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November 10, 2021

Jeanine D'Armiento, MD, PhD
Columbia University Irving Medical Center
630 West 168th Street
7th floor, room 421
New York, New York 10032

Dear Dr. D'Armiento:

SUBJECT: PARTIAL WAIVER OF AUTHORIZATION FOR SCREENING SUBJECTS
Sponsor: National Heart, Lung, and Blood Institute
Sponsor Pr. No.: AAAS8713
IRB Pr. No.: 20212809 IRB Study No.: 1310966
Protocol Title: Alpha-1 Antitrypsin Disease Cohort: Longitudinal Biomarker Study of Disease

On November 9, 2021, WCG IRB approved a request for a partial waiver of authorization for use and disclosure of protected health information (PHI). This review was conducted at a convened meeting. Please note that this letter is supplemental to the WCG IRB Certificate of Action for this study.

WCG IRB determined that documentation received from you satisfies the three requirements for a partial waiver of authorization under 45 CFR 164.512. These requirements are:

1. The use or disclosure of the PHI involves no more than minimal risk to the individuals, based on the following elements:

    a. An adequate plan to protect identifiers from improper use and disclosure;
    b. An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research (unless there is a health or research justification for retaining the identifiers, or such retention is otherwise required by law); and,
    c. Adequate written assurances that the PHI will not be reused or redisclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of PHI would be permitted by HIPAA.

2. The research could not be practicably conducted without access to and use of the PHI; and,

3. The research could not practicably be conducted without the waiver.

The Board determined that a waiver of authorization for the following protected health information and uses are needed and approved for this research:

> Information about potential subjects' past and present health, as well as demographic and contact information used to determine potential eligibility and to contact subjects to determine if they are willing to participate in this research study.

You may address the Board in person or in writing regarding its action. If you wish to address the Board in person or if you have questions, please contact Ranga Venkatesan, PhD, MS, RAC, at 360-252-2556, or e-mail regulatoryaffairs@wirb.com.

Sincerely,

Kelly FitzGerald, PhD
IRB Executive Chair and
Vice President IBC Affairs

KAF:RV:sm
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cc: Columbia University Institutional Office, Columbia University
Laura Fonseca, Columbia University Irving Medical Center
Study File