THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

OFFICE OF HUMAN RESEARCH ETHICS

720 MARTIN LUTHER KING JR. BLVD.
BLDG. #385, SECOND FLOOR
CAMPUS BOX 7097
CHAPEL HILL, NC 27599-7097

T: 919 966-5883
F: 919 966-1612
URL: HTTP://OHRE.UNC.EDU/

To: UNC Research Community

From: UNC-Chapel Hill OHRE/IRB

Approval Date: 6/4/2020
RE: Notice of IRB Approval by Expedited Review (under 45 CFR 46.110)
Submission Description: COVID Consent Information Sheet Modification

This COVID Consent Information Sheet has been modified and approved by the IRB for utilization during the COVID-19 pandemic for all studies where participants have not been diagnosed with COVID-19 and direct interactions with subjects will resume. All findings made previously for studies continue to be applicable.

For all studies that have previously been allowed to continue study activities due to direct benefit or will be given permission by their department to resume activities in alignment with the OVCR's updated guidance will be required to provide this consent addendum to subjects (unless there enrollment is due to diagnosis of COVID) that outlines the risk of COVID-19 and the risk mitigation strategy that has been outlined or will require a separate modification This is an information sheet only and does not need to be signed, however the conversation with participant's, the risk analysis for subject by subject continuation, and the outcome of the discussion should be documented in the subject's research record.

This approval letter is only for then the COVID Consent Information Sheet is used verbatim, except where "X's" and red formatting have been inserted to allow for study specific information, and does not require study by study submission. Please retain a copy of this "COVID Consent Addendum Letter" in your study files. This modification approval letter is not for any changes outside the "X's" and red formatting for general information, and either adding, revising or removing language, or your procedures for risk mitigation are different, will then require the study specific submission of a modification including a risk analysis to the IRB. If you need to make changes to this consent addendum outside the "X's" and red formatting as described above and unless you were previously approved to continue your study by the OVCR's office due to direct benefit you may not begin enrollment until the modification is approved.

Documents approved with this letter, as outlined above:

-COVID Consent Information Sheet for UNC and External Sites, Version 2.0, dated 6/4/2020

This COVID consent information sheet was reviewed in accordance with federal regulations governing human subjects research, including those found at 45 CFR 46 (Common Rule), 45 CFR 164 (HIPAA), 21 CFR 50 & 56 (FDA), and 40 CFR 26 (EPA), where applicable.

Cassandra Myers

Cassandra Myers, CIP
Director, Office of Human Research Ethics
University of North Carolina at Chapel Hill