**To**:

**From:** UNC-CH IRB

**Date:**

**Protocol title:**

**UNC IRB Study #:**

Dear Dr. :

You have expressed interest in ceding IRB review to the University of North Carolina at Chapel Hill (UNC-CH) for the IRB approved protocol listed above. Please follow the steps outlined below for UNC-CH to consider this responsibility:

1. Please contact your IRB to ensure that you follow their policies and requirements for ceding IRB review.
2. In order to add your site as a relying site, the UNC-CH IRB is required to establish an IRB Authorization Agreement (IAA), also known as a reliance agreement, with your institution.
   1. Please review the attached IRB authorization template so that you are aware of your responsibilities under this agreement.
   2. Please share a copy of the IAA and the attached IRB approval letter with your IRB office. If your institution agrees to rely on UNC-CH for IRB review and oversight, the IRB will facilitate the execution of the IAA (adding the site information and obtaining signature from the Institutional Official). If your IRB has questions about the agreement, they may contact the UNC-CH IRB at [IRBreliance@unc.edu](mailto:IRBreliance@unc.edu).
3. If your institution agrees to cede IRB review and oversight to the UNC-CH, please complete the attached Local Context Worksheet with your local context representative. The local context representative is typically an individual with knowledge of the institutional human research protection program and its policies as well as state and local law (e.g., IRB personnel).
4. Approved versions of the consent forms may be attached. Please insert institutional specific consent language regarding research-related injury and COI disclosures as applicable as well as local contact information. The sections are highlighted in yellow. A final consent will be approved specifically for your site with your required language for these sections only. All other sections will reflect the consent document that the UNC-CH IRB has approved.
5. The relying site is responsible for ensuring the accuracy of the information within the HIPAA Authorization and the compliance of the Authorization with the HIPAA Privacy Rule. UNC-CH IRB will serve as the privacy board for consideration of a waiver or limited waiver of HIPAA authorization. A limited waiver of HIPAA that allows access to PHI for eligibility screening has been granted.
6. The completed IAA, Local Context Worksheet (with any relevant documents), and site consent document(s) should be returned to the UNC IRB Liaison (listed below).
7. The UNC IRB Liaison will notify you when approval for your site is final by providing you a copy of the approval letter to add your site and approved site consent document(s). No work may begin at your site until you have been notified of your site’s approval.
8. Please contact the UNC IRB if you or your IRB have any questions regarding this process or the IAA.

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| UNC IRB Liaison:  Name:  Phone:  Email: | UNC IRB Contact:  Name: IRB Reliance Group  Emails: [IRBreliance@unc.edu](mailto:IRBreliance@unc.edu) |