Certificate of Action

Board Action Date: 10/11/2022	**Work Order Number**: 13-1592360-1
Sponsor: National Heart, Lung, and Blood Institute	**Protocol Approval Expires**: 11/09/2022
Sponsor Protocol Number: AAAS8713 **Amended Sponsor Protocol Number:** AAAS8713	**Continuing Review Frequency**: No CR Required
IRB Tracking Number: 20212809	
Protocol Title: Alpha-1 Antitrypsin Disease Cohort: Longitudinal Biomarker Study of Disease	

THE FOLLOWING ITEMS ARE APPROVED:
Advertisement - Screening Script - Questionnaires Have you ever smoked #35563322.0 - As Submitted
Advertisement - Letter - Alpha-1 antitrypsin deficiency (AATD) is #35563333.0 - As Submitted
Advertisement - Screening Script - Assessment of Eligibility Subject Must #35563325.0 - As Submitted
Advertisement Website - In May 2020 the National #35563328.0 - As Submitted
DSMB Report (03-03-2022)
DSMB Report (03-16-2022)
Instructions for Participant DBS Collection #35563330.0 - As Submitted
Revised Protocol (10-05-2022) Version 3.0

Please note the following information about this review:
Under the revised common rule (effective 1-21-2019), continuing review by the Board of the above referenced research is not required; however, the IRB will maintain our records and continue responsibility for exercising administrative and regulatory oversight of this research. The IRB will automatically charge an Ongoing Oversight fee for this administrative effort unless we are notified the research is closing. To avoid unnecessary fees due to closure, a closure form must be submitted for each site 30 days prior to expiration.

ALL WCG IRB APPROVED INVESTIGATORS MUST COMPLY WITH THE FOLLOWING:

Consistent with AAHRPP's requirements in connection with its accreditation of IRBs, the individual and/or organization submitting shall promptly communicate or provide, and where necessary cause each investigator to promptly communicate or provide, the following information relevant to the protection of human subjects to the IRB in a timely manner:

- Upon request of the IRB, a copy of the written plan between sponsor or CRO and site that addresses whether expenses for medical care incurred by human subject research subjects who experience research related injury will be reimbursed, and if so, who is responsible in order to determine consistency with the language in the consent document.
- Any site monitoring report that directly and materially affects subject safety or their willingness to continue participation. Such reports will be provided to the IRB within 5 days.
- Any findings from a closed research when those findings materially affect the safety and medical care of past subjects. Findings will be reported for 2 years after the closure of the research.

If this study includes data monitoring committee/data safety monitoring board, please note that the reports of all meetings of this committee should be submitted to the IRB even if the outcome of the meeting results in no changes to the study.

Federal regulations require that the IRB conduct continuing review of approved research. You will receive Continuing Review Report forms from WCG IRB when the expiration date is approaching.

Thank you for using WCG IRB to provide oversight for your research project.

This is to certify that the information contained herein is true and correct as reflected in the records of WCG IRB. WE CERTIFY THAT this IRB IS IN FULL COMPLIANCE WITH GOOD CLINICAL PRACTICES AS DEFINED UNDER THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) REGULATIONS, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) REGULATIONS, AND THE INTERNATIONAL CONFERENCE ON HARMONISATION (ICH) GUIDELINES.

DISTRIBUTION OF COPIES:
Contact, Company
Laura Fonseca, Columbia University

Investigator List

The following PIs received some or all of the approvals specified in this Certificate of Action (COA). Please review the COA for each PI listed below to confirm which approvals apply for each PI.

Barjaktarevic, Igor
D'Armiento, Jeanine
Drummond, Michael
Hogarth, Douglas
Pirozzi, Cheryl
Strange, Charlie
Wells, James
Wilson, Andrew