MEMORANDUM

To: Primary Investigators and Study Coordinators

From: Kevin Brown
Chair, CSUEB IRB

Date: March 17, 2020

Subject: Human Subjects Research at CSUEB and the Evolving COVID-19 Outbreak

As the COVID-19 coronavirus outbreak continues, the risk/benefit ratio for human subjects research participation must be carefully assessed. Both the ethical principles of research delineated in the Belmont Report and federal regulations for the protection of research participants dictate that we ensure the risk/benefit ratio be acceptable at all times. Universities such as Columbia have already paused certain types of human subjects research activities underway at their institutions and others such as the University of California system are considering their next steps. While we do not believe that such research at CSUEB should be brought to a halt at this time, we do strongly recommend that investigators take steps to decrease the likelihood that they will put themselves, members of their study teams, or their study participants at risk of becoming infected with or spreading the disease. Below are guidelines to follow with respect to overall planning and data collection activities

Establish Formal Plans

All investigators engaging in human subjects research should develop concrete and actionable plans for:

- Continuing or halting data collection.

- Regularly communicating the following to ensure everyone is operating under the procedures recommended by the University: Team, study sites, participants and their caregivers.

- Managing data now that the shelter in place order has been given.

Review Data Collection Procedures

As part of planning, investigators and study teams should revisit data collection procedures as well as the extent to which or circumstances under which data collection should be brought to a halt, either temporarily or permanently. Suggestions are provided here:

- Ensuring that that the research staff is healthy and check with study sites to determine whether there have been any identified cases or if anyone at the site is or has been quarantined when collecting data from populations at higher risk of suffering severe health consequences if they contract COVID-19 (e.g., older adults or those designated at

higher risk by the CDC) or in settings that bring large groups of people together in contained spaces (e.g., K-12 schools, close proximity living spaces).

- Avoid or minimize bringing groups of people together for data collection activities (e.g., focus groups, whole group interventions).
- Consider moving face-to-face data collections (e.g., interviews, surveys administered in person, some forms of observation) to telephone or online (e.g., Zoom) formats.
- Follow recommended guidelines for reducing exposure and, if prudent, pause study activities.
- Determine whether it is necessary to completely suspend research activities and if so, pause recruitment until the situation changes.

If an investigator or study team needs to alter data collection activities by shifting to phone or online, or another change needs to be made to a study protocol in order to protect participants or study personnel, a modification request should be submitted for approval prior to making the change. If an investigator needs to make a change to research plans and is unable to submit an amendment (e.g., immediate hazard or risk to research participants exists), these changes can be made and then reported to the IRB within 5 days, as a reportable event. Eliminating immediate hazards may include actions that reduce potential exposure to COVID-19 in regards to activities which are ongoing. A modification request must also be submitted with the event report. The CSUEB IRB encourages sponsors and investigators to take such steps as necessary to eliminate apparent additional risks to participants.

At the current time, the CSUEB IRBs will continue to review and approve research protocols that have been or will be submitted. However, any research team that has not yet begun research activities should ensure that doing so will not jeopardize members of the research team or participants. In addition, should the COVID-19 landscape change significantly, there may come a point when research activities including human research subjects will be restricted and application reviews might be paused in the interest of individual and public health.