

February 22, 2017

Committee for the Protection of Human Subjects
[Insert name of PEDSnet institution submitting protocol for NHR Determination]

Dear IRB:

In anticipation of your review of our protocol IRB XXXXX, titled XXXXXX (PI: XXX), we wanted to provide additional context to aid in your consideration of our request.

This study is operating within a research consortium called PEDSnet. All PEDSnet institutions endorse the PEDSnet Single Institutional Review Board (IRB) Policy which aims to establish a single IRB framework for multi-institutional research studies, thereby serving as a vehicle for investigators proposing multicenter studies to request ceded review. In the case of NHR, PEDSnet sites have additionally agreed to accept respective sites' determination of NHR. For any PEDSnet study not led by a PEDSnet affiliated institution, our governance dictates that a PEDSnet site will validate the determination made by this external institution.

The Overall PI of the study is Dr. XXXX, who resides at the [insert name of prime institution]. [Insert name of institution to whom this letter is being submitted]'s confirmation of NHR, will allow the remaining PEDSnet sites to acknowledge the determination made and participate in the network-wide study.

We hope this explanation provides helpful information in your review of this IRB submission. Please do not hesitate to contact me if any additional information is needed to complete the review.

Thank you for your consideration.

Sincerely,

[Insert investigator name]