

## ECU COVID-19 Human Subject Research Risk Assessment Information

During times of significant risks, uncertainty, amidst a pandemic, or state of unrest within a region, researchers must take extra precautions to assess risk and ensure that they and others are safe. A researcher must stop a research study if they do not believe they can keep themselves or others safe. The research participant may also stop participating at any time or refuse to answer any individual questions. The risk assessment process is a careful examination of what could cause harm, who/what could be harmed and will help you to determine what risk control measures are needed

OSHA has developed COVID-19 planning guidance to reduce the impact of the COVID-19 outbreak conditions on businesses, workers, customers, and the public. OSHA has divided job tasks into four risk exposure levels: very high, high, medium, and lower risk. This assessment will help facilitate the safe involvement of study participants, research staff, and students in your research.

**Lower Exposure Risk:** research protocols that do NOT require contact (within 6 feet for a total of 15 minutes or more over a 24-hour period) with people known to be, or suspected of being, infected with SARS-CoV-2 nor frequent close contact with the public.

- minimal contact with the study participants

**Medium Exposure Risk:** research protocols that require frequent close contact or sustained close contact with people who may be infected with SARS-CoV-2, but who are not known or suspected COVID-19 patients.

- Research participants in this risk group may have frequent contact with lab personnel where maintaining 6 feet distance is not possible.
- Research protocols that require direct contact with study participants, such as placement of wearable devices

**High Exposure Risk:** research protocols with high potential for exposure to known or suspected sources of COVID-19 and/or potential high risk for transmission with people who may be infected with SARS-CoV-2, but who are not known or suspected COVID-19 patients. Examples for this category include:

- Research protocols that involve lab personnel exposed to known or suspected COVID-19 patients.
- Research personnel collecting or handling specimens from people who are not known or suspected COVID-19 patients.

**Very High Exposure Risk:** research protocols with high potential for exposure to known or suspected sources of COVID-19 during specific laboratory procedures. Examples in this category include:

- Research personnel performing aerosol-generating procedures (e.g., intubation, cough induction procedures, bronchoscopies, some dental procedures and exams, or invasive specimen collection) on known or suspected COVID-19 patients.
- Research personnel collecting or handling specimens from known or suspected COVID-19 patients (e.g., manipulating cultures from known or suspected COVID-19 patients).