

## Pre-Study COVID-19 Information for Potential Subjects

A global pandemic has affected everyone with changes to the way people travel, work, and interact with others. A novel coronavirus (referenced as COVID-19 or SARS-CoV-2) has caused illness for many individuals exposed to it, although researchers are still trying to learn more about this virus. Therefore, many businesses, schools, and other facilities are taking measures to reduce the spread of the virus.

Because one way people interact with others is for the purpose of research, it is possible that the virus could be spread through contact between a human subject and others involved in the research. The University of Notre Dame Institutional Review Board (IRB) has asked all researchers who plan to be in personal contact with subjects to provide information about steps research teams are taking to minimize the spread of the virus.

While the risk of infection may be present in daily life, the IRB is encouraging investigators and subjects to carefully consider guidelines in place to ensure the health of all.

### Risks

While there is still much to learn about COVID-19, the virus is thought to spread mainly from person to person, and between people who are in close contact with one another. It is thought that an infected person coughing, sneezing, or talking may generate small droplets that can land in the mouths or noses of people who are nearby or possibly be inhaled into the lungs.

The Centers for Disease Control and Prevention (CDC) recommends that all people should:

- Avoid close contact with people who are sick, even inside their home
- Stay at least 6 feet (about 2 arms' length) from other people (especially for those at higher risk of illness).
- Wash hands often with soap and water
- Wear a cloth face cover or face mask when people have to go out in public
- Clean and disinfect frequently touched surfaces
- And more: <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html>

While every research study involves different procedures, the IRB has asked all researchers to take steps to reduce the chance that disease is spread. As a result, participants may be asked as a research subject to:

- Remain at a distance from research personnel, or others

- Wear a mask
- Wash hands
- Move to a different location
- Take other steps to minimize risk of disease spread

The IRB has asked researchers to clearly communicate to subjects the safety procedures in place for each study. These safety procedures are in place to not only protect subjects, but also everyone else involved in the study. Even if participants feel healthy, please note that some recent studies have suggested that COVID-19 may be spread by people who are not showing symptoms. If subjects feel unable to follow specific safety requests, please notify research personnel as soon as possible so they may determine whether you can participate in the research.

Some safety procedures are required to remain on the University campus (please see more here: <https://here.nd.edu/>), and failure to adhere to them may result in removal from the study.

### **Participation in research**

As always, the decision to participate in research is completely voluntary. Subjects may decide to withdraw from a study at any time. Subjects do not have to contact the researchers to inform them of the desire to withdraw, although it may be appreciated. If subjects are feeling ill or in any way concerned about their health, they should speak with a healthcare provider. Researchers are not able to provide medical advice or medical treatment through clinical care.

### **Confidentiality**

In all research studies, the IRB requires researchers to protect the confidentiality of subject data to the greatest extent possible. If subjects have already consented to participate in a study, the researchers may have explained the information they are collecting, who will have access to it, where it will be stored, and whether it will contain any identification information. Any changes to that process must be approved by the IRB and communicated to the subject. There are some circumstances in which researchers are required by law to disclose information. Currently, local and state public health authorities have been engaging in a practice called “contact tracing” in which information about individuals infected with COVID-19 is collected to learn where they have been and who they have been in contact with. In some cases, individuals may be interviewed directly. This information is only used for public health purposes, and to inform others that they may have had contact with an individual who tested positive for the virus.

It is possible that researchers are asked to provide information about subjects in order to complete “contact tracing.” No additional research data will be collected as a result of this process, but if the researchers are required they may provide basic information that identifies subjects to public health officials. If you are concerned about the possibility that identifying information may be provided for this purpose, we recommend that subjects withdraw from the study.

### **Questions**

If subjects have questions about the research currently being participated in, or plan to participate in, please contact the study team, or especially the principal investigator.

If subjects have questions about the COVID-19 virus, its recommended to review the following resources:

- CDC (<https://www.cdc.gov/coronavirus/2019-ncov/index.html>)
- Indiana State Health Department (<https://www.coronavirus.in.gov/>)
- St. Joseph County Health Department (<https://www.sjcindiana.com/302/Health-Department>)
- University of Notre Dame (<https://here.nd.edu/>)

If subjects have questions about personal health, please contact a healthcare provider.