The Ohio State University Consent to Participate in Research

Study Title: **The Ohio First Responders Stress and Health Study**

Principal Investigator: **Lisa Christian, PhD**

Sponsor: **Institute for Behavioral Medicine Research, The Ohio State University**

- **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. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **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.** If you decide to participate, you will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

Key Information About This Study

The following is a short summary to help you decide whether or not to be a part of this study. More detailed information is listed later in this form.

This study will look at stress, trauma, coping, and mental health among first responders during the COVID-19 pandemic. A secondary purpose of this study is to see how health is reflected in biological markers in the blood among a subset of participants. The research team is most interested in proinflammatory cytokines. These are immune markers found in the blood that increase in response to stress and are linked to risk for cardiovascular disease and other chronic illnesses.

1. Why is this study being done?

This study is being done in order to examine relationships among stress exposure, trauma, coping, and mental health among law enforcement, fire fighters, and emergency medical service providers in Ohio during the COVID-19 pandemic. A secondary purpose of this study is to examine how these factors affect biological health by collecting dried blood spot samples from a subset of participants. These results of this study will help to guide interventions targeting stress and health among first responders.

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

The questionnaire portion of this study will include up to 8000 eligible individuals.

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

If you take part in this study you will complete an online questionnaire which requires 15-20 minutes to complete. You also have the option of providing dried blood spot samples. If you participate in this part of the study, you will be mailed a package that has all the materials needed to collect 5 drops of blood at home. You will prick your finger and leave 5 drops of blood on a small sample collection card. You will mail your sample to The Ohio State University using a postage paid return envelope.

Follow-up questionnaires and dried blood spot collection are planned, with the first follow-up occurring at about one year later. Your continued participation is completely voluntary.

4. How long will I be in the study?

The online questionnaire will require about 15-20 minutes to complete. If you participate in the dried blood spot collection part of the study, this will require about 15 minutes to collect your samples, and an additional 4 hours for the sample to dry before mailing.

5. Can I stop being in the study?

You may leave the study at any time. 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.

6. 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.

Personal questions may make you uncomfortable and sensitive information on possible depression, alcohol use, and drug use will be obtained. You may choose not to answer any questions that make you uncomfortable.

7. 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 stress, trauma, and coping during the COVID-19 pandemic may affect the health of first responders.

8. 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.

9. Will my study-related information be kept confidential?

All study data will be collected in a completely anonymous manner to protect confidentiality. This means that no name, address, or other identifying information will be collected. In order to allow us to link your questionnaire answers over time (when a planned follow-up occurs in the future), and to link your questionnaires with your biological samples (if you choose to provide these), you will be asked to create a unique code that only you will know and that cannot be reasonably used to identify you.

Note: If you participate in the biological sample portion of the study, we will request your address in order to send you the collection materials. However, when you return the kit to us, it will only be labeled with your unique code, which you will create. We will never be able to link your name or address with your sample.

If we find information that significantly impacts your health, we **will not** share it with you. No information can be provided to participants about the results of any tests or biomarkers assessed because all questionnaire and dried blood spot samples will be collected and analyzed in a completely anonymous manner in order to protect confidentiality. Your questionnaires and biological samples (if applicable) will be identified only by a unique code that you create and that only you will know.

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

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

The questionnaire data and results of bio-specimen test results (if you choose to provide dried blood spots) may be used or shared with other researchers without your additional informed consent.

If you provide dried blood spot samples, these will be stored at The Ohio State University. Measures of health will be done by our team of researchers at The Ohio State University. Your blood samples will never be sent to any other researchers 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. Any samples still remaining after 7 years will be destroyed.

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

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

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).

11. What are the costs of taking part in this study?

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

12. Will I be paid for taking part in this study?

There is no direct compensation to you for participating in the study.

13. 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 the researcher immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

14. 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, 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.

15. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact the Principal Investigator, Lisa M. Christian at Lisa.Christian@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 Principal Investigator, Lisa M. Christian at Lisa.Christian@osumc.edu.