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at CHAPEL HILL

OFFICE OF HUMAN RESEARCH ETHICS

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To: UNC Research Community

From: UNC-Chapel Hill OHRE/IRB

Approval Date: 5/25/2020

RE: Notice of IRB Approval by Expedited Review (under 45 CFR 46.110)

Submission Description: COVID Information Sheet Modification

This COVID Information Sheet has been 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 or continue. 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 information sheet to subjects (unless enrollment is due to diagnosis of COVID) that outlines the risk of COVID-19 and the risk mitigation strategy that has been outlined. 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 when the COVID Information Sheet is used verbatim, except where "X's" have been inserted to allow for study specific information, and does not require study by study submission. Please retain a copy of this "COVID Information Sheet Approval Letter" in your study files. This approval letter not cover any changes outside the "X's" for general information. Either adding, revising or removing language, or changing procedures for risk mitigation, 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 information sheet outside the "X's" 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 Information Sheet for Participants, Version 1.0, dated 5/24/2020

This COVID 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.

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