

OFFICE OF HUMAN RESEARCH ETHICS

OFFICE OF THE DIRECTOR

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CHAPEL HILL, NC 27599-7097

RL: <u>NTTA /OHRE.UNC.EDU/</u>

[DATE]

[PI NAME] [PI TITLE] [NAME OF ORGANIZATION] [ADDRESS]

RE: [STUDY TITLE]

Dear Dr. [PI NAME]:

As the XXX of the UNC Office of Human Research Ethics (OHRE) at the University of North Carolina at Chapel Hill (UNC), I am witing to confirm our interest in serving as the single Institutional Review Board (IRB) for the grant proposal "[TITLE OF PROPOSAL]" with [PI NAME, DEGREE] as the Principal Investigator (PI). We understand that this trial will [PURPOSE OF STUDY].

We share your belief that this proposal is an important project, and OHRE and the UNC IRBs are ready to help you navigate any potential ethical and regulatory challenges you might face with establishing and maintaining a single IRB for your proposed multi-site research project.

UNC has a langstanding culture of respect for the IRB process, one in which investigators, staff and administrators are sincerely committed to the highest standards in research. We are fully accredited by the Association for the Accreditation of Human Research Programs (AAHRPP), having been reaccredited for another five year cycle in 2017. OHRE is responsible for the ethical and regulatory oversight of all human subjects research at UNC, administering the work of our multiple IRBs. These IRBs are collectively responsible for 6,200 active protocols, reflecting the breadth and depth of research across our multidisciplinary campus.

OHRE has long participated in central IRB efforts coordinated by NIH (e.g., the NCI Central IRBs) and by many research networks. An informal policy of the OHRE is to enact authorization agreements whenever possible. UNC typically executes 250 or more such agreements per year, allowing UNC to rely on another institution's IRB, or vice versa. With the recent requirement by

the NIH to utilize a single IRB review model for multicenter projects, the UNC IRB is well positioned to participate in reliance arrangements with other IRBs. Furthermore, UNC is firmly committed to the principles of shared review in multisite research and is interested in exploring ways to coordinate and streamline reviews.

I wish you success in this grant application and stand ready to support this project in any way possible.

Regards,