INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR RESEARCH

Longitudinal SARS-CoV-2 antibody testing in IU undergraduate students
A privately funded research study

ABOUT THIS RESEARCH

You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

TAKING PART IN THIS STUDY IS VOLUNTARY

You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled, and will not affect your relationship with Indiana University.

Please review the rest of this document for more details about this study and the things you should know before making a decision about whether to participate in this study.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to assess whether receiving the results of an antibody test changes protective behavior to avoid SARS-CoV-2 infections. Behaviors include mask-wearing, physical distancing, limiting close contacts/avoiding crowds, handwashing, and avoiding contact with high-risk individuals.

You were selected as a possible participant because you are a current IU undergraduate student. All participants must be 18 years old or older, currently living in Monroe County, and a current IU undergraduate student.

The study is being conducted by Indiana University's Dr. Molly Rosenberg and Dr. Christina Ludema from the Department of Epidemiology and Biostatistics, Dr. Jon Macy from the Department of Applied Health Science, and Dean David Allison from the School of Public Health. The study is funded by donations from four private donors to the Indiana University Foundation. The antibody test kits that will be used in this study are donated by the United Arab Emirates.

HOW MANY PEOPLE WILL TAKE PART?
If you agree to participate, you will be one of 1,700 participants taking part in this research.

WHAT WILL HAPPEN DURING THE STUDY?
If you agree to be in the study, you will do the following things:

- Respond to a web-based baseline survey, which will take approximately 30 minutes to complete. The baseline survey is designed to collect data on participant demographics, SARS-CoV-2 protective behaviors, alcohol drinking habits, nicotine use, and personality profile.
- Participate in two rounds of SARS-CoV-2 serological testing, once at the beginning (September 10-13) and once at the end of the study (November 15-18). The serological testing visits will involve in-person laboratory testing for SARS-CoV-2 antibodies. The laboratory test involves a fingerstick to provide a small blood sample for the antibody test kits. Each visit will require approximately 5-10 minutes to complete.
- Respond to bi-weekly follow-up web-based behavioral surveys (4 total surveys), which will take approximately 5 minutes each to complete.
- Receive a secure link to your test results via email. You can opt out of receiving your test results via email.

We will randomize all participants to a trial arm that immediately receive results (within about 24 hours) or a trial arm with a delayed provision of results (after 4 weeks).

WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?
Possible risks include: loss of confidentiality; pain, bleeding, fainting, or infection from the fingerstick; anxiety from awaiting results, negative reaction to receiving results, or potential discomfort from some survey items.

WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THE STUDY?

We don't expect you to receive any benefit from taking part in this study, but we hope to learn things which will help scientists in the future.

HOW WILL MY INFORMATION BE PROTECTED?

Efforts will be made to keep your personal information confidential. Although the study team will do everything possible to protect participant information, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. No information which could identify you will be shared in publications about this study. Rigorous efforts will be made to keep the personal information obtained in the study confidential. To minimize the risk of breach of confidentiality, we will use secure software to collect and store the data. The survey data and antibody test results will be collected and stored using the REDCap platform and servers. The REDCap platform has strong data security (see: https://kb.iu.edu/d/bddn). Additionally, for analysis, the merged dataset will be stored securely in a password-protected remote Box Health Data folder, which is designed with extra protections for protected health information (PHI) (https://kb.iu.edu/d/bfrt).

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, and any state or federal agencies who may need to access your medical and/or research records (as allowed by law).

WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?

Information or specimens collected from you for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information or specimens are shared. Since identifying information will be removed, we will not ask for your additional consent.

WILL I BE PAID FOR PARTICIPATION?

We will use a tiered compensation scheme to incentivize the sustained participation necessary for this study. You will be eligible to receive compensation of $30 total value in cash or gift cards if you complete all study procedures.

- Completion of the baseline survey and baseline serological testing procedures can earn participants $10.
- Completion of each of the four web-based behavioral surveys can earn participants $3 for a total of $12 possible compensation.
- Finally, completion of the endline serological testing can earn participants an additional $8.

The total possible value of compensation for a participant completing all study procedures is $30, with incrementally lower compensation values for those with incomplete study procedures. All compensation will be delivered to participants at the end of the study follow-up period.

WILL IT COST ME ANYTHING TO PARTICIPATE?

There is no cost to you for taking part in this study. You will not be responsible for these study-specific costs: serological testing visits.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?

For questions about the study, contact the researcher, Dr. Rosenberg, by email at rosenmol@indiana.edu or by phone at (812) 856-2509. After business hours, or in the event of an emergency, you may also contact Dr. Rosenberg by email at rosenmol@indiana.edu or by phone at (804) 839-6884.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the IU Human Subjects Office at 800-696-2949 or at irb@iu.edu.

CAN I WITHDRAW FROM THE STUDY?

If you decide to participate in this study, you can change your mind and decide to leave the study at any time in the future. If you decide to withdraw, call any research staff member or one of the principal investigators and inform the research staff member of your decision. Once you express that you would like to be withdrawn from the study, you will be immediately removed from the study. You will receive the dollar amount compensation up to when you withdrew according to the previously described payment arrangement.

PARTICIPANT'S CONSENT

In consideration of all of the above, I give my consent to participate in this research study. I will be given a copy of this informed consent document to keep for my records. I agree to take part in this study.

Participant's First Name:_____

Participant's Last Name:_____

Participant's E-Signature:_____ **Date**:_____