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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: 5/25/2021

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

Submission Description: Discontinuation of COVID Consent Information Sheet Modification

The COVID Consent Information Sheet has been discontinued/withdrawn and is no longer required for in-person interactions with participants. All findings made previously for studies continue to be applicable.

This modification approval letter is only for the discontinuation of the COVID Information sheet. If you otherwise altered your processes or procedures and would like to revise due to changes in operational status of UNC-Chapel Hill, these will still require study specific submission including a risk analysis to the IRB.

Previously approved documents discontinued/withdrawn with this letter, as outlined above:

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

The discontinuation of 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 CFR26 (EPA), where applicable.

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