

## Consent Statement

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University or with Gallup or your membership in the Gallup Panel. You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.

### Key Information About the NCHAT Stress Biology Study (NCHAT-BIO)

This study will look at how daily life experiences, emotions, and stress may affect health by looking at biological markers in your blood. This study seeks to collect data from many types of people and will allow researchers at The Ohio State University the opportunity to get results that apply to the US population and people like you. The study will ask you to collect your own blood by finger stick and then mail those samples back to The Ohio State University. Your data will be linked with questionnaire data you provided via your participation in NCHAT.

#### 1. Why is this study being done?

This study will help social scientists understand the effects of stress emotions, and daily experiences on the health of individuals and families. The purpose of this study is to see how health is reflected in biological markers, particularly immune markers called proinflammatory cytokines which are associated with risk for cardiovascular disease and other chronic health conditions. This biological marker information will be used with the other data you have provided in NCHAT to better understand stress and health.

#### 2. How many people will take part in this study?

Up to 4,035 adults will take part in this study.

#### 3. What will happen if I take part in this study?

If you take part in this study you will give 5 drops of blood from a prick of the finger. Giving the blood spots will take less than 10 minutes and is not very painful. You will also complete a brief questionnaire.

Gallup will mail you a small package that has all the materials you need to collect 5 drops of blood at home. You will prick your finger and leave 5 drops of blood on a small blood spot card. You will mail your blood spots to The Ohio State University (OSU) using the postage paid return envelope.

Gallup will assign you a random identification number and send you the materials for collecting your blood spots. Your random identification number will be on your blood spot card. After you mail your blood spot card to OSU, OSU will send Gallup the identification number from the card they receive. Gallup will use their record of names and identification numbers to send you your payment for participating.

Gallup will **never** share your name or contact information with The Ohio State University. The Ohio State University will **never** share your blood spots or the results of your blood spots with Gallup.

These dried blood spot samples will be stored at The Ohio State University (OSU). Measures of health will be done by a team of researchers at OSU, Northwestern University, and the University of California Los Angeles (UCLA). Your blood samples will never be sent to any other institution for any reason.

In addition, your blood specimens will **never** be used for genetic research (mapping your DNA or whole genome sequencing) at any time.

The types of tests that may be conducted are listed below.

**Inflammatory Markers** are associated with risk for cardiovascular disease and other chronic health conditions. Examples include C-reactive protein (CRP), interleukin-6 (IL6), and tumor necrosis factor  $\alpha$  (TNF- $\alpha$ ).

**Appetite Hormones** affect feelings of hunger and are linked with risk for obesity. These include adiponectin, insulin, and leptin.

**Reproductive Health Markers** provide an indication of the health of the reproductive system; for example, in women, Anti-Müllerian hormone (AMH) provides information about fertility, which has been linked with stress in some studies.

**Immune Function** may be assessed by measuring markers including levels of cytomegalovirus (CMV) and Epstein-Barr virus (EBV) antibodies. These are viruses that most people carry. Higher antibodies are linked with greater stress exposure.

**Blood Cell Function** may be assessed to determine how the functioning of cells in the body are affected by factors including stress and poor sleep.

**COVID-19 Antibodies** may be examined to determine prior exposure to the novel coronavirus. These data may be used to see if COVID-19 antibody levels are

associated with differences in inflammatory markers, which are the main focus of this study (see first item above).

#### **4. Can I request information about the results of my tests?**

No information can be provided to participants about the results of any tests or biomarkers assessed because the biological samples will be received and processed by researchers in a completely de-identified manner. The results of biological tests can never be linked with participant names or other identifying information to maintain participant confidentiality. Gallup will never receive the results of the tests. Researchers at the Ohio State University, Northwestern University, and the University of California Los Angeles (UCLA) will never receive the names or contact information of people who participated.

#### **5. How long will I be in the study?**

If you participate in this study you will complete a one-time finger prick that should take no more than 10 minutes. You will then need to let your samples dry for at least 4 hours before sealing and mailing. After a dried blood spot is used for a test it will be destroyed. After 12 years any remaining dried blood spots will be destroyed.

#### **6. Can I stop being in the study?**

You may leave the study at any time, including having your stored dried blood spots destroyed and having the results of any tests already conducted removed from the dataset. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University or Gallup. To withdraw from the study, please contact Gallup [Panel Support](mailto:galluppanel@gallupmail.com) at [galluppanel@gallupmail.com](mailto:galluppanel@gallupmail.com).

#### **7. What risks, side effects or discomforts can I expect from being in the study?**

The potential risks of drawing blood include a bruise and/or infection at the site of the finger prick. This risk is low.

#### **8. What benefits can I expect from being in the study?**

There is no direct benefit to you by your participation in this research study other than a sense of satisfaction by helping with research that may benefit others. Anticipated benefits to society include gaining information about how daily experiences, emotions, and stress may affect the health of individuals and families.

#### **9. What other choices do I have if I do not take part in the study?**

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

## **10. Will my study-related information be kept confidential?**

The blood spots that you send to the researchers at The Ohio State University will be mailed without any information that could be used to identify you as an individual. Only an anonymous ID, created by Gallup, will be used to identify your sample. This ID may also be used to link your data to other surveys you have completed or will complete as part of the Gallup Panel to be used as part of this research.

The Ohio State University Institutional Review Board and/or the Office of Responsible Research Practices may access the bloodspot samples to ensure that they are handled and stored in a manner that is compliant with Ohio State University policies.

The National Institutes of Health (NIH) issues Certificates of Confidentiality for all NIH-funded studies, including this study. This Certificate provides extra protection for you and your study information. The Certificates are issued so that our study team and Gallup cannot be required to disclose any identifiable information collected about you as a part of this study in a lawsuit or legal proceeding. This is a layer of protection over and above the already existing protections in place for you and your information.

However, these protections do not apply in some situations. For example, we may have to release your information if a law requires us to do so, if the NIH that is funding this study requests the information, or if the FDA tells us to release this information. Please talk to your study team, or contact the Office of Responsible Research Practices at 614-688-8641, if you have questions. Please visit the NIH website at <https://humansubjects.nih.gov/coc/faqs> to learn more.

## **11. Will my de-identified information and bio-specimens be used or shared for future research?**

Your bio-specimens (dried blood spots) will never be shared with researchers beyond the core team at the Ohio State University, Northwestern University, and the University of California Los Angeles (UCLA). The resulting data, but not the actual dried blood spots may be used by researchers at other institutions. No identifying information will ever be given to researchers. Also, no data will ever be shared with Gallup.

## **12. What are the costs of taking part in this study?**

There are no costs to you for taking part in this study.

## **13. Will I be paid for taking part in this study?**

You will receive a total of up to \$55 if you provide all 5 dried blood spots. You will receive \$5 for agreeing to provide the samples and an additional \$50 electronic gift card

after you return the blood samples by mail. By law, payments to subjects are considered taxable income.

Your blood samples will never be sold or used to make new products or technologies. Therefore, there will be no additional compensation from future use of your blood samples.

#### **14. What happens if I am injured because I took part in this study?**

If you suffer an injury from participating in this study, you should notify Gallup. Gallup will immediately work with the researchers at The Ohio State University, who will determine if you should obtain medical treatment. The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University and Gallup has no funds set aside for the payment of health care expenses for this study.

#### **15. What are my rights if I take part in this study?**

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By consenting to participate in this study, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

#### **16. Who can answer my questions about the study?**

For questions, concerns, or complaints about the study you may contact the Stress, Behavioral Immunology, and Health Disparities Lab at 614-293-5262 or [stresslab@osumc.edu](mailto:stresslab@osumc.edu).

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact the **Gallup Panel Support at 1-888-297-8999**.

If you have other questions about the Gallup Panel, please contact Gallup Panel Support by sending an email to [galluppanel@gallupmail.com](mailto:galluppanel@gallupmail.com) or by calling 1-888-297-8999 from 8:00 a.m. to 8:00 p.m. Eastern Time, Monday through Thursday, or 8:00 a.m. to 6:00 p.m. Eastern Time on Fridays.