Salus IRB

January 24, 2025

Samuel B Reichberg, MD, PhD
New York Biologics, Inc.
41 Oak Grove Road
Southampton, New York 11968

Re: Sponsor: New York Biologics, Inc.
Study Title: Surplus Sample Collection
Salus Number: 01015

Dear Samuel B Reichberg, MD, PhD:

Salus IRB determined that continuing review of the research involves no more than minimal risk and qualifies for expedited review in accordance with 21 CFR 56.110, under the following research category: 5

Using the expedited review process, the following actions occurred on the above referenced study: IRB extended approval was granted on **January 15, 2025**.

Approved:

- Principal Investigator
- Investigative site(s)
- Collection Protocol v.2020
- Explanation of Retrieval Protocol Letter dated December 22nd, 2023
- Applied FDA's Guidance: Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable

Please review the items requiring reporting to Salus IRB in the following guidance documents located on the Salus IRB website:

- Salus_IRB_Investigator_Reporting_Responsibilities.pdf; and
- Reporting_Guidelines_for_UPs_Deviation_and_Other_Safety_Information.pdf.

IRB approval is granted on **January 15, 2025** and expires on **January 14, 2026**. A Continuing Review Report is required prior to the expiration date. As a courtesy, Salus IRB will send a reminder notice prior to the approval expiration date. Even if this notice is not received, the Principal Investigator is ultimately responsible for submitting the Continuing Review Report prior to study expiration.

If the research ends before the expiration date, you must complete and submit the Final Report Form.

Please visit our website at www.versiticlinicaltrials.org/salusirb to access specific submission forms and reporting requirements.

Salus IRB is appropriately constituted, organized, and conducts ethical review in accordance with the U.S. Food and Drug Administration (21 CFR Parts 50 and 56), the Department of Health and Human Services (45 CFR Part 46), the ICH Guideline for Good Clinical Practice E6(R2), and the ethical principles outlined in the Belmont Report.

We are pleased to be your IRB of record and look forward to the successful completion of this research.

If you have any questions or concerns, please contact our office at (512) 380-1244 or by email at salus@salusirb.com.

Sincerely,

Salus IRB