

Attachment 3.8

Anniston Community Health Survey: Follow-up Study and Dioxin Analyses Informed Consent Form

TITLE OF RESEARCH: Anniston Community Health Survey: Follow-up Study and Dioxin Analyses
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UAB INVESTIGATOR: Prof. Stephen Mennemeyer
SPONSOR: National Institutes of Health, Agency for Toxic Substances and Disease Registry

University of Alabama at Birmingham Institutional Review Board Protocol #: F120626005
Centers for Disease Control and Prevention Institutional Review Board Protocol#: 6323

Study Overview/Purpose: You were part of the Anniston Community Health Survey (ACHS) during 2005-2007. That survey gave us useful information about polychlorinated biphenyls (PCB) levels in Anniston. We found associations between PCBs and health measures such as blood pressure and diabetes in some groups of people in Anniston, but we would like to study those more. Scientific research also suggests that additional aspects of health may be related to exposure to PCBs and other chemicals and metals. We would like to study those important research questions here in Anniston. You and others who participated in the ACHS last time are the only ones who can help us gather this information.

Researchers from the Agency for Toxic Substances and Disease Registry (ATSDR), the National Institutes of Health (NIH), and the University of Alabama at Birmingham (UAB) are conducting this study. The Calhoun County Health Department (CCHD) is helping with key parts of this study. NIH and ATSDR are paying for this study.

What to Expect at Your Appointment: The appointment will take about two hours. We will ask your name, address, and date of birth to make sure we are talking with the right person. We will measure your weight, height, and blood pressure and ask you to answer some questions. One of our staff members will interview you. One of our trained staff will draw 125-mL (about 10 tablespoons) of blood from a vein in your arm. If your weight is less than 110 pounds, we will draw 50-ml of blood. If you are currently pregnant or in jail (including house arrest) you cannot participate in the study.

Certain medical conditions might interfere with our drawing blood or might affect the results of our lab tests. If you have one of these conditions, you may not be able to take part in all of the study. However, you can still do an interview and have your weight, height, waist and blood pressure measured.

We ask that you fast for at least eight hours before we draw your blood. If you take diabetes medications, take them as usual. If fasting fits your meal and medication plan, please do so. If

Participant Initials: _____

you must eat to take your medication, please eat only a fat-free or low-fat food before your appointment.

We appreciate you taking part in this study. If you complete all parts of the study, we will give you a \$100 gift card. If you only answer the questionnaire, we will give you a \$50 gift card. If you only donate blood, we will give you a \$50 gift card.

Questions We Will Ask: We will ask about your health in general and since the last study. We will also ask about your family health history. We will ask things such as diet, jobs, and hobbies where you could have been exposed to chemicals. We will also ask about your health behaviors such as exercise and use of alcohol or tobacco. If you do not know or do not remember an answer, just say so. If you do not want to answer some questions, just say so.

PCBs Measured in Blood: We will test your blood again for the PCBs we measured during 2005-2007 to see if they have changed. We also will measure other PCBs we didn't measure before. We will let you know the level of PCBs currently in your blood.

Other Chemicals Measured in Blood: We will test for other chemicals often found with PCBs. These include dioxins, pesticides, metals, and other related chemicals.

Other Blood Tests: We will test your blood for health markers such as cholesterol, insulin, and thyroid hormones. Most of these markers are things your doctor might look at, and they may help us learn more about possible associations between PCB exposures and health outcomes.

Learning about Test Results: We will send you a letter with your test results. We think we will finish all of the tests within about one year after we draw your blood. If your test results suggest a health problem, we will contact you when we get your lab results.

Storing Blood for Future Use: After we test your blood, there may be some left over. We would like to save this leftover blood for other research projects. You can decide whether or not we may use your blood for other projects about Anniston or PCBs, as well as other tests related to the environment or other health topics that are relevant (but not necessarily specific) to the residents of Anniston. The leftover blood samples will be stored by the study number only. ATSDR will keep a separate dataset that can link your study number with your name. If you change your mind later about letting us use your blood for other projects, you can contact us and we will remove your samples. We do not expect the results of these other tests to be important to your health. We do not plan to give you the results of these future tests but we may contact you if we learn something that is important.

Costs: You do not have to pay to be part of this study. The blood tests are free.

Participant Initials: _____

Risks: Your only risks from taking part in this study are for possible minor problems from having your blood drawn. It may hurt a little when the blood is drawn, and you may have some bruising afterward where the blood is drawn. We will do our best to prevent these problems.

Benefits: Within three months of blood collection, we will send your health test results, along with a letter that you can share with your doctor. Due to the time it takes for analysis, we will send your chemical test results as much as 3 to 9 months later than your health test results. We think that the study will help to address important research questions to better understand the role of PCB exposures in possible associations with health outcomes. We also will use results from the study to inform and educate the Anniston community about exposure to PCBs and other chemicals and metals.

It Is Your Decision: You can choose to be part of this study or not. During your appointment, you can stop at any time by telling the staff that you do not want to go on. You can refuse to answer any questions or have your blood drawn. There is no penalty for refusal or withdrawal from the study.

Privacy: We will protect all of the information that you give us to the extent possible under law. We will store your answers and test results using a study number, not your name. We will keep your records in locked files at the CCHD office in Anniston. ATSDR and UAB will protect any computer files with your information. Only designated study staff will have access to your information and your test results. Other scientists may request information from this study. If we share the information with them, your study number, not your name, will be used. If requested by a court, we may have to give them your data with identifiers.

Use of Collected Information: We will write reports or scientific articles about the study results. We will combine everyone's responses to get a picture of the health issues of people in Anniston as they relate to PCBs. These reports or articles will be available to the public after the study is finished. The results in the reports will be shown in a way that individuals cannot be identified.

Questions:

If you have any questions about the study, or if you decide later that you do not want to participate, please contact:

Ms. Lori Bell

Calhoun County Health Department

3400 McClellan Blvd

Anniston, AL

Phone: (256) 237-7523 or toll-free at (855) 822-1778

Participant Initials: _____

For questions about your rights in participating in this study, please contact:

CDC/ATSDR Human Research Protection Helpline

Phone: toll-free at (800) 584-8814

or

Mr. Jonathan E. Miller

Director, UAB Institutional Review Board

Phone: (205) 934-3789 or toll-free at (800) 822-8816

If you feel you have been harmed by this study, please contact:

Stephen T. Mennemeyer Ph.D.

Phone: (205) 975-8965

Email: smenneme@uab.edu

If you do not understand what we are asking you to do, feel free to ask questions now. If you have no further questions and agree to be in this study, please sign the consent form below.

Participant Initials: _____

PARTICIPANT CONSENT

I have read and/or have been told about the purpose of the study. I have been given a chance to ask questions and my questions have been answered. I have been given a copy of this form. I choose to take part in the study. By signing this consent form, I agree to take part in the *Anniston Community Health Survey: Follow-up Study and Dioxin Analyses*.

Participant's Name (Print)

Participant's Signature

Date

If you will allow us to keep any blood left over after testing, please sign on the line below. If you will not allow us to keep your leftover blood, do not sign below.

YES. I will allow my leftover blood samples to be stored and used for future tests on Anniston or PCBs, as well as other tests related to the environment or other health topics that are relevant (but not necessarily specific) to the residents of Anniston.

Participant's Signature

Date

Participant Initials: _____