Supporting Statement
For OMB Review and Approval of

Agency for Toxic Substances and Disease Registry (ATSDR)
Anniston Community Health Survey: Follow-up and Dioxin Analyses
(ACHS-II)

Part A. Justification

Date: October 2013

ATSDR Division of Toxicology and Human Health Sciences

Marian Pavuk, PhD, MD
Principal Investigator
Phone: 770-488-3671
Fax Number: 770-488-1537
Email: MPavuk@cdc.gov

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PART A. JUSTIFICATION

A.1. Circumstances Making the Collection of Information Necessary

This is a new Information Collection Request (ICR) for the Agency for Toxic Substances and Disease Registry (ATSDR) titled *Anniston Community Health Survey: Follow-up and Dioxin Analyses (ACHS-II)*. ATSDR is authorized to conduct the study under the 1980 Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), and as amended by the 1986 Superfund Amendments and Reauthorization Act (SARA) (Attachment 1). This proposed effort is funded under an Inter-Agency Agreement (CDC IAA#: 11AT100100, 12AT12-ANNISTON) between the National Institutes of Health (NIH) (procurer) and ATSDR (recipient).

The Agency requests Office of Management and Budget (OMB) approval for two years to complete this information collection.

Background

Polychlorinated biphenyls (PCBs) were manufactured at the former Monsanto facility in Anniston, Alabama, from 1929 to 1971. Releases into the air and water via volatilization, deposition into landfills, and migration into surface water led to substantial environmental contamination, human exposure and community health concerns, and ultimately litigation and settlement in state and federal court (Grunwald, 2001; Love, 2007).

From 2003 to 2007, the ATSDR funded the Anniston Environmental Health Research Consortium (AEHRC), a university and community partnership charged to plan and conduct the 2005-2007 Anniston Community Health Survey (ACHS) (Grant #U50/ATU473215). The initial consortium study found baseline serum PCB levels among 766 Anniston Cohort members that were three-to-seven-fold higher than among the general U.S. population, and that were positively associated with hypertension, elevated blood pressure, and diabetes in select Cohort subgroups (Goncharov et al., 2010, 2011, Pavuk et al., 2009a, Silverstone et al., 2012).

Currently, the ATSDR, the National Institutes of Health (NIH), and university investigators will conduct a cross-sectional research study as a follow-up to the 2005-2007 ACHS. Called the ACHS-II, its respondents will spend about 2 hours in the study. A sample of 500 respondents from the original ACHS Cohort will be recruited.

There are 209 possible PCB congeners that have different chemical and toxicological properties; based on their patterns of chlorination, PCB congeners may be classified as non-*ortho* (also called coplanar) PCBs or *ortho*-substituted PCBs. They can also be broadly classified based on their toxicological similarity with dioxins as dioxin-like or non-dioxin-like (Hansen, 1998). O*rtho*-

PCBs include both dioxin-like (mono-*ortho* PCBs) and non-dioxin-like (all other *ortho*-PCBs). Non-*ortho* coplanar PCB congeners (co-PCBs) are all dioxin-like.

The major goal of the ACHS-II is to obtain repeated measures, six to eight years after baseline, identical to the original panel of ACHS 35 *ortho*-PCB congeners. The original panel was selected because it represents the majority of steady-state and episodic PCB congeners that are found in humans (Hansen, 2001) and did not include non-*ortho* co-PCBs.

This new research aims to more fully assess exposures to both dioxin-like and non-dioxin-like PCBs and to complement them with the measurements of dioxins, furans, and related chemical compounds. This addition of dioxins and dioxin-like analytes is supported by evidence from a nested pilot study in the ACHS, where high levels of co-PCBs were found among a subset of 65 Cohort members (Pavuk et al., 2009b).

Additional exposure biomarkers, not previously assessed, will include heavy and trace metals, specifically lead, mercury, chromium, manganese, and selenium (Alissa et al., 2011; Hectors et al., 2011). Since 1917, this community has been the site of extensive lead pipe production, long-term presence of ferro-manganese smelters, as well as mercury use and releases from PCB production (Love, 2007). None of the metals was previously measured in the ACHS adults.

Questionnaire items for self-reported health, demographic, dietary, and lifestyle factors will be administered by personal interview. The reassessment of self-reported health outcomes will be complemented with objective measures of health in the form of clinical biomarkers. Biomarkers of clinical outcomes will include thyroid hormones, glycemic parameters, lipid profiles, and inflammatory and liver cytokines.

The 60-day Federal Register Notice of the proposed information collection (IC) was published on September 20, 2012 (Attachment 2) and is further discussed in Section A.8.

A.1.1. Privacy Impact Assessment

The following sections provide a program overview of the data collection system, the information to be collected, and a discussion on whether this IC will host a website.

Overview of the Data Collection System

An index to the six IC forms and a graphical representation of the data collection system (Information Flow Chart) is found on the cover page of Attachment 3. Each line in the estimated annualized burden table in Section A.12 reflects one of the six IC forms (denoted with "*" below). The ACHS-II IC will be implemented in four phases: recruitment; eligibility screening; enrollment and informed consent; and personal interviews.

The study population and eligibility requirements are detailed in Section B.1. In summary, the surviving ACHS Cohort members with PCB measurements will be asked to participate again in the ACHS-II to enroll a sample of 500 respondents.

1) *Recruitment:* Trained study staff will mail the Recruitment Information Packet (Attachment 3.1 - Invitation Letter, Attachment 3.2 – Study Factsheet) to ACHS Cohort members. A List of Chemicals (Attachment 3.2a), will be sent only if requested by the respondent.

2) *Eligibility Screening:* Eligibility requirements are discussed in Section B.1. The staff will use the Recruitment Telephone Script (*Attachment 3.3) to determine eligibility by computer-assisted telephone interview (CATI). The Survey for Refusals (*Attachment 3.4) will be administered by CATI to enable assessment for non-response bias.

   An appointment for the consent process and the personal interview will be scheduled at a choice of the CCHD, the West Anniston study office, or at a home visit. The Appointment Reminder Card (Attachment 3.5) with instructions for the appointment will be mailed. A few days before the appointment, trained staff will call to remind the eligible person of his or her appointment (Attachment 3.6 - Reminder Telephone Script).

   Recruitment and eligibility screening progress and final dispositions will be recorded by trained study staff (Attachment 3.7 – Recruitment Tracking Form).

3) *Consent and Enrollment:* Informed consent will be documented on a paper-and-pencil form (Attachment 3.8). Next, each respondent will be asked to update his or her contact information in a computer-assisted personal interview (CAPI) (*Attachment 3.9), if necessary, so that results reports will be mailed to an accurate address.

4) *Personal Interview:* The IC will be conducted by interview, clinical assessments, and blood collection for analytical measurements of specific contaminants. Each respondent will be asked to bring in all of his or her medications to be recorded on the paper-and-pencil Medications Form (*Attachment 3.10). Clinical assessments will be recorded on the paper-and-pencil Body and Blood Pressure Measures Form (Attachment 3.11). At the time of the blood draw, hardcopy screening questions for blood collection will also be completed (*Attachment 3.12 - Blood Draw Form). The Questionnaire will be administered by CAPI (*Attachments 3.13b and 3.13c). Appointment progress and data collection completion will be recorded by trained study staff (Attachment 3.14 – Appointment Tracking Form).

Items of Information to be Collected

Contact Information. Social Security Numbers (SSN) were not collected for the ACHS Cohort. For the ACHS-II recruitment activities, trained University of Alabama (UAB) study staff will abstract

IIF from ACHS records (name, address, phone number, date of birth, date of the ACHS interview, original ACHS study ID) to recruit, schedule appointments, obtain informed consent, and conduct interviews. An ACHS-II study identification number (ID) number will be assigned to each respondent. Contact information will be updated during recruitment as needed. The uses of IIF from the ACHS Cohort List or updated for the ACHS-II are noted by stage in the Information Flow Chart (Attachment 3 – Overview of Data Collection System).

Records of interview responses will be labeled with the ACHS-II study ID only. The following interview responses will be collected, processed, and stored in deidentified files: 1) *Medications* (*Attachment 3.10); 2) *Body Measurements* (Attachment 3.11); 3) *Blood Draw* (*Attachment 3.12); 4) *Questionnaire* (Attachments 3.13a, *3.13b, & *3.13c); and 5) *Laboratory Analytes*. Blood and serum specimens and analytical results will be labeled by study ID number only. Laboratory personnel will not see or have access to any records with IIF.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

No federal, UAB, or health department websites will be developed to collect information for the ACHS-II. No websites or website information are directed at children under 13 years of age. Respondents will be at least 18 years of age.

A.2. Purpose and Use of Information Collection

This will be a one-time data collection. Under contract with ATSDR (CDC Contract #: 200-2011-40834), trained study staff from the UAB will conduct the study along with subcontracted staff from the Calhoun County Health Department (CCHD) in Anniston, AL. ATSDR will provide support for project activities such as study design, sample collection, data analysis, and interpretation.

Analysis of biochemical specimens will be provided by laboratories from the Centers for Disease Control and Prevention (CDC) National Center for Environmental Health (NCEH), universities, and community medical centers. The laboratories will perform the analytical assays over the multiyear project period (Attachment 4.1). This table indicates the laboratory points of contact, Clinical Laboratory Improvement Amendments (CLIA) reference laboratories, CLIA approved laboratory procedures, the analytes to be reported, and blood specimen requirements.

The original ACHS examined and found relationships between health status with a limited panel of PCBs. The main research goals for the ACHS-II are: 1) to obtain repeat measurements of 35 *ortho*-PCBs; 2) to measure serum polychlorinated dibenzo-dioxins (PCDDs), polychlorinated dibenzo-furans (PCDFs), and co-PCBs; 3) to calculate the total dioxin toxic equivalents (TEQs); and to evaluate changes in health indicators, including obesity, since the baseline examination in 2005-2007.

The ACHS-II will re-examine the occurrence of diabetes, hypertension, thyroid disease, autoimmune diseases and other health outcomes with changes in *ortho*-PCBs since baseline. In addition to the *ortho*-PCBs, we propose to examine health status of Anniston residents in association with dioxin-like co-PCBs, PCDDs, and PCDFs, all not previously assessed. Measuring the full spectrum of these compounds is the only way to distinguish between dioxin-like and non-dioxin-like health effects of these toxic chemicals.

For the first time for the ACHS Cohort, study investigators also propose to assess polybrominated diphenyl ethers (PBDEs) and heavy and trace metals (lead, mercury, chromium, manganese, selenium). PBDEs were not manufactured in Anniston, but in the last 20 years, PBDES have become have become – like PCBs – ubiquitous persistent organic pollutants that bio-accumulate in the environment, bio-magnify up the food chain, and have been detected in significant amounts in animals and humans (Costa et al., 2008; Lorber, 2008; Schecter et al., 2004). Different PBDE formulations (penta-, octa-, deca-PBDEs), PBDE congeners (e.g. 47, 99, 153, 209), and their metabolites have been shown to have endocrine-disrupting effects, interacting with androgen, progesterone, estrogen, and thyroid receptors. PBDEs have been reported to decrease levels of total and free thyroxin in adult animals, while chronic exposure in rats and mice also targeted liver and kidneys (Costa et al., 2008). Mechanisms related to neurotoxicity of PBDEs and their hydroxylated metabolites have been described, including binding to thyroid hormone receptors and transport proteins, disruption of Ca^{2+} homeostasis, and modulation of GABA and nicotinic acetylcholine receptor function (Dingemans et al., 2011). There has been intensive study of human health outcomes related to exposures to brominated compounds in pregnancy and during prenatal, infant, and early childhood periods. Numerous recent studies reported on associations between PBDEs and neurodevelopmental (Gascon et al., 2012; Herbstman et al., 2010), reproductive (Abdelouahab et al., 2011; Harley et al., 2010; Main et al., 2007), and hormonal outcomes (Chevrier et al., 2010, 2011, Eggesbø et al., 2011; Leijs et al., 2012; Stapleton et al., 2011; Kim et al., 2013). To a lesser extent, environmental exposures to brominated flame retardants and hormone levels, atherosclerosis, diabetes and metabolic syndrome were also examined in studies of general populations (Lee et al., 2011; Lim et al., 2008; Lind et al., 2012; Turyk et al., 2008).

Anniston has been the site of extensive lead pipe production since 1917, has had a long-term presence of ferro-manganese smelters, and also mercury use and releases from PCB production. Environmental exposures to various heavy metals have been implicated in potentially contributing to the development of cardiovascular disease and diabetes, although the precise mechanisms of action and interactions with other environmental exposures remain to be elucidated (Alissa and Ferns, 2011; Hectors et al., 2011). We will study whether PBDEs and heavy metals could act as confounders or effect modifiers of potential associations between health outcomes and PCBs (Supporting Statement B, Section B.4.).

Reportable clinical tests, action levels, and comparison values in the form of normal ranges or interpretive guidelines are provided in Attachment 4.2. The reportable tests include: 1) thyroid tests; 2) glycemic parameters; 3) lipid profiles; 4) liver function tests; 5) heavy metals; and 6)

trace metals. Comparison values and action levels for the heavy metals are based on the 50th-to-95th percentiles from the National Health and Nutrition Examination Survey (NHANES); CDC/ATSDR guidelines, policies, and case definitions; or occupational standards. Until the time that NHANES reference ranges are released for blood manganese and for blood selenium, external clinical chemistry references will be used (see references in Attachment 4.2).

Reportable environmental chemicals (PCBs, dioxins, furans, pesticides, and PBDEs) are listed in Attachment 4.3. Reference ranges are based on the 50th-to-95th percentiles from the NHANES (http://www.cdc.gov/exposurereport/index.html).

A.2.1. Privacy Impact Assessment Information

Why this information is being collected. The data collected from this study will provide invaluable information on the current status of serum PCB levels in this community with historically high levels of environmental contamination. It will also provide informed estimates on whether serum PCB levels in this community have decreased, increased, or remained stable. In addition, a more complete assessment of current or ongoing exposures to PCBs is planned, to determine changes in congener profiles in respondents with and without a recognized chronic disease. This novel information will address important research questions not addressed in other environmental research studies. It will also inform mechanistic understanding of whether the causative agents of the adverse effects are the dioxin-like compounds including co-PCBs, or the non-dioxin-like *ortho*-PCBs. Enhancement of the proposed list of analytes and questionnaire items will create a more complete profile of community exposures to chemicals other than PCBs.

Most studies evaluate possible associations between persistent organic pollutants and diabetes, heart disease or other health outcomes using a single analytical measure of serum or adipose tissue. The study follow-up design provides advantages over a simple cross-sectional design in that actual measured change in many covariates of interest will be available, especially for the exposure variables. Having repeated measures available for PCBs and other chemicals of interest is the major strength of this follow-up study. Availability of repeated measures for clinical analytes is an additional strength, together with the previously unmeasured potential confounders (such as heavy metals, PBDEs, glycated hemoglobin, and auto-immune parameters). In addition, changes over time in body weight, BMI, and other health related variables can now be evaluated and tested.

Intended use of the information. The primary use of the ACHS-II data is for scientific research. This research will add to the weight of evidence about the potential impact of these classes of chemical exposures on human health, such as obesity, diabetes, heart, autoimmune, and thyroid disease. These associations have only been addressed in a few follow-up cohorts based in the United States (Turyk et al., 2009; Lee et al., 2010; Vasiliu et al., 2006; Wu et al., 2013), often as secondary analyses of data collected for other purposes. The scientific community may

examine peer-reviewed study findings from the ACHS-II for consistency with the results of different PCB studies and among different populations.

More immediate uses of the study findings will be to inform and educate Anniston residents further about their own exposure to PCBs, a more extensive panel of dioxins, furans, and dioxin-like chemicals, and a panel of heavy and trace metals. We will also share the results of further analyses and potential findings of associations between health outcomes and exposure to chemicals/metals with the Anniston community, clearly conveying the limits of the study for drawing causal conclusions on either an individual or population level.

Collection of information in identifiable form. As previously described in Section A.1, IIF will be collected, managed, and stored by the UAB in their already established record system. The IIF will also be a deliverable to the ATSDR. UAB and ATSDR will use IIF for the purposes of sampling, screening, recruitment, and results reporting to respondents. For the ACHS-II records, ATSDR will be the final recipient of the IIF (to keep for potential re-contacting of respondents).

The UAB will deliver all field-collected records to the ATSDR at the end of the study. IIF such as name, current address, phone number, date of birth, date of the ACHS interview, the original ACHS study ID number will be retained. Date of the ACHS-II interview and assigned ACHS-II study ID number will be stored along with all IIF in a separate master key dataset. IIF will not be linked with files used for statistical analysis and will not appear in any reports generated from this data set.

Impact on privacy. Because the UAB will collect, store, manage, and maintain IIF on their already established record system, there would be a likely effect on the respondent's privacy if a breach of data security occurred. Therefore, its established record system has stringent safeguards in place as described in Section A.10.

For ATSDR, research datasets will include only deidentified information that might be considered sensitive, such as pregnancy status in the past year among female respondents or sensitive questions on reproductive outcomes, fertility, or fecundability. These files will not have associated information that might directly identify these respondents. IIF will be stored in a separate master key dataset, which will enable investigators to link the respondent's research data with his or her IIF. Maintaining this contact information is necessary to provide results of the tests or re-contact them. Therefore, after delivery of data to the ATSDR, the data will become part of the Privacy Act System of Records Notice (SORN 09-19-0001 – "Records of Persons Exposed or Potentially Exposed to Hazardous Substances"). Stringent data security measures will be in place, including administrative, physical, and technical controls as described in Section A.10.

Data Sharing. De-identified research datasets will be available to all study investigators listed in Table 1. We will de-identify the datasets by removing the following: date of birth, address, former address(es), phone number, date of the ACHS interview, and the original ACHS study ID

number. Social security numbers were not collected in original ACHS and will not be collected in ACHS II either. Age will replace date of birth because it is the necessary variable in exposure and health outcome analyses.

There will be no public use dataset. Release of the de-identified data to outside investigators will have to be approved by both the ATSDR PI and the lead co-investigator at NIH (Dr. Linda Birnbaum). A data use agreement (DUA) will be prepared, detailing the condition of use of the data and proposed analyses for each outside project. The DUA condition of use will specify that: 1. Our data cannot be merged with public data in such a way that individuals may be identified; 2. Our data cannot be enhanced with public data sets with identifiable, or potentially identifiable, data; 3. One of the study investigators listed in Table 1 must be a co-investigator on any outside research project to guarantee adherence to the agreed conditions of use; 4. Each data release will be cleared by a specific IRB request to the investigator's home institution prior to data release.

After the approved project with the outside researchers is completed, further or secondary analyses of electronic datasets will not be permitted and can only be undertaken with additional approval(s). Written confirmation of understanding the conditions of use will be required from the lead scientist and institution. Copies of statistical code and datasets used in statistical analyses by the outside investigators will be kept by ATSDR/NIH.

A.3. Use of Improved Information Technology and Burden Reduction

This IC will use a variety of IC modes to assure data quality and to reduce burden. The estimated annualized burden for this IC is 226 hours (see Section A.12). Of these hours, an estimated 91.2% percent of the total burden hours for this IC will be collected by electronic reporting. The following forms will be administered by CATI: Recruitment Telephone Script (Attachment 3.3) and Survey for Refusals (Attachment 3.4). The following forms will be administered by CAPI: Update Contact Information Form (Attachment 3.9) and Questionnaire (Attachment 3.13). The following IC forms will be administered by paper-and-pencil: Medications Form (Attachment 3.10), and Blood Draw Form (Attachment 3.12).

Under its contract with the ATSDR, the UAB offers its established information and research technology services through its Survey Research Unit (SRU – see http://www.uab.edu/cores/survey-research-unit). As part of the university's Research Core Facilities, the SRU mission is to produce scientifically valid survey results to achieve research goals. For this IC, UAB will provide expertise in survey design, interviewing, and reporting from CATI stations, field-based face-to-face interviewing, and mailing and recruitment services.

For both CATI and CAPI, trained SRU interviewers will ask each question and will record responses using portable or desktop personal computers. Responses will be recorded using computer-assisted personal and telephone interview (CAPI & CATI) software (WinCati,

Sawtooth Technology, Northbrook, IL. See (see general information at http://www.sawtooth.com/index.php/software/products/wincati/ and privacy policy at http://www.sawtooth.com/index.php/site-information/privacy-policy/). The software application is a custom suite of HyperText Markup Language (HTML) tools created by the Multimedia Information Technology Services of UAB's School of Public Health.

UAB developers will program skip logic and editing functionality such as field restrictions and automatic validity checks to help ensure data quality and minimize missing data. The CATI and CAPI data methods will also eliminate question sequencing errors. It will improve respondent reporting and reduce the number of data errors especially since responses to a large number of potential questions regarding food consumption will not apply to every respondent. Using the CATI and CAPI, the interview will be automatically tailored to each specific individual.

Interviewers will conduct interviews with respondents using tablet computers. Data collected will be immediately uploaded and stored on secure servers housed within UAB's School of Public Health. No interview data will remain on the tablet computers. A small supply of paper questionnaires will be maintained for use in case of unforeseen computer problems. However, it is not expected that paper-based questionnaire administration will be required.

Study information will be entered in the study dataset by the trained interviewers following the checks and quality control procedures for data entry. Only the authorized UAB SRU personnel will be allowed to manipulate the study data to prepare the study datasets. Data from hardcopy documents will be double entered with discrepancies compared and corrected.

UAB will prepare draft datasets to record response rates and questionnaire responses to send to ATSDR for review and approval. UAB will also keep and deliver a shipping log of blood samples sent to the CDC laboratory in Microsoft Excel format. The log will include the include vial type, volume, ID code, date, and carrier details. Lab results will be delivered to ATSDR by the participating laboratories. The lab dataset will be merged by study ID with the questionnaire data to create a combined questionnaire and lab dataset. UAB will work with ATSDR to resolve missing values.

Consent forms that collect the signature of respondents will be paper instruments and a copy will be given to each respondent. Height, weight, and other applicable body measures and blood pressure will be recorded on a paper form and transferred to an electronic form. Data on medication use will be collected directly in electronic format using a CATI.

A.4. Efforts to Identify Duplication and Use of Similar Information

The ATSDR efforts to identify duplication of the proposed IC included attendance at national meetings, and consultations with state and other agencies and community representatives. Based on information gathered from these activities, ATSDR worked with the NIH and its other

key personnel to develop the study design, data collection methods, and privacy protections. The following table presents the ACHS-II research team.

Table 1. Investigators and Key Study Personnel

Name	Affiliation
PRINCIPAL INVESTIGATORS	
Marian Pavuk, MD, PhD	ATSDR – Principal Investigator; Senior Epidemiologist
Stephen Mennemeyer, PhD	UAB – Co-Principal Investigator; Professor, School of Public Health
CO-INVESTIGATORS	
Linda Birnbaum, PhD, DABT, ATS *	NIH – Investigator; Director, NIEHS/NTP
Paul Wolff	UAB – Research Coordinator
Paul Jung, MD, MPH, MBA, MA *	NIH – Chief of Staff, NIEHS
Mike Sanders, PhD, DABT *	NIH – Director, NCI Laboratory of Toxicology and Toxicokinetics
Stephanie Davis, MSPH	ATSDR, Epidemiologist
Michael Lewin, MS	ATSDR, Mathematical Statistician
COLLABORATORS (UNDER CONTRACT)	
Lori Bell	Calhoun County Health Department - Director (UAB subcontract)
Andreas Sjödin, PhD *	CDC NCEH Division of Laboratory Sciences
Kathleen Caldwell, PhD *	CDC NCEH Division of Laboratory Sciences
Matt Cave, MD *	University of Louisville, Louisville, KY
Santica Marcovina, PhD *	Northwest Lipid Metabolism and Diabetes Research Laboratories, Seattle, WA
Arlon Sheffield *	Jacksonville Medical Center, Jacksonville, AL
Allen Silverstone, PhD *	SUNY Upstate Medical Center, Syracuse, NY
Carol Spencer, PhD *	University of Southern California, Los Angeles, CA
CONSULTANTS	
Scott Bartell, PhD *	University of California Irvine, Irvine, CA
Christie Shelton, PhD *	Jacksonville State University, Jacksonville, AL

* Will not receive IIF; will handle deidentified specimens or records only

Since 2008 when the first results from the ACHS were presented at the Anniston Community Meeting and at the 6th PCB Workshop organized by the University of Iowa, the need for an extended panel of contaminants was discussed. When the additional results on hypertension were presented at the 2009 International Dioxin Symposium, the idea of a follow-up study was discussed for the first time in view of the strong associations reported for hypertension and blood pressure. Investigators from NIH, ATSDR, and various academic institutions were involved in comprehensive discussion related to undertaking such complex effort.

The following year, ATSDR investigators organized a special session on Anniston at the 2010 International Dioxin Symposium in San Antonio, TX. The symposium also included face-to-face meetings and discussions with consultants and other stakeholders interested in evaluating the need and possibility for an Anniston follow-up study. These consultations with NIH and other investigators familiar with the design and results of the ACHS continued over the course of 2011 when the first steps were taken in the development of design, protocol, and analytical plans for the proposed study. UAB investigators involved in the first Anniston study were consulted over

possible collaboration on the follow-up study. Several factors were crucial to the planning efforts. These included the close relationship developed with the Anniston community and their representatives during the ACHS. Many years were spent interacting with the community through community meetings, personal communications, and radio programs. In addition, during these years, community representatives were involved in agency presentations, briefings, and discussions.

EPA cleanup efforts in Anniston also provide a background to the ATSDR study activities. Consultation with EPA on the ongoing activities in Anniston as well as participation at the EPA community meetings helped to identify study goals and priorities.

Table 2. ATSDR External Consultations

Name	Affiliation	Phone	Email
OUTSIDE CONSULTANTS			
John Schell	Exponent	(832) 325-5703	jshell@exponent.com
ACADEMIC INSTITUTIONS			
Allen Silverstone, PhD	SUNY Upstate Medical University	(518) 402-7800	ajf01@health.state.ny.us
Jim Olson	SUNY Buffalo	(717) 787-9614	tbarron@state.pa.us
Scott Bartell, PhD	University of California Irvine	(608) 266-1253	anderha@dhfs.state.wi.us

Since 2009, ATSDR has also had ongoing consultations with CDC laboratory scientists to determine appropriate sample collection and analytical methods, and choice of analytes. The CDC NCEH Division of Laboratory Sciences (DLS) produces periodic biomonitoring reports and national reference values on the U.S. general population exposure to environmental chemicals, such as the *Fourth National Report on Human Exposure to Environmental Chemicals 2009* (CDC, 2009) and the *Updated Tables, February 2011* (see http://www.cdc.gov/exposurereport).

Table 3. Consultations with CDC NCEH Laboratories

Name	Affiliation	Phone	Email
Kathleen Caldwell, PhD	Inorganic and Radiation Toxicology Branch	(770) 488-7990	kcaldwell@cdc.gov
Antonia Calafat, PhD	Organic Analytical Toxicology Branch	(770) 488-7891	acalafat@cdc.gov
Andreas Sjodin, PhD		(770) 488-4711	asjodin@cdc.gov
Wayman Turner, PhD		(770) 488-7974	wturner@cdc.gov

Ongoing Consultations with Other Analytical Laboratories. Associations with diabetes reported in the ACHS results warranted repeated measures of a glycemic panel. In consultation, glycated hemoglobin was added to the list of analytes. A more extensive lipid profile was also suggested in light of results related to blood pressure and hypertension where lipid lowering medications were noted effect modifiers. The addition of phospholipid and free fatty acids were suggested to better estimate total lipid concentrations; they would also better account for poor diabetes

control. New markers of inflammation and liver damage were identified in relation to PCB exposures; therefore, these were discussed in detail as possible biomarkers in this study. Repeated measurements of thyroid hormones and antibodies were also discussed as crucial in relationship to exposures to PCBs and other dioxins. The same analytical laboratory, USC, was engaged in the ongoing discussion about the analytical plans for the ACHS-II. Attachment 4 presents the analytical plan for the ACHS-II.

Table 4. Consultations with External Laboratories

Name	Affiliation	Phone	Email
Carol Spencer, PhD	University of Southern California	(626) 993-2809	cspencer@usc.edu
Matt Cave, MD	University of Louisville	(502) 852-5252	matt.cave@louisville.edu
Santica Marcovina, PhD, ScD	Northwestern Lipid Research Laboratory	(206) 685-3331	smm@u.washington.edu
Arlon Sheffield	Jacksonville Medical Center Clinical Biochemistry Laboratory	(256) 782-4196	Arlon.Sheffield@JMCHealth.com
Allen Silverstone, PhD	State University of New York Upstate Medical University	(315) 464-5440	silversa@upstate.edu

For the most part, the same laboratories will perform the analyses of the same specific analytes [PCBs and pesticides – NCEH/Division of Laboratory Sciences; thyroid tests – University of Southern California (USC), Clinical Laboratories Endocrine Services; glycemic parameters – Northwest Lipid Metabolism and Diabetes Research Laboratories (NWLRL); autoimmune parameters – SUNY Upstate Medical University; Attachment 4.1].

Because we expanded the lipid profiles, adding phospholipids and free fatty acids to more precisely adjust for total lipid levels and diabetes-related changes, NWLRL will now perform these tests instead of Jacksonville Medical Center Clinical Biochemistry Laboratory (JMC). The results of total cholesterol, triglycerides, and HDL and LDL cholesterols should be comparable between two Clinical Laboratory Improvement Amendments (CLIA)-certified laboratories. We can also adjust for the inter-laboratory variability in the statistical analyses.

New laboratory analytes include dioxins, furans, and co-PCBs (NCEH/Division of Laboratory Sciences), polybrominated diphenyl ethers (NCEH/Division of Laboratory Sciences), heavy and trace metals (NCEH/Division of Laboratory Sciences), standard liver tests (JMC), and inflammatory and liver cytokines (University of Louisville).

The ATSDR is also providing a review of existing reports and publications related to the Anniston PCB site, including the results of the ACHS. Although the ACHS previously provided a one-time cross-sectional picture of PCBs and health in Anniston, AL, no similar data on repeated measures in this uniquely exposed community currently exists. In particular, this study aims to examine the relationship between health and a much more complete panel of chemical

exposures than before. This new information will enable a more detailed examination of the association between health and toxic exposures.

To evaluate whether PCB levels in residents of Anniston were elevated, ATSDR sampled 103 volunteers in Anniston in 1995 (ADPH, 2001). The volunteers were selected based on the proximity of their residences to the plant. Ten milliliters of blood were collected, and analyses were conducted by the Pacific Toxicology Laboratory. PCB blood levels (total PCBs based on Aroclor standards) ranged from non-detected (<5 ppb) to 303 ppb (ng/g whole weight). Thirty-one of 103 persons had undetectable levels; 28 people had levels above 20 ppb; and 5 persons had levels above 100 ppb. Age was a major determinant of PCB levels, with 61% of those above 50 years of age having levels above 20 ppb while no person below 28 years of age had PCB levels above 20 ppb.

Data collected between 1996 and 1998 from over 3,000 plaintiffs in one of the litigation efforts in Anniston (Abernathy vs. Monsanto) were submitted for ATSDR review in 1999 (ATSDR, 2000). Almost half of the samples were below the detection limit (3 to 5 ng/g whole weight), the remaining samples had measured PCB levels. Samples were analyzed as total PCB based on Aroclor standards by the LabCorp laboratory in Burlington, North Carolina. Over 17% of the subjects had PCB levels above 20 ppb (ng/g whole weight). Data verification and quality control procedures, if any, were not described in the dataset provided to the agency. In a smaller study by Hansen et al. (2003), authors identified up to 47 PCB congeners or pair of congeners in one or more of the 12 blood samples collected from Anniston residents in 2000. The sum of these PCBs ranged from 0.68 ng/g whole weight in an 8 year old child to 71.6 ng/g whole weight in a 69-year old female.

All of the above studies were non-systematic, using a convenience sample or volunteers and did not collect any information (other than age) on variables that may confound the assessment of exposure. No exposure data other than PCBs were collected other than in only a few individuals. No follow-up data or repeated measurements of PCBs or other contaminants exist in this population.

The results of exposure investigations that documented the presence of elevated levels of PCBs in some Anniston residents and in various environmental matrices caused community concerns over potential health effects due to PCBs exposure. In response to those concerns and following congressional hearings, the ATSDR funded the Anniston Consortium to conduct exposure and health studies in Anniston, which became known as the ACHS.

The ACHS was the first opportunity to collect health outcome data among Anniston residents. It was the first time that hypertension (Goncharov et al., 2010), blood pressure (Goncharov et al., 2011) and type 2 diabetes were shown to be associated with PCB exposures in this population (Silverstone et al., 2012). This current study represents a unique opportunity to obtain longitudinal data in this sample of Anniston residents that can contrast the change in PCB levels

with newly developed and prevalent health outcomes. It is also an opportunity to evaluate confounding with a more focused collection of risk factor information

A.5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this data collection.

A.6. Consequences of Collecting the Information Less Frequently

The ACHS-II is a one-time data collection. There are no legal obstacles to reduce the burden.

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

This request fully complies with the regulation 5 CFR 1320.5.

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

A. 60-day Federal Register Notice was published on September 20, 2012, Vol. 77, No. 183, pp. 58394-5 (Attachment 2). No comments or inquiries were received during the public comment period.

B. In addition to the consultations discussed in Section A.4, the ATSDR consulted with subject matter experts from appropriate state agencies and programs in Alabama on various topics related to the development of the ACHS-II questionnaire and for heavy metals reporting requirements. These consultations were crucial, as detailed information on dietary exposures to environmental chemicals was not collected in the first Anniston survey.

Table 5. Consultations with Alabama State Agencies

Name	Title	Phone	Email
ALABAMA DEPARTMENT OF PUBLIC HEALTH (ADPH)			
Karon C. Lewis, MS, MPH	Adult Blood Lead Epidemiology and Surveillance (ABLES-CDC NIOSH)	(334) 206-2026	karon.lewis@adph.state.al.us
John A. Guarisco, Ph.D.	Environmental Toxicology	(502) 852-5252	john.guarisco@adph.state.al.us
ALABAMA DEPARTMENT OF CONSERVATION AND NATURAL RESOURCES (ADCNR)			
William C. Nichols	Division of Wildlife & Freshwater Fisheries	(334) 242-3883	Nick.Nichols@dcnr.alabama.gov
David Hayden	Division of Wildlife & Freshwater Fisheries	(334)242-3469	David.Hayden@dcnr.alabama.gov
ALABAMA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT (ADEM)			
Michael Len	Aquatic Assessment Unit	(334) 260-2787	mlen@adem.state.al.us

In 2012, questionnaire items on fish, game, and wildlife were developed with input from Alabama Department of Public Health (ADPH), Alabama Department of Conservation and Natural Resources (ADCNR), and the Alabama Department of Environmental Management (ADEM). Particular focus was placed on the assessment of consumption of locally grown foods, wildlife, and game from the Coosa River Basin, the site of the greatest source of environmental PCB contamination.

ATSDR contacted environmental toxicology staff from the ADPH Division of Epidemiology to develop the diet module for the questionnaire. In particular, ATSDR sought advice on the dietary assessment of fish and wildlife. Fish and shellfish intake questions will be used to assess relationships between past-week and past 12-month dietary habits with chemical analytical measures. Dietary fish modules are designed for consistency with Alabama Department of Public Health advisories on cooking and cleaning methods.

ATSDR contacted ADEM environmental scientists to understand the patterns of ecological PCB and mercury monitoring data in Alabama lakes, rivers, and streams collected by the ADEM. The ADPH and the ADEM use this state monitoring information to develop fish advisories throughout the state, and in particular for the Anniston area. In this manner, ATSDR developed the questionnaire items for the relevant Alabama river basins where PCB contamination was greatest.

ATSDR contacted the ADCNR fisheries staff to identify the appropriate wild caught fish species most likely to be consumed from Alabama waters. In addition, state experts were consulted on wild fowl and wildlife most likely to be hunted and consumed by Alabama sportsmen. In particular, ADCNR advised ATSDR about migratory vs. resident species of wild fowl, and their aquatic vs. terrestrial habitats.

Because of the proposed inclusion of heavy and trace metals, ATSDR contacted ADPH staff in the Division of Epidemiology to learn about the state's reporting requirements for adult blood lead surveillance. These state-and-CDC reporting practices were taken into consideration in the development of reporting thresholds for respondent results from the analytical labs. As part of the CDC NIOSH ABLES program, following this advice assured that consistency with guidance from CDC/ATSDR environmental programs was achieved (Attachments 4.2 & 4.3).

A.9. Explanation of Any Payment or Gift to Respondents

As a token of thanks for respondents' interest and for their willingness to participate, a $100 gift card will be offered to each respondent who takes part in both the interview and the blood draw. This token of appreciation is recommended for a number of reasons.

First, the population is extremely fatigued, yet the longitudinal design of this research design does not allow for replacement respondents from the general public. If the cohort members refuse to be involved, we have no way of replacing these individuals.

Second, the size of the incentive is designed to motivate the respondent to travel to the clinic, as well as cover travel costs.

Third, the questionnaire is more extensive questionnaire than administered in the ACHS. Some respondents may spend more time on these questions based on their personal histories. The ACHS-II includes detailed questions on health and reproductive history information, physical activity, weight loss or gain, personal behaviors, work, and hobbies. The ACHS-II includes a more extensive exposure history such as patterns of dietary intake, cooking practices, and sources of local foods.

Fourth, the study exam includes anthropometric and blood pressure measurements, as well as a detailed review of all current medications (Attachment 3.13).

Fifth, due to the extensive number of analytical measurements, the respondents will be asked to provide an amount of blood (125-mL) that is larger than most other biomonitoring studies.

If the respondent does not provide a blood sample but does participate in the interview (questionnaire and other clinical measuremnets), a $50 gift card will be offered. Offering a $50 gift card for this part of the information collection is consistent with the justification above – even without the blood sample, the respondent information obtained via qusitonnaire and clinical measurements is critical, and the fatigued population needs an incentive to travel to participate. Likewise, for choosing to take part only in the blood draw, a $50 gift card will be offered.

Payments will be documented on the Appointment Tracking Form (Attachment 3.14).

A.10. Assurance of Confidentiality Provided to Respondents

A.10.1. Privacy Impact Assessment Information

This supporting statement is taking the place of a full privacy impact assessment. The Office of the Chief Information System Security Officer has reviewed the subject Request for Proposal Statement of Work (RFP/SOW). The requested Information Technology (IT) Security and Privacy clearances were granted on 03/25/2012. It was determined that the Privacy Act is applicable. The pertinent system of records notice (SORN) is 09-19-0001, “Records of Persons Exposed or Potentially Exposed to Hazardous or Toxic Substances.” ATSDR has contracted with the UAB who will recruit and enroll members of the ACHS Cohort to conduct the study. Respondents will

be informed of test results at the conclusion of the study; hence, full names and addresses must be maintained. Other items of IIF such as phone number and date of birth are also needed. Privacy measures will be in place as described in the administrative, physical, and technical control sections. Paramount is the use of a study ID on data collection instruments, IIF being kept separately from the questionnaire responses, with access to the master key dataset strictly limited to a small number of authorized study personnel. The link will be maintained by both the UAB and the ATSDR during the study.

As part of the human subjects protections, the respondent will be informed that provision of information is voluntary in invitational materials (Attachment 3.2) and during informed consent. Written informed consent will be obtained on the day of the respondent's appointment (Attachment 3.8 – Informed Consent Form).

The ATSDR PI and the UAB project director will be responsible for all required staff training and certification, periodic checks of procedures and data collection methods, privacy, and security of data, as well as the access of authorized personnel and contractors to different types of data. For this IC, all study staff will be under the direct supervision of the UAB on-site supervisor. Under a subcontract with the UAB, the CCHD will supply office space at the health department for interviews, clinical assessments, and blood draws. For the convenience of the respondent, the UAB will also set up a satellite study office in West Anniston. The UAB will hire and assign its own staff to conduct the interviews. The CCHD nurses will be detailed to the UAB to do the clinical assessments and the blood draws. The CCHD nurses will accompany the UAB interviewers for the at-home interviews for those who cannot come to either the CCHD or the West Anniston study office. At the end of each day, all study records and blood samples will be transported to the CCHD study office for secure storage and processing.

At UAB, electronic system security is, at a minimum, maintained via tiered permissions based on individual and group settings, centrally enforced password policy requiring complex passwords that must be changed on a periodic basis, centrally managed desktop and server antivirus packages, desktop firewalls, and at-least-twice-daily backups of all server based storage. UAB Information Technology (IT) provides intrusion detection, twice daily vulnerability scans of all personal computers and a campus firewall service. Pretty Good Privacy (PGP) is a data encryption and decryption computer program that provides cryptographic privacy and authentication for data communication. Per UAB policy, university departments are responsible for controlling laptop security, their drives must be encrypted using PGP. Individual desktop personal computers are physically secured and have encrypted hard drives using PGP All information stored on desktop computers used on behalf of ATSDR shall be secured either through a Federal Information Processing Standard (FIPS) 140-2 compliant encryption solution or through adequate physical security and operational controls at the desktop's residing location. All mobile devices, portable media and transfer data files (including e-mail attachments) that contain sensitive information shall be encrypted according to FIPS 140-2 as well.

Once collected from the respondents, all hardcopy informed consents and data collection forms will be stored in locked files in locked rooms in secure facilities at the Anniston study offices and at UAB.

Upon receipt of the study information, data security at CDC/ATSDR will be maintained in compliance with the CDC/ATSDR Protection of Information Resources Policy and the CDC/ATSDR IT Security Program Implementation Standards. These policies apply to all authorized ATSDR employees and contractors.

Physical controls – CDC/ATSDR issues identity credentials based on the Federal Information Processing Standards (FIPS) Publication 201 for Personal Identity Verification (PIV) authentication of government employee and contractor identities. Security measures for physical access to secured facilities include the use of PIV Cards, security guards, and closed circuit TV monitoring.

Technical Controls – CDC/ATSDR policy requires employees to gain authorized logical access to its information systems through a unique electronic identity (User ID). The computer-controlled limits on what can be done by the user are assigned based on program roles and privilege requirements.

Administrative Controls – Only a limited number of authorized study personnel at either contractor or ATSDR sites will have access to the IIF. Authorized CDC/ATSDR employees and contractors are required to:

- Complete required privacy and information security refresher training.
- Read, acknowledge, sign (if online completion is not available), and comply with the HHS Rules of Behavior, as well as other applicable CDC/ATSDR- and system-specific rules of behavior before gaining access to the CDC/ATSDR's systems and networks.
- Adhere to the requirements set forth in the CDC/ATSDR IT Security Program Implementation Standards, and other security policies and procedures that minimize the risk to CDC systems, networks, and data from malicious software and intrusions.
- Abide by all applicable acceptable use policies and procedures regarding use or abuse of CDC/ATSDR IT resources.

All study records are subject to the ATSDR Comprehensive Record Control Schedule (CRCS), B-371, which contains authorized disposition instructions for ATSDR's administrative and program records. ATSDR is legally required to maintain its program-related records in accordance with disposition instructions contained in this comprehensive records control schedule. These retention periods have a direct impact on completing Freedom of Information Act requests and in applying the requirements of the Privacy Act.

Institutional Review Board Approval. The research protocol for the proposed data collection was submitted to the CDC and the UAB IRBs. IRB approval was received on 12/10/2012 and on 12/13/2012 from the respective institutions. On 02/20/2013, the NIH reliance agreement with

CDC was executed; therefore, the CDC IRB approval memo was updated on 02/21/2013 to reflect that all research partners were subject to appropriate human subjects regulatory oversight (Attachment 5).

A.11. Justification for Sensitive Questions

Reproductive Outcomes. Men and women will be asked about problems with fertility and pregnancy outcomes (Attachment 3.13b). These questions may be considered embarrassing. During informed consent, trained study staff will advise respondents that they may choose not to answer any questions they wish (Attachment 3.8). They will be trained to ask these questions in a very sensitive manner.

This information is needed to assess the relationship between exposure to PCBs and fertility and other reproductive outcomes in the Anniston cohort. These adverse reproductive outcomes have been previously reported among other PCB and dioxin exposed populations living in other parts of the world (Balabanic et al., 2011; Pflieger-Bruss et al., 2004).

Pregnant Women. Being pregnant is an exclusion for the study and will be asked in the Recruitment Telephone Script (Attachment 3.3). Respondents will be informed in recruitment materials (Attachments 3.1 & 3.2) and during the consent process (Attachment 3.8) that pregnant women will be excluded. This is a minimal risk precaution. For this purpose, all women less than 60 years of age will be screened for pregnancy before the blood draw (Attachment 3.12).

A history of pregnancy or breastfeeding in the past 12 months will also be asked during the interview of women less than 60 years of age (Attachment 3.13b). The 60-year threshold is consistent with the venipuncture procedures for the NHANES. The threshold takes into account the large variability of age at menopause among women, and selecting the upper age is also a precaution in the event that cases of advanced maternal age is encountered. Women will be asked the lifetime total number of pregnancies and the lifetime total duration of breastfeeding (Attachment 3.13b).

This information on pregnancy and breastfeeding is needed to assess physiological events that mobilize many lipophilic compounds, such as PCBs, dioxins, pesticides, and PBDEs, from body stores in adipose tissue. With physiologic disequilibrium, these toxic compounds are released into the blood stream to affect target organs in the endocrine system, the immune system, and the reproductive organs. They will be examined in relation to self-reported health outcomes and clinical biomarkers.

Serving a sentence or being under house arrest. Persons identified as serving a sentence (including house arrest) will be excluded from the study. The language has been specifically requested by the CDC IRB because the study was not approved for the inclusion of prisoners.

Smoking and Alcohol Consumption. Information on smoking and alcohol consumption is needed as important confounders or effect modifiers of the exposures and clinical measures of interest. For example, cigarette smoke is a potential source of cadmium, and liver function tests may be modified by alcohol consumption.

Weight Loss or Weight Gain and Measures of Obesity. During the clinical assessment portion of the interview, trained study staff will take measures of height, weight, and waist circumference (Attachment 3.11). In addition, questions will be asked about moderate or high weight loss or weight gain in the past year relative to current weight (Attachment 3.13b & 3.13c). Some respondents may be embarrassed by these assessments.

This information is needed to assess risk factors for diabetes, hypertension, and the metabolic syndrome. In the ACHS, PCB exposures were associated with these health outcomes. In the ACHS-II, these relationships will be re-examined; however, they will be examined in relationship to a greatly expanded panel of analytes. This will contribute to a more detailed picture of health and chemical exposures in the Anniston Cohort.

A.12. Estimates of Annualized Burden Hours and Costs

A. The burden estimates published in the 60-day FRN were based on informal testing by UAB among UAB staff.

The ATSDR is requesting a two-year approval for this information collection; therefore, the annualized burden hours represent one-half of the total estimated for this IC. From the 766 members of the ACHS Cohort, we anticipate that 66 have died based on the SSDI review and that 35 have moved away based on the Anniston population decline of approximately five percent between the 2000 and the 2010 Censuses (USCB, 2011), and five may be ineligible at screening (e.g., currently pregnant or serving criminal sentence). We used these estimates to calculate the number of respondents for each line in the burden table. These estimates are also graphically represented in Attachment 3 (Information Flow Chart).

There are no costs to respondents other than their time. In total, respondents will spend about 2 hours in the study, including travel time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs)	Total Burden (in hrs)
Adults who took part in first Anniston Community	Recruitment Telephone Script	333	1	2/60	11
	Survey for Refusals	160	1	1/60	3

Health Survey	Update Contact Information Form	250	1	1/60	4
	Medications Form	250	1	3/60	12
	Blood Draw Form	250	1	2/60	8
	Questionnaire	250	1	45/60	188
				Total	226

B. Estimated annualized burden costs are presented. To estimate the cost to the respondent, the May 2011 median hourly wage was selected for all occupations in the Anniston-Oxford, AL metropolitan statistical area (MSA).

Estimated Annualized Burden Costs

Type of Respondents	Total Burden (in hours)	Hourly Wage Rate	Total Burden Costs
Adults who took part in first Anniston Community Health Survey	226	$14.40	$3,254
		Total	$3,254

Source: BLS, 2011. May 2011 Metropolitan and Nonmetropolitan Area Occupational Employment and Wage Estimates: Median Hourly Wage for All Occupations. http://www.bls.gov/oes/current/oes_11500.htm#00-0000 .

A.13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There will be no additional capital and maintenance costs for respondents or record keepers.

A.14. Annualized Cost to the Government

The NCI/NIEHS has transferred first year funding for executing this study to ATSDR under a three year proposed interagency agreement (CDC IAA#: 11AT1-001-00, 12AT12-ANNISTON) for the Anniston Community Health Survey: Follow-up and Dioxin Analyses.

The total estimated cost to the government is $2.3 million, based on the current actual costs for the first year spent in protocol and ICR development, and the estimated costs for this program's request to collect information over the next 2 years.

The estimated average annualized cost of the program is $782,000.

- Personnel: $195,000 per year. This is based on percentages of time spent on the project by ATSDR and NCI/NIEHS investigators.

- Travel: $10,000 per year. This amount is based on the number of site visits conducted before and during data and sample collection following the General Services Administration Schedule for travel and per diem.
- Contracts: $297,000 per year. This amount is based on the approved and planned contracts for data and sample collection and the clinical tests analyses by the outside academic laboratories.
- Direct Transfers to NCEH/DLS: $280,000. This includes chemical analyses of PCBs, dioxins, dibenzofurans, PBDEs, and heavy metals.

A.15. Explanation for Program Changes or Adjustments

This is a new information collection.

A.16. Plans for Tabulation and Publication and Project Time Schedule

On the day of the interview, the respondent will receive his or her Body and Blood Pressure Measures Report (Attachment 6.1). In the event that clinically significant laboratory results are detected, such as for toxic metals like mercury and lead, the principal investigators will notify the respondent expeditiously (Attachment 6.2 - Advance Reporting Script). Upon completion of data collection and laboratory analysis ATSDR will tabulate and report individual final results of laboratory analyses back to the respondent. These include the Clinical Tests Results Report (Attachment 6.3) and the PCBs, Dioxins, and Other Chemicals Results Report (Attachment 6.4).

Summary reports from the study will be prepared and released to the public in the form of peer-reviewed scientific journal publications.

The first year of the program period was dedicated to planning and protocol development, development of documentation for CDC and UAB IRB review.

IC procedures will begin upon the date of OMB approval. Therefore, the two years of information collection will require a timely approval of this ICR to complete this federal acquisition.

The schedule for project completion is as follows:

Activity	Time Schedule*
Recruitment letters sent to respondents	1-4 month after OMB approval

Respondents enrolled, interviewed, clinical assessments taken, and blood specimens collected	2-18 months after OMB approval
Field work, laboratory analysis complete	19-21 months after OMB approval
Data validation, data entry, data analysis complete	22 months after OMB approval
Respondent results reporting complete	23 months after OMB approval
Summary study reports complete	24 months after OMB approval

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

The ACHS-II will display the OMB Control Number and expiration date on all data collection forms as required.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

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