

Appendix E: UB Consent Form



University at Buffalo Institutional Review Board (UBIRB)

Office of Research Compliance | Clinical and Translational Research Center Room 5018

875 Ellicott St. | Buffalo, NY 14203

UB Federalwide Assurance ID#: FWA00008824

Title of research study: ***A Longitudinal Examination of Mental and Physical Health among Police Associated with COVID-19***

Version 1 Date: June 26, 2020

Investigator: *John M. Violanti, Ph.D (SUNY at Buffalo)*

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

Why am I being invited to take part in a research study?

You are being invited to take part in this research study because you are a Buffalo, NY police officer and a participant in our previous studies on the Buffalo Police department. We are interested in learning about your experience with COVID-19 as a law enforcement officer, and your health and well-being. We will use coded de-identified health information that you gave to us in the previous study.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

This proposed research seeks to address changes in psychological stress and physical health of police officers prior to and after the continuing onset of the COVID-19 pandemic.

How long will the research last and what will I need to do?

We expect that you will be in this research study for approximately two hours. You will be asked to give a blood sample only during your first visit and fill out questionnaires asking about how you feel about the COVID-19 virus and how it has affected you. ***We will ask you to repeat part of the study in 8-12 months, but for a shorter period of time (approximately one hour) just to answer questionnaires.***

More detailed information about the study procedures can be found under ***“What happens if I say yes, I want to be in this research?”***

Is there any way being in this study could be bad for me?

The anticipated risks associated with your participation in this study are no greater than those ordinarily encountered in daily life or the performance of routine questions. Questions on the survey concern how you feel about your well-being and health. You are under no obligation to answer any questions you do not want to answer. Your decision to participate in the survey or not will have no effect on your position in your agency, as your identity will be completely secured.

More detailed information about the risks of this study can be found under ***“Is there any way being in this study could be bad for me? (Detailed Risks)”***

Will being in this study help me in any way?

We cannot promise any benefits to you for taking part in this research, other than it will help other officers in the future. We hope that your participation in this survey and testing along with that of the other officers will clarify how today’s law enforcement officers deal with stress and how it may affect your health with the hope that we can continue to help inform officers and agencies about how to best address health and stress problems, especially concerning disaster situations like COVID-19.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You may choose not to enroll in this study. Your alternative to participating in this research study is to not participate.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at

Dr. John M. Violanti, Ph.D.
University at Buffalo, SUNY
271 Farber Hall
Buffalo, NY 14214

violanti@buffalo.edu

[716-829-5481](tel:716-829-5481)

You may also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu.

This research will be reviewed and approved by an Institutional Review Board (“IRB”). An IRB is a committee that provides ethical and regulatory oversight of research that involves human subjects. You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu if:

- You have questions about your rights as a participant in this research
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You want to get information or provide input about this research.

How many people will be studied?

We expect that about 200 officers from your department who have participated at UB before will be asked to participate.

What happens if I say yes, I want to be in this research?

If you agree to participate in this research, we will ask you to come into our clinic at the University at Buffalo. We will ask you to fast the evening before your visit, and we will draw a blood sample the morning you arrive at the clinic. You will be asked to give a small amount of blood (approximately 4 tablespoons) as part of this study. We may ask you if we can draw an additional amount of blood (approximately 1 ½ tablespoons) to check the accuracy (quality control) of our measurements. The blood draw will be done by a trained phlebotomist. There are minimal risks during the process of drawing blood including: minor discomfort, bruising at the site of the blood draw, occasionally lightheadedness or fainting, and very rarely infection. Blood analysis will be used only for science. The blood samples are stored and tested with an identifying number only and your name or any other identifying information will not appear on the samples. This sample is for research purposes only. We will provide you with a light breakfast if you desire. We will also use information and frozen blood samples you provided us in the previous study you participated in here at UB. The frozen blood samples will be tested for various levels in your blood (cholesterol for example) both from your previous visit blood and the new blood sample we will be taking. We will retain what is left of those samples once again and freeze them for future research.

You will have your blood pressure taken while you are comfortably seated. The technician will place a cuff that is appropriate for your size on your right arm and will measure your blood pressure three times. With your forearm resting comfortably on the table, he/she will count your radial pulse for 30 seconds. There are no risks associated with measuring the blood pressure or heart rate. This procedure will take approximately 15 minutes. These measurements are for research purposes only. Your height, weight, abdominal height, waist circumference and neck circumference will be measured and recorded. This procedure will take approximately 10 minutes to complete. These measurements are for research purposes only.

You will be asked to complete several surveys about how COVID-19 has affected your feelings and well-being. Nothing in the surveys is designed to diagnose or treat any health condition. You may skip any questions that you do not want to answer at any time, without any consequence. The entire visit is estimated to take two hours or less.

Cortisol is a hormone in your body that is released throughout the day and during stressful situations. A standard procedure has been developed to test cortisol levels. This procedure consists of saliva testing. This test is for research purposes only.

To test this, we will ask you to take saliva samples the day after you leave the clinic- *four in the morning when you awaken, one at lunchtime, one at dinner, and one when you go to sleep*. We will provide you with small cotton rolls to place in your mouth (similar to dental rolls) to take these samples along with instructions on how to take the samples.

After this first visit we would like to contact you again in about 6-8 months to have you fill out the same surveys you filled out during the first visit. You will not have to come into the clinic or give a blood or saliva samples for this-we will mail the surveys to you with a return stamped envelope for you to return the surveys. After completion your visits, we will provide you \$150.00 for the first visit and \$50.00 for the second time you participate.

Note: Female Participants:

Prior to undergoing any of the following tests, you will be given a pregnancy test. The test we are currently using is a one step hCG Test for the qualitative detection of hCG in urine. This test is to ensure that you are not pregnant and are therefore not exposed to potential harm. If you are pregnant, you will not be able to participate in any tests.

Procedure: We will give you a cup to provide a urine sample. The interviewer or nurse will fill a dropper (provided) with a small sample of the urine. Four drops of the urine are added to the sample well on the tester. Results are read within 5 minutes. There are no known risks associated with this procedure. This test will not be used in any other analysis.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to appear at the clinic at the appointed time. If you cannot come in, please advise the clinic staff one day ahead if possible. You will be responsible for fasting after 10 pm the night before your morning appointment at the clinic to provide a blood sample. You will be responsible for reading the survey questions carefully and answering the questions as honestly as possible, to the best of your ability.

What happens if I say yes, but I change my mind later?

You can leave the research at any time and it will not be held against you. However, we will only provide the incentive for the portion of the study you have completed. Please advise the researchers a reasonable time ahead if you decide to leave the research. Any data that has been collected up to the point of your withdrawal will still be used by the researchers in their analysis.

Is there any way being in this study could be bad for me? (Detailed Risks)

There are no known risks associated with these procedures other than a slight pain from a blood draw. There are many safeguards to protect your confidentiality and information and identity. Some of the questions about stress and anxiety may make you feel uncomfortable. At any time you are not comfortable answering any questions, you may skip those questions. If you feel you need help, we will refer you to a mental health professional or peer support person familiar with police work.

What happens to the information collected for the research?

We will limit your information to only those persons working on the study. You will be assigned an ID number to protect your identity. Any reports or study publications resulting from this study will only provide statistics and no identifying information. In addition, we also do not ask any personally identifying questions in the survey. The survey data collected will be stored electronically utilizing a Box cloud “sensitive storage” area, which is an encrypted platform. Access to the data will be restricted to members of the research team only. Once the data has been analyzed and the study has been completed, the data will be retained for use after your second visit and a possible follow-up study over time. Blood samples will be stored in a university biological storing laboratory freezer and are identified only by coding. Your identifying information is not labeled on the samples. Efforts will be made to limit the use and disclosure of your personal information, including research study and medical or education records, to people who have a need to review this information. Organizations that may inspect and copy your information include the University of Buffalo Institutional Review Board (IRB) and representatives of this organization. This may be done to ensure that your data is secure. Private, identifiable information will be kept confidential and will only be used for research and statistical purposes. In the *unlikely* event the identity your identity cannot be maintained, we will explicitly notify you. We will explicitly inform you what information will be disclosed under what circumstances, and to whom; and any risks that might result from this disclosure will explicitly provide written consent prior to participating in the research. Your frozen blood samples collected from a past study for which you gave consent will be utilized as part of this study. These samples are in a university biological storing laboratory freezer and are identified only by coding. Your identifying information is not labeled on the samples.

Can I be removed from the research without my OK?

Not applicable/No

What else do I need to know?

N/A

Who is paying for this research?

The National Institute for Occupational Safety and Health (NIOSH).

What medical costs am I responsible for paying?

You and your private or public health insurance company will not be charged for any of the tests or procedures done for this study.

Who will pay for my medical care if participating in this research harms me?

It is important that you tell your study doctor if you feel that taking part in this study has injured you or caused you to become ill. You will receive medical treatment if you are injured or become ill as a result of this study. Your doctor will explain the treatment options to you and tell you where you can get treatment. The University at Buffalo makes no commitment to provide free medical care or payment for any unfavorable outcomes that result from your participation in this research. Medical services will be billed at the usual charge and will be your responsibility or that of your third-party payer but you are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research. By accepting medical care or accepting payment for medical expenses, you are not waiving any of your legal rights.

Will I receive anything for my participation in this research?

As a token of our appreciation for your participation, we will provide you with \$150.00 for completion of the first visit in the clinic. As an additional token of appreciation we will provide you with \$50.00 for the second time you participate at a later date.

What are my alternatives to participating in this research study?

The alternative is not to participate.

What will I be told about clinically relevant research results?

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the researchers return test results to you, it may be because they think you could have a health risk and want to recommend that the test should be re-done by a certified clinical laboratory to check the results. If this happens, then you may want to get a second test from a certified clinical laboratory, consult your own doctor, or get professional genetic counseling. You may have to pay for those additional services yourself.

F. What are your rights after signing this authorization?

All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspects of this research study, and that future questions will be answered by the researchers listed on the front page of this form. By signing this form, I understand that I do not waive any of my legal rights including the right to seek compensation

for injury related to negligence or misconduct of those involved in the research. By signing this form, I agree to participate in this research study. A copy of this consent form will be given to me. I have read and understand what procedures are to be performed and what is expected of me as a result of my voluntary participation in this study.

I consent to participate in the following procedures for this research project as outlined:

- | | | |
|--------------|----------------------|-----------------------------------|
| Procedure #1 | _____ | Saliva Samples (Cortisol testing) |
| | <i>Pt's Initials</i> | |
| Procedure #2 | _____ | Blood Samples |
| | <i>Pt's Initials</i> | |
| Procedure #3 | _____ | Blood Pressure and Heart Rate |
| | <i>Pt's Initials</i> | |
| Procedure #4 | _____ | Body Measurements |
| | <i>Pt's Initials</i> | |
| Procedure #5 | _____ | Completion of Questionnaires |
| | <i>Pt's Initials</i> | |

Signature Block for Capable Adult

Your signature documents your permission to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

_____	_____
Signature of subject	Date

Printed name of subject	
_____	_____
Signature of person obtaining consent	Date

Printed name of person obtaining consent	

DNA samples

Researchers may look at inherited factors which are related to diseases by examining DNA from the stored samples. *Be advised that the National Institute of Occupational Safety and Health who sponsors this study has a federal certificate of confidentiality in force and any data collected during this study cannot be used for any purpose other than for research.* By signing this form, you are giving consent for any future studies of DNA. The blood samples will remain the property of the Department of Epidemiology and Environmental Health at the University at Buffalo, and may be shared with other researchers. Confidentiality will be strictly maintained. All names will be removed from samples. Results of studies may be reported only as statistics in medical journals or at meetings. Individuals in the study will not be identified in any way. By signing this form, you understand that at any point in the future and for any reason, you may choose to have your blood samples withdrawn from the Biological Specimen Bank and destroyed.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

I consent that samples of my DNA will be indefinitely stored for future research of factors that may influence disease. *I will not be identified in any way and this data will not be used for any purposes other than research.*

Signature of subject

Date

Printed name of subject

Signature of person obtaining consent

Date

Printed name of person obtaining consent