SCHOOL OF MEDICINE
DEPARTMENT OF GENETICS

December 4, 2019

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 004

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
  Professor of Pediatrics and Genetics
  Director, Medical Genetics Residency Program
  Division of Pediatric Genetics and Metabolism
  Department of Pediatrics
  University of North Carolina Medical Center
  Chapel Hill, NC 27599-7487
  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, so we have summarized the majority of the results in this report, including enrollment and sequencing results. Investigators are continuing to analyze and publish the final data and we will plan to submit a final report next year. Thank you in advance for the FDA's review of this annual report.

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

Sincerely,

Cynthia M. Powell, MD