

UNIVERSITY OF UTAH INSTITUTIONAL REVIEW BOARD

75 South 2000 East #140, Salt Lake City, UT 84112 | http://irb.utah.edu | 801-581-3655

July 1, 2023

To Whom it May Concern:

The Food and Drug Administration (FDA) conducted site inspections at the University of Utah Institutional Review Board (IRB) in 2004, 2007, 2012, 2017, and 2022. The purpose of these inspections was to determine whether IRB procedures for the protection of human subjects complied with Title 21 of the Code of Federal Regulations (CFR), Parts 50 and 56. These regulations apply to clinical studies of products regulated by the FDA.

Subsequent to all of these inspections, the FDA determined that the IRB adhered to the applicable statutory requirements and regulations governing the protection of human subjects. There were no findings identified during any of the site inspections.

Sincerely,

DocuSigned by:

Ann Johnson, PhD, MPH

Director

Institutional Review Board & Human Research Protection Program University of Utah

Certificate Of Completion

Envelope Id: D8EFF3511F3049CA852AB1C7A6E32EE9

Subject: Complete with DocuSign: fda_inspection_history_letter-2023.docx

Source Envelope:

Document Pages: 1 Signatures: 1 Certificate Pages: 1 Initials: 0

AutoNav: Enabled

Envelopeld Stamping: Enabled

Time Zone: (UTC-07:00) Mountain Time (US & Canada)

Status: Completed

Envelope Originator:

Lisa Rigtrup 75 2000 E

Salt Lake City, UT 84132 Lisa.Rigtrup@hsc.utah.edu IP Address: 73.63.104.90

Record Tracking

Status: Original

Jun 8, 2023 | 11:30

Holder: Lisa Rigtrup

DocuSigned by:

Lisa.Rigtrup@hsc.utah.edu

Signature Adoption: Pre-selected Style

Using IP Address: 136.36.156.5

Location: DocuSign

Signer Events

Ann Johnson

ann.johnson@hsc.utah.edu

IRB & HRPP DIRECTOR, UNIVERSITY OF UTAH

The University of Utah - Assoc. VP Research

Integrity

Security Level: Email, Account Authentication

(None)

Electronic Record and Signature Disclosure:

Not Offered via DocuSign

Signature **Timestamp**

Sent: Jun 8, 2023 | 11:31

STORM Viewed: Jun 12, 2023 | 21:13 -32E9785A2257457... Signed: Jun 12, 2023 | 21:14

In Person Signer Events	Signature	Timestamp
Editor Delivery Events	Status	Timestamp
Agent Delivery Events	Status	Timestamp
Intermediary Delivery Events	Status	Timestamp
Certified Delivery Events	Status	Timestamp
Carbon Copy Events	Status	Timestamp
Witness Events	Signature	Timestamp
Notary Events	Signature	Timestamp
Envelope Summary Events	Status	Timestamps
Envelope Sent Certified Delivered Signing Complete Completed	Hashed/Encrypted Security Checked Security Checked Security Checked	Jun 8, 2023 11:31 Jun 12, 2023 21:13 Jun 12, 2023 21:14 Jun 12, 2023 21:14
Completed	Socially Ghodica	