University of Maryland Baltimore

Statement of Risk

 Notice to Research Subjects Prior to Enrollment or Continued Participation in Research Activities

The novel coronavirus, COVID-19 is extremely contagious and is believed to spread mainly from person-to-person contact. Infection may result in personal injury, illness, permanent disability, or death. Despite having put in place preventive measures to reduce the spread of COVID-19, UMB cannot guarantee that any individual will not become infected with COVID-19 when on the UMB main campus or at related off campus sites.

The University of Maryland, Baltimore (“UMB”) employees conduct research that involves participation by individuals who voluntarily enroll in studies after completing a process of informed consent approved by the UMB Institutional Review Board (IRB). UMB programs have begun controlled re-opening of research activities in accordance with campus guidelines as approved by the UMB President, acting in consultation with Deans, health and safety experts and academic advisors. Decisions to resume research take into account the measures needed to limit risk to research subjects, staff, and others. Participation in a clinical trial or other research will potentially increase an individual’s risk of contracting COVID-19. Before enrolling in, or continuing enrollment in research, individuals should inform themselves fully of the risks to themselves, and potentially to family members and close contacts.

As a condition of participation in UMB approved research during the COVID-19 emergency, you are required to follow safety rules in your daily life which include:

* Keep a safe distance (at least 6 feet apart) from others.
* Avoid touching your mouth and eyes.
* Wash your hands often, using soap and water (for 20 seconds) or hand sanitizer.
* Wear a mask to cover your nose and mouth.
* Always cover your cough using your shirt or elbow, not your hand.
* Stay home when you are feeling sick.
* Monitor yourself daily for symptoms and report symptoms to the principal investigator, study coordinator or other UMB contact as instructed before coming to the UMB campus.

If you are sick, have any symptom(s) of COVID-19, or have had any recent contact with COVID-19 case(s), you must inform a member of the research staff and receive authorization before being present on the UMB campus or at any remote location where UMB approved research is conducted.

STUDY RESEARCH STAFF CONTACT FOR COVID-19 SYMPTOMS:

[NAME]

[PHONE]

[EMAIL]

If you wish to receive more information about enrolling or continuing to participate in UMB research during the COVID-19 pandemic, please contact the study staff listed above or the UMB Office of Human Research Protections (410)706-5037 to discuss your options.

\_\_\_\_\_\_ I understand the above risks and would like to enroll or continue to participate in the study.

\_\_\_\_\_\_ I do not wish to enroll or to continue to participate in the study.

\_\_\_\_\_\_ I wish to speak with someone about COVID-19 risk and enrollment or continued participation in the study.

[INSERT STANDARD IRB INFORMED CONSENT SIGNATURE BLOCK]

 AND/ OR UTILIZE DOCUMENT CONTENTS AS PART OF VERBAL NOTIFICATION TO PARTICPANT/LAR