PONCE RESEARCH INSTITUTE
PONCE MEDICAL SCHOOL FOUNDATION, INC.

April 27, 2020

Dear PHSU community:

Due to COVID emergency, the PMSF/PHSU IRB is issuing a temporary statement to be followed by all researchers. The IRB recommends pausing all research protocols with human participants involving in-person interactions/interventions that had been evaluated and approved by the PMSF/PHSU Institutional Review Board (IRB) prior to the emergency. These restrictions will be in place until the quarantine is lifted by our administration. These suggestions should be provisional, and they might change as additional information is available and always in accordance with administrative recommendations.

Any research procedures that involve in-person interactions/interventions with participants must be immediately paused. Research procedures involving no direct in-person interaction/intervention with participants may continue (e.g. data analysis, online surveys, telephone interviews). This applies to both exempt and non-exempt research studies.

During this pause, Investigators should consider whether it is feasible to modify their in-person research procedures to use alternative methods for data gathering (e.g. telephone, online, Zoom, Skype, or other means). If alternative methods to in-person participation are feasible investigators are encouraged to do so by submitting an amendment to the study in order to secure IRB approval prior to the implementation of changes. If the study cannot be conducted without the in-person participant interaction/ intervention, then new participant enrollment and any ongoing in-person participant interactions/interventions must be immediately paused.

An investigator may implement changes to approved research prior to obtaining IRB approval if such changes are necessary to eliminate apparent immediate hazards to the participants as provided for in federal regulations (45 CFR 46.108(a)(3)(iii) under the 2018 Rule. In such cases, the Principal Investigator must promptly notify the IRB of any changes as soon as possible.

If pausing the research protocol might have direct harm to participants, these studies may continue subject to the following: any in-person participant interactions/ interventions must be minimized and alternatives for in-person data collection should be considered if feasible. Investigators should consider their ability to continue with the research based on current and future staffing resources and facility restrictions. Investigators should consider the rapidly changing environment of the pandemic and plan for research continuity, such as facility closures, illness of

research team or lack of required personal protective equipment. New participants should not be enrolled without prior permission from the IRB. Projects actively studying COVID-19 should also follow all recommendations.

Once again, modified procedures to eliminate or minimize the need for in-person contact are recommended and the investigator must continue to monitor the changing COVID-19 situation.

Investigators and their research personnel should work with their study sponsors and others to evaluate impacted studies and develop a plan appropriate to their research procedures, including financial considerations. For questions on how to contact a study sponsor and other considerations related to sponsored projects, please email the Office of Sponsored Programs.

Best regards,

Simón Carlo, MD
IRB Chair