Ethical & Independent Review Services
A Shared Commitment to Ethical Research

IRB APPROVAL CERTIFICATION

Continuing Review - Study

E&I IRB #2 - IRB00007807

Roster dated January 12, 2021

IRB Signature

Signature Jean Taylor-Woodbury By TM 1/20/2021

Jean Taylor-Woodbury, RN, MS, ANP-BC, Chair — Teresa Majors — Date

Review and Approval Information

E&I Study Number 01015 - 21
Review Process Expedited 5

Approval Date Tuesday, January 19, 2021
Expiration Date Thursday, January 20, 2022 at 11:59 PM

This document certifies the IRB's continuing review approval of the items identified under "Documents Approved" to be conducted by the named Principal Investigator.

Included in this certification is the 01/19/2021, 21A modification approval of bolded item by expedited process, completed prior to the release of the approved continuing review documents.

Applied FDA's Guidance: Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable.

Study

Surplus Sample Collection

Client New York Biologics, Inc.
Sponsor New York Biologics, Inc.

Principal Investigator

Samuel B. Reichberg, MD, PhD

E&I PI Number 17023 - 002

Address

New York Biologics, Inc.
41 Oak Grove Road
Southampton, NY 11968

Performance Sites

New York Biologics, Inc., 41 Oak Grove Road, Southampton, NY 11968

Documents Approved	Document #	Version	Date
Explanation of Collection Protocol (Letter)			**December 30, 2020**
Collection Protocol			2020

Stipulations of Approval

1. No subjects may be involved in any study procedure prior to the IRB approval date or after the expiration date, unless otherwise stated in this letter. Investigators and sponsors are responsible for initiating Continuing Review proceedings.
2. All protocol modifications must be IRB approved prior to implementation. This includes any addition or change of recruitment materials, change of investigator, or performance site address. (Exception: If necessary to eliminate apparent immediate hazard to subjects.)
3. Report to E&I within five working days of learning if any of the following occur:
   - Unanticipated problems involving risk to human subjects or others;
   - Unanticipated Serious Adverse Events and Safety Reports;
   - Protocol deviations, violations, and exceptions that impact subject welfare or safety or study integrity including changes intended to reduce immediate risk to subjects;
   - Use of an investigational product in an emergency situation; and
   - Claims for compensation or for medical care for research-related injury.

This is a multi-sided document.

4. Advertising and recruitment materials must be approved by E&I prior to use or publication.

Copies to:

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END