performing on-line monitoring of 5 percent of all calls placed so that action can be taken to correct poor interviewing practices.

- Identifying best interviewing practices and sharing them with the entire interviewing staff through regular project meetings, interviewer debriefings, and refresher training.

- Arranging ongoing training for interviewers and supervisors to improve their skills and alert them to protocol changes and revisions.

- In-person follow-up by field interviewers with reluctant or hard-to-reach respondents (as described above).

b. Response Rates

The target response rate for the *Follow-up Study* is 80 percent. The rate will be calculated as follows:

$$\frac{\text{Completed Interviews}}{\text{Initial Sample} - \text{Ineligibles}}$$

Although it is well-known that response rates, in general, are declining, especially in telephone surveys, Abt Associates (CDC's contractor for this study) has a proven record of maintaining high response rates over time. Abt expects to achieve the targeted response rate of 80 percent, which is consistent with other follow-up studies that Abt Associates has conducted. In the *Longitudinal Studies of CFS in Sedgwick County, Kansas*, Abt Associates achieved a 73 percent detailed telephone interview response rate in the first follow-up. Abt Associates achieved similarly high response rates on the National Osteoporosis Risk Assessment (N.O.R.A.) Study, a large observational registry of over 200,000 US women aged 50 and older. The N.O.R.A. survey used a multi-modal (mail with telephone follow-up) methodology in which respondents were contacted approximately every other year. In the first follow-up survey, the study achieved an overall response rate of 82 percent. An 80 percent response rate was achieved in the second and third follow-up surveys.

c. Analysis of Non-response

Although a variety of methods will be used to maximize response, some degree of non-response is inevitable. Weighted estimates of demographic characteristics (age, sex, race, and ethnicity) from the *Baseline Survey* were compared with estimates from the 2000 Census, to determine how closely the weighted study population mirrors the general population. Overall comparisons were made, as were comparisons for the metropolitan, urban, and rural strata. Some systematic differences between persons selected for detailed interviews and the Census were found. In all three strata, the younger age groups (18-39 years) and blacks were under-represented, and the age group 40-59 years and white/other were over-

represented. Males were under-represented in the Metropolitan and Rural strata. Hispanics were under-represented in the Metropolitan stratum and slightly over-represented in the Urban and Rural strata.

Male respondents, black respondents, and respondents who were aged 18-39 constituted a smaller proportion of detailed interview respondents than of the Census population in all three strata. Respondents reporting Hispanic ethnicity appeared to be under-represented only in the Metropolitan stratum. In most categories the nonresponse adjustment reduced the difference between the respondents and the Census, by amounts that range from slight to substantial. The general pattern remained, however. In all three strata the respondents to the detailed interview had lower percentages than the Census who are aged 18-39 or Black. The Metropolitan and Rural strata had lower percentages of males. The Metropolitan stratum had a lower percentage of Hispanics, but the Urban stratum had a higher percentage.

Comparisons between respondents and nonrespondents were also performed. In all three strata, as expected, a higher proportion of nonrespondents were male or from the age group 18-39 years. In the Metropolitan and Urban strata, a higher proportion of nonrespondents were Black; but in the Rural stratum the percentage of Blacks among respondents was higher than among nonrespondents (27.46% and 25.74%, respectively).

Similar analyses will be completed for the *Follow-up Study*.

4. Tests of Procedures or Methods to be Undertaken

The instrument and procedures for the proposed *Follow-up Study* have been used in four CDC CFS public health research program studies previously approved by OMB: the *San Francisco Study* (OMB #0920-0336); the *Sedgwick County Studies* (OMB #0920-0401); the *National Pilot Survey for Chronic Fatigue Syndrome* (OMB #0920-0498); and, most recently, the *Survey of Chronic Fatigue Syndrome and Chronic Unwellness in Georgia* (OMB #0920-0638).

Because of this experience and the fact that revisions to the detailed interview questionnaire are quite minor (primarily text revisions to reflect the fact that this is a follow-up interview and deletion of

items that were required only at baseline), CDC does not believe additional testing of the survey instrument or procedures is necessary.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The contractor, Abt Associates Inc., developed the statistical design for the study. Abt Associates also worked closely with CDC staff to develop the survey and instrument designs and will collect all data and participate in some data analysis. The project director, Scott Royal, oversees Abt Associates' staff. The names, roles, and telephone numbers for Abt staff are included in Exhibit B.5.1 below.

Exhibit B.5.1. Names, Roles and Telephone Numbers for Abt Associates Staff

Activity	Abt Staff Member	Telephone Number
Sample Design	David C. Hoaglin, PhD	(617) 349-2814
Survey and Instrument Design	Rebecca Devlin Marjorie Morrissey Johnny Blair	(312) 867-4037 (312) 867-4061 (301) 634-1825
Data Collection	Scott Royal, PhD	(703) 919-0189

Two CDC personnel are responsible for receiving and approving materials prepared by Abt Associates. William Reeves, M.D., is CDC's principal investigator and can be contacted at (404) 639-0221. Joann House is CDC's project officer and can be reached at (404) 639-3748.

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Attachment 1

Authorizing Legislation

Authorizing legislation supporting this data collection effort is described below and specific to the Department of Health and Human Services, the organization within the Executive Branch under which the CDC resides.

From the U.S. House of Representatives Downloadable U.S. Code
[uscode.house.gov]
[Laws in effect as of January 5, 1999]
[Document affected by Public Law 104-134 Section 101(d)]
[Document affected by Public Law 104-140 Section 1(a)]

[CITE: 42USC241]

TITLE 42 - THE PUBLIC HEALTH AND WELFARE
CHAPTER 6A - PUBLIC HEALTH SERVICE
SUBCHAPTER II - GENERAL POWERS AND DUTIES
Part A - Research and Investigations

-HEAD-
Sec. 241. Research and investigations generally

-STATUTE-

(a) Authority of Secretary

The Secretary shall conduct in the Service, and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man, including water purification, sewage treatment, and pollution of lakes and streams. In carrying out the foregoing the Secretary is authorized to –

(1) collect and make available through publications and other appropriate means, information as to, and the practical application of, such research and other activities;
(2) make available research facilities of the Service to appropriate public authorities, and to health officials and scientists engaged in special study;
(3) make grants-in-aid to universities, hospitals, laboratories, and other public or private institutions, and to individuals for such research projects as are recommended by the advisory council to the entity of the Department supporting such projects and make, upon recommendation of the advisory council to the appropriate entity of the Department, grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research;
(4) secure from time to time and for such periods as he deems advisable, the assistance and advice of experts, scholars, and consultants from the United States or abroad;
(5) for purposes of study, admit and treat at institutions, hospitals, and stations of the Service, persons not otherwise eligible for such treatment;
(6) make available, to health officials, scientists, and appropriate public and other nonprofit institutions and organizations, technical advice and assistance on the application of statistical methods to experiments, studies, and surveys in health and medical fields;
(7) enter into contracts, including contracts for research in accordance with and subject to the provisions of law applicable to contracts entered into by the military departments under sections 2353 and 2354 of title 10, except that determination, approval, and certification required thereby shall be by the Secretary of Health and Human Services; and
(8) adopt, upon recommendations of the advisory councils to the appropriate entities of the Department or, with respect to mental health, the National Advisory Mental Health Council, such additional means as the Secretary considers necessary or appropriate to carry out the purposes of this section.

The Secretary may make available to individuals and entities, for biomedical and behavioral research, substances and living organisms. Such substances and organisms shall be made available under such terms and conditions (including payment for them) as the Secretary determines appropriate.

(b) Testing for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects; consultation

(1) The Secretary shall conduct and may support through grants and contracts studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects. In carrying out this paragraph, the Secretary shall consult with entities of the Federal Government, outside of the Department of Health and Human Services, engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct for such entity studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects.

(2)

(A) The Secretary shall establish a comprehensive program of research into the biological effects of low-level ionizing radiation under which program the Secretary shall conduct such research and may support such research by others through grants and contracts.

(B) The Secretary shall conduct a comprehensive review of Federal programs of research on the biological effects of ionizing radiation.

(3) The Secretary shall conduct and may support through grants and contracts research and studies on human nutrition, with particular emphasis on the role of nutrition in the prevention and treatment of disease and on the maintenance and promotion of health, and programs for the dissemination of information respecting human nutrition to health professionals and the public. In carrying out activities under this paragraph, the Secretary shall provide for the coordination of such of these activities as are performed by the different divisions within the Department of Health and Human Services and shall consult with entities of the Federal Government, outside of the Department of Health and Human Services, engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct and support such activities for such entity.

(4) The Secretary shall publish a biennial report which contains -

(A) a list of all substances (i) which either are known to be carcinogens or may reasonably be anticipated to be carcinogens and (ii) to which a significant number of persons residing in the United States are exposed;

(B) information concerning the nature of such exposure and the estimated number of persons exposed to such substances;

(C) a statement identifying (i) each substance contained in the list under subparagraph (A) for which no effluent, ambient, or exposure standard has been established by a Federal agency, and (ii) for each effluent, ambient, or exposure standard established by a Federal agency with respect to a substance contained in the list under subparagraph (A), the extent to which, on the basis of available medical, scientific, or other data, such standard, and the implementation of such standard by the agency, decreases the risk to public health from exposure to the substance; and

(D) a description of (i) each request received during the year involved -

(I) from a Federal agency outside the Department of Health and Human Services for the Secretary, or

(II) from an entity within the Department of Health and Human Services to any other entity within the Department, to conduct research into, or testing for, the carcinogenicity of substances or to provide information described in clause (ii) of subparagraph (C), and (ii) how the Secretary and each such other entity, respectively, have responded to each such request.

(5) The authority of the Secretary to enter into any contract for the conduct of any study, testing, program, research, or review, or assessment under this subsection shall be effective for any fiscal year only to such extent or in such amounts as are provided in advance in appropriation Acts.

(c) Diseases not significantly occurring in United States

The Secretary may conduct biomedical research, directly or through grants or contracts, for the identification, control, treatment, and prevention of diseases (including tropical diseases) which do not occur to a significant extent in the United States.

(d) Protection of privacy of individuals who are research subjects

The Secretary may authorize persons engaged in biomedical, behavioral, clinical, or other research (including research on mental health, including research on the use and effect of alcohol and other psychoactive drugs) to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.

-SOURCE-

(July 1, 1944, ch. 373, title III, Sec. 301, 58 Stat. 691; July 3, 1946, ch. 538, Sec. 7(a), (b), 60 Stat. 423; June 16, 1948, ch. 481, Sec. 4(e), (f), 62 Stat. 467; June 24, 1948, ch. 621, Sec. 4(e), (f), 62 Stat. 601; June 25, 1948, ch. 654, Sec. 1, 62 Stat. 1017; July 3, 1956, ch. 510, Sec. 4, 70 Stat. 490; Pub. L. 86-798, Sept. 15, 1960, 74 Stat. 1053; Pub. L. 87-838, Sec. 2, Oct. 17, 1962, 76 Stat. 1073; Pub. L. 89-115, Sec. 3, Aug. 9, 1965, 79 Stat. 448; Pub. L. 90-174, Sec. 9, Dec. 5, 1967, 81 Stat. 540; Pub. L. 91-513, title I, Sec. 3(a), Oct. 27, 1970, 84 Stat. 1241; Pub. L. 91-515, title II, Sec. 292, Oct. 30, 1970, 84 Stat. 1308; Pub. L. 92-218, Sec. 6(a)(2), Dec. 23, 1971, 85 Stat. 785; Pub. L. 92-423, Sec. 7(b), Sept. 19, 1972, 86 Stat. 687; Pub. L. 93-282, title I, Sec. 122(b), May 14, 1974, 88 Stat. 132; Pub. L. 93-348, title I, Sec. 104(a)(1), July 12, 1974, 88 Stat. 346; Pub. L. 93-352, title I, Sec. 111, July 23, 1974, 88 Stat. 360; Pub. L. 94-278, title I, Sec. 111, Apr. 22, 1976, 90 Stat. 405; Pub. L. 95-622, title II, Sec. 261, 262, Nov. 9, 1978, 92 Stat. 3434; Pub. L. 96-88, title V, Sec. 509(b), Oct. 17, 1979, 93 Stat. 695; Pub. L. 99-158, Sec. 3(a)(5), Nov. 20, 1985, 99 Stat. 879; Pub. L. 99-570, title IV, Sec. 4021(b)(2), Oct. 27, 1986, 100 Stat. 3207-124; Pub. L. 99-660, title I, Sec. 104, Nov. 14, 1986, 100 Stat. 3751; Pub. L. 100-607, title I, Sec. 163(1), (2), Nov. 4, 1988, 102 Stat. 3062; Pub. L. 103-43, title XX, Sec. 2009, June 10, 1993, 107 Stat. 213.)

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AMENDMENTS

1993 - Subsec. (b)(4). Pub. L. 103-43 substituted "a biennial report" for "an annual report" in introductory provisions.

1988 - Subsec. (d). Pub. L. 100-607 redesignated concluding provisions of subsec. (a) of section 242a of this title as subsec. (d) of this section, substituted "biomedical, behavioral, clinical, or other research (including research on mental health, including" for "research on mental health, including", and substituted "drugs)" for "drugs,".

1986 - Subsec. (a)(3). Pub. L. 99-570 struck out "or, in the case of mental health projects, by the National Advisory Mental Health Council;" after "Department supporting such projects" and struck out "or the National Advisory Mental Health Council" after "appropriate entity of the Department". Subsec. (c). Pub. L. 99-660 added subsec. (c).

1985 - Subsec. (a)(3). Pub. L. 99-158, Sec. 3(a)(5)(A), substituted "as are recommended by the advisory council to the entity of the Department supporting such projects or, in the case of mental health projects, by the National Advisory Mental Health Council; and make, upon recommendation of the advisory council to the appropriate entity of the Department or the National Advisory Mental Health Council, grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research" for "as are recommended by the National Advisory Health Council, or, with respect to cancer, recommended by the National Cancer Advisory Board, or, with respect to mental health, recommended by the National Advisory Mental Health Council, or with respect to heart, blood vessel, lung, and blood diseases and blood resources, recommended by the National Heart, Lung, and Blood Advisory Council, or, with respect to dental diseases and conditions, recommended by the National Advisory Dental Research Council; and include in the grants for any such project grants of penicillin and other antibiotic compounds for use in such project; and make, upon recommendation of the National Advisory Health Council, grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research: Provided, That such uniform percentage, not to exceed 15 per centum, as the Secretary may determine, of the amounts provided for grants for research projects for any fiscal year

through the appropriations for the National Institutes of Health may be transferred from such appropriations to a separate account to be available for such research grants-in-aid for such fiscal year". Subsec. (a)(8). Pub. L. 99-158, Sec. 3(a)(5)(B), substituted "recommendations of the advisory councils to the appropriate entities of the Department or, with respect to mental health, the National Advisory Mental Health Council, such additional means as the Secretary considers" for "recommendation of the National Advisory Health Council, or, with respect to cancer, upon recommendation of the National Cancer Advisory Board, or, with respect to mental health, upon recommendation of the National Advisory Mental Health Council, or, with respect to heart, blood vessel, lung, and blood diseases and blood resources, upon recommendation of the National Heart, Lung and Blood Advisory Council, or, with respect to dental diseases and conditions, upon recommendations of the National Advisory Dental Research Council, such additional means as he deems".

1978 - Pub. L. 95-622 designated existing provisions as subsec. (a), redesignated former pars. (a) to (h) as (1) to (8), respectively, substituted "Secretary" for "Surgeon General" wherever appearing, and inserted following par. (8) provisions relating to authority of Secretary to make available to individuals and entities substances and living organisms, and added subsec. (b).

1976 - Subsecs. (c), (h). Pub. L. 94-278 substituted "heart, blood vessel, lung, and blood diseases and blood resources" for "heart diseases" and "National Heart, Lung and Blood Advisory Council" for "National Heart and Lung Advisory Council".

1974 - Subsec. (c). Pub. L. 93-348, Sec. 104(a)(1), redesignated subsec. (d) as (c) and substituted "research projects" for "research or research training projects" in two places, "general support of their research" for "general support of their research and research training programs" and "research grants-in-aid" for "research and research training program grants-in-aid". Former subsec. (c), authorizing Surgeon General to establish and maintain research fellowships in the Public Health Service with such stipends and allowances, including traveling and subsistence expenses, as he may deem necessary to procure the assistance of the most brilliant and promising research fellows from the United States and abroad, was struck out. Subsec. (d). Pub. L. 93-348, Sec. 104(a)(1)(C), redesignated subsec. (e) as (d). Pub. L. 93-282 substituted "mental health, including research on the use and effect of alcohol and other psychoactive drugs" for "the use and effect of drugs" in former concluding provisions of section 242a(a) of this title. See 1988 Amendment note above. Subsecs. (e), (f). Pub. L. 93-348, Sec. 104(a)(1)(C), redesignated subsecs. (f) and (g) as (e) and (f), respectively. Former subsec. (e) redesignated (d). Subsec. (g). Pub. L. 93-352 struck out "during the fiscal year ending June 30, 1966, and each of the eight succeeding fiscal years" after "Enter into contracts". Notwithstanding directory language that amendment be made to subsec. (h), the amendment was executed to subsec. (g) to reflect the probable intent of Congress and the intervening redesignation of subsec. (h) as (g) by Pub. L. 93-348. Pub. L. 93-348, Sec. 104(a)(1)(C), redesignated subsec. (h) as (g). Former subsec. (g) redesignated (f). Subsecs. (h), (i). Pub. L. 93-348, Sec. 104(a)(1)(C), redesignated subsecs. (h) and (i) as (g) and (h), respectively.

1972 - Subsecs. (d), (i). Pub. L. 92-423 substituted "National Heart and Lung Advisory Council" for "National Advisory Heart Council".

1971 - Subsecs. (d), (i). Pub. L. 92-218 substituted "National Cancer Advisory Board" for "National Advisory Cancer Council".

1970 - Subsec. (d). Pub. L. 91-513 added subsec. (d). See 1988 Amendment note above. Subsec. (h). Pub. L. 91-515 substituted "eight" for "five" succeeding fiscal years.

1967 - Subsec. (h). Pub. L. 90-174 substituted "five" for "two" succeeding fiscal years.

1965 - Subsecs. (h), (i). Pub. L. 89-115 added subsec. (h) and redesignated former subsec. (h) as (i).

1962 - Subsec. (d). Pub. L. 87-838 inserted "or research training" in two places.

1960 - Subsec. (d). Pub. L. 86-798 authorized the Surgeon General, upon recommendation of the National Advisory Health Council, to make grants to public or non-profit universities, hospitals, laboratories, and other institutions to support research and research training programs, and to make available for such research and research training programs, up to 15 per centum of amounts provided for research grants through the appropriations for the National Institutes of Health.

1956 - Subsecs. (g), (h). Act July 3, 1956, added subsec. (g) and redesignated former subsec. (g) as (h).

1948 - Subsec. (d). Acts June 16, 1948, Sec. 4(e), and June 24, 1948, Sec. 4(e), made provisions applicable to the National Advisory Heart Council and the National Advisory Dental Research Council, respectively. Subsec. (d). Act June 25, 1948, continued in basic legislation the authority to purchase penicillin and other antibiotic compounds for use in research projects. Subsec. (g). Acts June 16, 1948, Sec. 4(f), and June 24, 1948, Sec. 4(f), made provisions applicable to the National Advisory Heart Council and the National Advisory Dental Research Council, respectively.

1946 - Subsec. (d). Act July 3, 1946, made the National Advisory Mental Health Council the body to make recommendations to the Surgeon General on awarding of grants-in-aid for research projects with respect to mental health. Subsec. (g). Act July 3, 1946, gave National Advisory Health Council the right to make recommendations to carry out purposes of this section.

-CHANGE-

CHANGE OF NAME
"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in subsec. (a)(7), and "Department of Health and Human Services" substituted for "Department of Health, Education, and Welfare" in subsec. (b)(1), (3), and (4)(D)(I), (II), pursuant to section 509(b) of Pub. L. 96-88 which is classified to section 3508(b) of Title 20, Education.

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EFFECTIVE DATE OF 1978 AMENDMENT
Sections 261 and 262 of Pub. L. 95-622 provided that the amendments made by those sections are effective Oct. 1, 1978.

EFFECTIVE DATE OF 1974 AMENDMENT
Section 104(b) of Pub. L. 93-348 provided that: "The amendments made by subsection (a) (amending this section and sections 242a, 282, 286a, 286b, 287a, 287b, 287d, 288a, 289c, 289c-1, 289g, 289k, and heading preceding section 289l of this title) shall not apply with respect to commitments made before the date of the enactment of this Act (July 12, 1974) by the Secretary of Health, Education, and Welfare for research training under the provisions of the Public Health Service Act amended or repealed by subsection (a)."

EFFECTIVE DATE OF 1972 AMENDMENT
Amendment by Pub. L. 92-423 effective 60 days after Sept. 19, 1972, or on such prior date after Sept. 19, 1972, as the President shall prescribe and publish in the Federal Register, see section 9 of Pub. L. 92-423, set out as a note under section 218 of this title.

EFFECTIVE DATE OF 1971 AMENDMENT
Amendment by Pub. L. 92-218 effective 60 days after Dec. 23, 1971, or on such prior date after Dec. 23, 1971, as the President shall prescribe and publish in the Federal Register, see section 7 of Pub. L. 92-218, set out as a note under section 218 of this title.

FEMALE GENITAL MUTILATION
Pub. L. 104-134, title I, Sec. 101(d) (title V, Sec. 520), Apr. 26, 1996, 110 Stat. 1321-211, 1321-250; renumbered title I, Pub. L. 104-140, Sec. 1(a), May 2, 1996, 110 Stat. 1327, provided that:

"(a) Congress finds that –

"(1) the practice of female genital mutilation is carried out by members of certain cultural and religious groups within the United States; and

"(2) the practice of female genital mutilation often results in the occurrence of physical and psychological health effects that harm the women involved.

"(b) The Secretary of Health and Human Services shall do the following:

"(1) Compile data on the number of females living in the United States who have been subjected to female genital mutilation (whether in the United States or in their countries of origin), including a specification of the number of girls under the age of 18 who have been subjected to such mutilation.

"(2) Identify communities in the United States that practice female genital mutilation, and design and carry out outreach activities to educate individuals in the communities on the physical and psychological health effects of such practice. Such outreach activities shall be designed and implemented in collaboration with representatives of the ethnic groups practicing such mutilation and with representatives of organizations with expertise in preventing such practice.

"(3) Develop recommendations for the education of students of schools of medicine and osteopathic medicine regarding female genital mutilation and complications arising from such mutilation. Such recommendations shall be disseminated to such schools.

"(c) For purposes of this section the term 'female genital mutilation' means the removal or infibulation (or both) of the whole or part of the clitoris, the labia minor, or the labia major.

"(d) The Secretary of Health and Human Services shall commence carrying out this section not later than 90 days after the date of enactment of this Act (Apr. 26, 1996)."

SENTINEL DISEASE CONCEPT STUDY

Section 1910 of Pub. L. 103-43 directed Secretary of Health and Human Services, in cooperation with Agency for Toxic Substances and Disease Registry and Centers for Disease Control and Prevention, to design and implement a pilot sentinel disease surveillance system for identifying relationship between occupation of household members and incidence of subsequent conditions or diseases in other members of household, and required Director of the National Institutes of Health to prepare and submit to Congress, not later than 4 years after June 10, 1993, a report concerning this project.

STUDY OF THYROID MORBIDITY FOR HANFORD, WASHINGTON

Section 161 of Pub. L. 100-607, as amended by Pub. L. 102-531, title III, Sec. 312(e)(1), Oct. 27, 1992, 106 Stat. 3506, directed Secretary of Health and Human Services, acting through Director of Centers for Disease Control and Prevention, to conduct a study of thyroid morbidity of the population, including Indian tribes and tribal organizations, in vicinity of Hanford, in State of Washington, authorized Director to contract out portions of study, and required Director, not later than 42 months after Nov. 4, 1988, to transmit a report, including such study, to Congress, chief executive officers of States of Oregon and Washington, and governing officials of Indian tribes in vicinity of Hanford, Washington.

NATIONAL COMMISSION ON SLEEP DISORDERS RESEARCH

Section 162 of Pub. L. 100-607 directed Secretary of Health and Human Services, after consultation with Director of National Institutes of Health, to establish a National Commission on Sleep Disorders Research to conduct a comprehensive study of present state of knowledge of incidence, prevalence, morbidity, and mortality resulting from sleep disorders, and of social and economic impact of such disorders, evaluate public and private facilities and resources (including trained personnel and research activities) available for diagnosis, prevention, and treatment of, and research into, such disorders, and identify programs (including biological, physiological, behavioral, environmental, and social programs) by which improvement in management and research into sleep disorders could be accomplished and, not later than 18 months after initial meeting of Commission, to submit to appropriate Committees of Congress a final report, and provided for termination of the Commission 30 days after submission of final report.

RESEARCH WITH RESPECT TO HEALTH RESOURCES AND SERVICES ADMINISTRATION

Section 632 of Pub. L. 100-607 provided that with respect to any program of research pursuant to this chapter, any such program carried out in fiscal year 1987 by an agency other than Health Resources and Services Administration (or appropriate to be carried out by such an agency) could not, for each of fiscal years 1989 through 1991, be carried out by such Administration.

CONTINUING CARE FOR PSYCHIATRIC PATIENTS IN FORMER CLINICAL RESEARCH CENTER AT NATIONAL INSTITUTE ON DRUG ABUSE

Pub. L. 99-117, Sec. 10, Oct. 7, 1985, 99 Stat. 494, provided that: "In any fiscal year beginning after September 30, 1981, from funds appropriated for carrying out section 301 of the Public Health Service Act (this section) with respect to mental health, the Secretary of Health and Human Services may provide, by contract or otherwise, for the continuing care of psychiatric patients who were under active and continuous treatment at the National Institute on Drug Abuse Clinical Research Center on the date such Clinical Research Center ceased operations."

ANALYSIS OF THYROID CANCER; CREATION AND PUBLICATION OF RADIOEPIDEMIOLOGICAL TABLES

Pub. L. 97-414, Sec. 7, Jan. 4, 1983, 96 Stat. 2059, provided that:

"(a) In carrying out section 301 of the Public Health Service Act (this section), the Secretary of Health and Human Services shall -

"(1) conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the risks of thyroid cancer that are associated with thyroid doses of Iodine 131;

"(2) conduct scientific research and prepare analyses necessary to develop valid and credible methods to estimate the thyroid doses of Iodine 131 that are received by individuals from nuclear bomb fallout;

"(3) conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the exposure to Iodine 131 that the American people received from the Nevada atmospheric nuclear bomb tests; and

"(4) prepare and transmit to the Congress within one year after the date of enactment of this Act (Jan. 4, 1983) a report with respect to the activities conducted in carrying out paragraphs (1), (2), and (3).

"(b) (1) Within one year after the date of enactment of this Act (Jan. 4, 1983), the Secretary of Health and Human Services shall devise and publish radioepidemiological tables that estimate the likelihood that persons who have or have had any of the radiation related cancers and who have received specific doses prior to the onset of such disease developed cancer as a result of these doses. These tables shall show a probability of causation of developing each radiation related cancer associated with receipt of doses ranging from 1 millirad to 1,000 rads in terms of sex, age at time of exposure, time from exposure to the onset of the cancer in question, and such other categories as the Secretary, after consulting with appropriate scientific experts, determines to be relevant. Each probability of causation shall be calculated and displayed as a single percentage figure.

"(2) At the time the Secretary of Health and Human Services publishes the tables pursuant to paragraph (1), such Secretary shall also publish -

"(A) for the tables of each radiation related cancer, an evaluation which will assess the credibility, validity, and degree of certainty associated with such tables; and

"(B) a compilation of the formulas that yielded the probabilities of causation listed in such tables. Such formulas shall be published in such a manner and together with information necessary to determine the probability of causation of any individual who has or has had a radiation related cancer and has received any given dose.

"(3) The tables specified in paragraph (1) and the formulas specified in paragraph (2) shall be devised from the best available data that are most applicable to the United States, and shall be devised in accordance with the best available scientific procedures and expertise. The Secretary of Health and Human Services shall update these tables and formulas every four years, or whenever he deems it necessary to insure that they continue to represent the best available scientific data and expertise."

TERMINATION OF ADVISORY COMMITTEES

Pub. L. 93-641, Sec. 6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

-SECREF-

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 242, 242a, 254c, 263, 282, 284, 284f, 7610 of this title.

Attachment 2

Congressional Language Regarding CFS
2003—2006

Attachment 3

Questionnaire for Telephone Interview

Attachment 4

Follow-up Study Protocol

Attachment 5

60-Day Federal Register Notice

[Federal Register: October 25, 2006 (Volume 71, Number 206)]
[Notices]
[Page 62473-62474]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr25oc06-63]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-07-0638]

Proposed Data Collections Submitted for Public Comment and Recommendations

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 Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-5960 and send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an e-mail to omb@cdc.gov.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the

[[Page 62474]]

burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Follow-up Study of Chronic Fatigue Syndrome in Georgia--Reinstatement-0920-0638--Coordinating Center for Infectious Diseases (CCID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC is planning a follow-up study of Chronic Fatigue Syndrome (CFS) in metropolitan, urban and rural communities in Georgia. This is in response to Congressional recommendations that the Centers for Disease Control and Prevention (CDC) sustain efforts to identify biomarkers for CFS, educate health care providers about the diagnosis and treatment of CFS, and better inform the public about it to aid early detection and

improve patient care.

In 2004, OMB approved the information collection, Survey of Chronic Fatigue Syndrome and Chronic Unwellness in Georgia, under OMB Number 0920-0638. This study provided baseline information on CFS and other unexplained fatiguing illness in metropolitan, urban, and rural regions in Georgia. Data from the proposed Follow-up Study of Chronic Fatigue Syndrome in Georgia will be used to describe the clinical course of CFS and evaluate behavioral and biochemical factors associated with outcome. This follow-up study will also determine access to and utilization of health care by persons with CFS and measure direct and indirect economic burden due to the illness. As part of a control strategy, the information from this follow-up study will be used in national and pilot regional provider education programs designed to teach health care providers how to evaluate, diagnose and manage patients with CFS.

The proposed study builds on information from the Georgia survey with the objective of collecting clinical information that will help in the treatment of CFS and will help to interpret results obtained from testing biologic specimens (i.e., identify biomarkers of CFS). This follow-up study begins with a detailed telephone interview of persons who participated in the earlier survey and volunteered to be contacted again. The interview is similar (with minor modifications) to the original interview and is intended to obtain additional data on participant health status during the last twelve-month period. Eligible subjects with CFS, other fatiguing illnesses, and well controls will be asked to participate in clinical evaluations.

Estimated Annualized Burden Hours

Respondents	Number of Respondents	Number responses per respondent	Average burden/response in hours)	Total burden hours
Telephone interview	2,870	1	30/60	1,435
Clinical Evaluation	338	1	450/60	2,535
Total				3,970

Dated: October 19, 2006.
Joan F. Karr

Attachment 6

Advance Letter

Abt Associates Inc.

[DATE]

[NAME]
[ADDRESS]
[CITY, STATE, ZIP CODE]

Dear NAME:

I am writing to ask for your continued help with an important health study. Between 2004 and 2005, you took part in a study of fatiguing illness in Georgia. The Centers for Disease Control and Prevention (CDC) is conducting a follow-up research study. We appreciate your participation, and we would like to invite you to take part in the follow-up study.

The public health of the country is important to all of us. Thousands of people are limited in the amount of time they can spend at work or with family because of fatiguing illness. For that reason, CDC would like to learn more about the causes of fatiguing illness. This information may help in treating and preventing such illnesses.

Within the next few weeks, we will call you to conduct an interview. The interview will take about 20 minutes. It contains most of the questions asked during your last interview. We need to interview both fatigued and non-fatigued people. You may choose not to answer any question. All information you give will be kept private and used only in summary form.

More information about this study is on the back of this letter. If you have any questions about this study, or if your telephone number has changed since we last spoke with you, please call Abt Associates, toll-free, at 1-800-786-4816.

We hope you will agree to continue to be part of this important health study. Thank you in advance for your help.

Sincerely,

Scott W. Royal

Scott Royal
Project Director

What is the Centers for Disease Control and Prevention (CDC)?

CDC is sponsoring this research study of fatiguing illness. CDC, located in Atlanta, Georgia, is a federal agency responsible for protecting the health and safety of the nation. CDC studies health problems to treat and prevent illnesses.

What is Abt Associates?

CDC has chosen Abt Associates to conduct the interviews for this study. Since 1988, Abt Associates has helped CDC with many CFS studies. Abt Associates has telephone interviewers in Hadley, Massachusetts, and field staff across the US.

What is CFS?

CFS stands for chronic fatigue syndrome. CFS is a poorly understood illness. People with CFS have bad, long-lasting fatigue. This fatigue cannot be explained by another medical or psychiatric problem. They also have many other symptoms that their doctors cannot explain. The cause or causes of CFS have not been found. There is no test that can be given for CFS. CFS is diagnosed by ruling out other illnesses as the cause of the fatigue.

How long will the telephone interview take?

The interview should take about 20 minutes.

Can a friend or relative take my place?

Another person cannot take your place in this research study.

How can I find out more about fatiguing illnesses?

You can visit CDC's Chronic Fatigue Syndrome website: www.cdc.gov/ncidod/diseases/cfs

How do I know my information will be kept private?

Privacy is mandated by law. Only researchers at Abt Associates will know your name and other information that identifies you. They will not share this information with CDC. All staff at Abt Associates sign pledges of confidentiality. They may be fined and imprisoned if they reveal any private information.

Study results will be published only in summary form. US law requires that your name not be linked with any information you provide.

What happens if I change my mind about participating?

Your participation is voluntary. This means you can choose to take part or not. It also means that you can stop taking part at any time. If you want to stop being in this study, please let Abt Associates know. You may also tell the Abt Associates interviewer when he/she calls you.

Whom can I call to find out more about this study?

If you have more questions about this study, call Dr. Jim Jones at CDC. Dr. Jones' number is: 1-404-639-3748. Please note that calls to this telephone number may be toll calls.

If you have questions about your rights in this research study, please call CDC's Deputy Associate Director for Science, toll-free, at 1-800-584-8814. Please leave a brief message with your name and phone number. Be sure to say that you are calling about CDC protocol #4121. Someone will return your call as soon as possible.

Attachment 7A

Non-Contact Letter

[DATE]

[SUBJECT]
[ADDRESS]
[CITY, STATE, ZIP CODE]

Dear [SUBJECT],

In 2004 or 2005, you took part in a study of fatiguing illness in Georgia. The Centers for Disease Control and Prevention (CDC) is conducting a follow-up research study. We appreciate your participation. We would like to invite you to take part in the follow-up study.

The interview will take about 20 minutes. The interview contains most of the questions asked during your last interview. We are interviewing both fatigued and non-fatigued people.

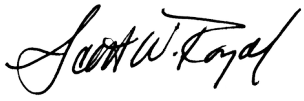
We have been trying to reach you by phone, but we have not been able to contact you. Within the next few days, an interviewer from Abt Associates will again call you. Abt Associates Inc. is the research firm CDC has hired to collect information for this study. If you want to call us at a more convenient time, our toll-free number is 1-800-786-4816.

I hope that you will help with this study. Thousands of people are limited in how much time they can spend at work or with family because of fatigue. The economic, social, and emotional costs of this illness are quite high. Because little is known about fatiguing illness, this study is very important. We need your help.

If you have any questions about your rights in this study, you may call the CDC Deputy Director for Science toll-free at 1-800-584-8814. Please leave a message, and your call will be returned. If you have any other questions about this research study, call Dr. Jim Jones at the CDC. Dr. Jones' number is: 1-404-639-3748. Please note that this call may be a toll call.

Thank you in advance for your help.

Very truly yours,



Scott Royal
Project Director

Attachment 7B

Refusal Letter

[DATE]

[SUBJECT]
[ADDRESS]
[CITY, STATE, ZIP CODE]

Dear [SUBJECT],

In 2004 or 2005, you took part in a study of fatiguing illness in Georgia. The Centers for Disease Control and Prevention (CDC) is conducting a follow-up research study. We very much appreciate your participation. We would like to invite you to take part in the follow-up study.

When our interviewer last called, you said that you did not want to continue to take part in this study. I am writing to ask you to reconsider. The interview will take about 20 minutes. It contains most of the questions asked during your last interview. We are interviewing both fatigued and non-fatigued people for this study.

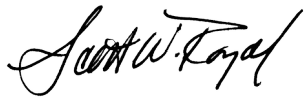
An interviewer from Abt Associates will call you in the next few days. Abt Associates Inc. is the research firm CDC has hired to collect information for this study. If you want to call us at a more convenient time, our toll-free number is 1-800-786-4816.

I hope that you will continue to help with this important study. Thousands of people must limit the time they can spend at work or with family because of fatigue. The economic, social, and emotional costs of this illness are quite high. Because little is known about fatiguing illness, this study is very important. We need your help.

If you have any questions about your rights in this study, you may call the CDC Deputy Director for Science toll-free at 1-800-584-8814. Please leave a message, and your call will be returned. If you have any other questions about this research study, call Dr. Jim Jones at the CDC. Dr. Jones' number is: 1-404-639-3748. Please note that this call may be a toll call.

Thank you in advance for your help.

Very truly yours,



Scott Royal
Project Director