SCHOOL OF MEDICINE
DEPARTMENT OF GENETICS

December 16, 2020

Food and Drug Administration
Center for Devices and Radiological Health
IDE Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

IDE ANNUAL REPORT Annual Progress Report 005

Dear FDA Review Team:

Pursuant to 21 CFR 312, I am submitting an Annual Report for IDE# G150258.

- This is an original IDE submission.
- The device under review for this trial is the following: NC NEXUS (North Carolina Newborn Exome Sequencing for Universal Screening) research study and its intended use is to investigate the potential of genome scale next generation sequencing to augment and extend current newborn screening in a diverse pediatric population
- The sponsor of this IDE is Cynthia Powell, MD and her contact information is the following:
  Cynthia M. Powell, MD
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  Director, Medical Genetics Residency Program
  Division of Pediatric Genetics and Metabolism
  Department of Pediatrics
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  919-966-4202 (phone) ; 919 966-3025 (fax)
- The “device” is not manufactured, thus there is no manufacturer information.

The NC NEXUS project has completed its funding cycle and enrollment, and the results are summarized in this report, including enrollment and sequencing results. Investigators have completed their analyses and the study is now complete. As this is the only study approved by this IDE, we request that the FDA formally close this IDE. Thank you in advance for the FDA’s review of this annual and final report.

The e-copy is an exact duplicate of the paper copy

Sincerely,

Cynthia M. Powell, MD