A WIRB-Copernicus Group Company

Western Institutional Review Board
1019 39th Ave SE / Suite 120
Puyallup WA 98374
800.562.4789
www.wirb.com

April 6, 2020

David Albert Woodard, MD
Piedmont Heart Institute
1968 Peachtree Road, NW
95 Building, Suite 5015
Atlanta, Georgia 30309

Dear Dr. Woodard:

SUBJECT: WAIVER OF AUTHORIZATION APPROVED
Sponsor: Aziyo Biologics, Inc. IRB Study No.: 1282271
Sponsor Pr. No.: CPR-2212A IRB Pr. No.: 20200825
Institution Tracking No.: 1585090
Protocol Title: RETROSPECTIVE EXPERIENCE OF CIED IMPLANTATION WITH PIEDMONT ATHENS REGIONAL ELECTROPHYSIOLOGY

On April 3, 2020, Western Institutional Review Board (WIRB) **approved** a request for a waiver of authorization for use and disclosure of protected health information (PHI) for the above-referenced research. This review was conducted through expedited review. Please note that this letter is supplemental to the WIRB Certificate of Action for this study.

WIRB determined that documentation received from you satisfies the three requirements for a 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 has determined that this waiver of authorization for the use and access of the protected health information as described in the above referenced protocol, and in the information provided in the submitted waiver of authorization form, is necessary for conduct of this research.

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 WIRB Regulatory Affairs at 360-252-2500, or e-mail RegulatoryAffairs@wirb.com.

Sincerely,

Kelly FitzGerald, PhD
Vice President, IRB Affairs

KAF:tb
W:\Documents\Correspondence\Waiver\Woodard 20200825
cc: Stephanie Richardson, Aziyo Biologics, Inc.
Robert Townsend, Aziyo Biologics, Inc.
Study File

This document electronically reviewed and approved by Abraham, Lindsay on 4/6/2020 10:29:17 AM PST. For more information call Client Services at 1-360-252-2500.