

 <b>SUNY DOWNSTATE</b> Health Sciences University	Approved on:	04/30/2021
	Expires on:	03/19/2023
	Study number:	1524262-13

Title: Validation of the Ultrasensitive Laser-Based RCA-SOFIA Platform for Detection of PD-Associated alpha-Synuclein Oligomers in Human Blood

Summary:

We have developed a laser-based immunoassay for detecting and quantitating brain-derived biomarkers using biofluids (blood, cerebrospinal fluid) from animals and humans with neurodegenerative diseases and neurologic disorders. This assay, termed RCA-SOFIA, involves indirectly linking an antigen-antibody complex to a nucleic acid which is then simultaneously amplified and fluorescently labelled followed by fiberoptic detection. The study design for this project includes: (i) a-SynO assay development using RCA-SOFIA and a commercially available, but "homebrew" required, single molecule array (SIMOA) platform, (ii) Characterizing the analytical metrics associated with in vitro a-SynO detection, (iii) Validating RCA-SOFIA and SIMOA "homebrew" in vivo by detection of a-SynO in stratified PD (and control) patient bloods with and without exosome preparation.

Inclusion criteria: Participants will range in age from 40-85 years and will be diagnosed with PD. Patients will be divided into two groups, early PD and advanced PD. Early PD subjects must have a Hoehn and Yahr (H&Y) score of I-II, and advanced PD subjects a H&Y score of III-V. The projected enrollment for each group based will be 20 subjects. A total of 60 subjects will be recruited (20 early PD, 20 advanced PD, 20 healthy age-matched controls).

Exclusion criteria include: A history of a parkinsonian syndrome other than idiopathic PD, including but not limited to Lewy body disease, progressive supranuclear palsy, multiple system atrophy, drug-induced parkinsonism, essential tremor, and any contraindication to phlebotomy. Also pregnant women will be excluded from the study.

Start Date: March 20,2020

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End Date: Active, still recruiting

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