



THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

OFFICE OF HUMAN RESEARCH ETHICS

720 MARTIN LUTHER KING JR. BLVD.
BLDG. #385, SECOND FLOOR T: 919 966-5883
CAMPUS BOX 7097 F: 919 966-1612
CHAPEL HILL, NC 27599-7097 URL: [HTTP://OHRE.UNC.EDU/](http://OHRE.UNC.EDU/)

To: UNC Research Community

From: UNC-Chapel Hill OHRE/IRB

Approval Date: 6/10/2020

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

Submission Description: COVID Consent Information Sheet Modification

A certified Spanish translation of the COVID Consent Information Sheet, Version 2.0, dated 6/4/2020 has been approved 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.

As a reminder if you are planning to enroll non-English speaking participants this should be identified in your IRBIS application and other patient facing material (e.g., consents, brochures, recruitment material) should be appropriately translated and approved by the IRB.

This approval letter is only for the Spanish- COVID Consent Information Sheet as 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 "Spanish COVID Information Letter" in your study files if you will be utilizing the Spanish translation. 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:

- Spanish COVID Consent Information Sheet, Version 2.0, dated 6/4/2020
- Translation Certification

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