



Mercy Health St. Vincent Medical Center
2213 Cherry St.
Toledo, OH 43608

Dear Lucas County, First Responders and Health Department Staff,

You are here today to have a blood draw to test for COVID-19 antibodies today as part of an employment-required health assessment. If the blood test for antibodies is positive, your employer may also require a nasal swab of your nose (PCR test), and you may be requested to complete a self-report survey of possible symptoms.

We are asking you to consider volunteering for a research study that would allow Mercy Health St. Vincent Toledo to have access to your positive or negative test results and survey information. We will deidentify all the data and only report results as a summative report. We hope the information from this research may increase the body of medical knowledge about COVID-19 immunity for front line workers who are exposed to COVID-positive individuals. We are especially interested in individuals who have a positive antibody result, which may indicate some degree of immunity and correlating that positive antibody result finding to any symptoms. Many people have had COVID-19 and had no symptoms but test positive for antibodies. Others have tested positive but were unaware of some of the COVID-19 symptoms they had until they complete a symptom checklist.

Research participation is voluntary, you may withdraw your consent to have your results in the research at any time prior to final data analysis, and whether you decide to participate in the study will have no impact on your employment with Lucas County or your care at Mercy Health St. Vincent. The expected duration/time for being in the study is the time to read this letter and sign the consent form. Any blood draws, nasal swabs or self-report surveys are required by your employer and are not part of the study. The study simply gives us your permission to review your results as part of a group analysis.

This study was reviewed and approved by the Mercy Health North Institutional Review Board, Toledo OH, IRB#2020-24 on 5/29/2020. A copy of the this form will be included with your medical record and the original will be kept by the principle investigator for the study.

The procedure for those who agree to participate is the investigators will develop a master list of all individuals who agreed to be in the study. We will only receive a copy of the positive or negative lab test result, a copy of the positive or negative nasal swab test result if done, and a copy of the self-report survey if done. We will remove all names and identifiers

and assign a numerical deidentified code. Only the code will be used to enter the data into a database and analyze the results. This consent form will cover the initial baseline testing, and follow-up testing at 3 months and 6 months. The results will only be reported as group data – no individual data will be reported. We hope to have the study published and we will share the results with Lucas County to openly distribute to all employees.

Thank you for considering sharing your results with us. We appreciate your interest and willingness to help us improve our knowledge about COVID-19 immunity. If you have any questions, please contact the principle investigator for this study, Dr. James Tita or Michelle Haynes, a Clinical Research Nurse, at the contact information listed below.

Sincerely,

Dr. James Tita DO, Email: James_Tita@mercy.com , Office Phone: 419-251-4919,

2222 Cherry Street, Suite 1400, Toledo, OH 43608

Michelle Haynes BSN, RN, CCRN, Email: Michelle_Haynes@mercy.com , Phone: 419-251-4919

Informed Consent Form research study “Initial Screening of a high-risk cohort of Lucas County First Responders for prevalence of antibody positivity to SARS-Cov-2 – A prospective study”
IRB# 2020-24 Approved 5/29/2020

I have reviewed the information for this research study and have no questions regarding the study.

I am voluntarily consenting to be in the research study and give permission for my COVID-19 antibody testing, any PCR nasal swab testing and any self-reported survey results to be reviewed by the investigators in hopes of gaining new knowledge about COVID-19 acquired immunity. My results will be de-identified and only reported as a group result.

I AGREE to allow the results of all COVID-19 antibody tests, and possible PCR nasal swabs and any self-reported surveys to be shared with Dr. James Tita/investigators for the purposes of this research study.

Name of Subject: (Print Name)

Signature of Subject

Time am /pm

Date