Official Title: Study to Evaluate the Safety, Tolerability and Immunogenicity of INO-4700 for Middle East Respiratory Syndrome Coronavirus (MERS-CoV) in Healthy Volunteers

NCT Number: NCT04588428

Document Date: Statistical Analysis Plan Version 2.0: 12-August-2021

STATISTICAL ANALYSIS PLAN

Sponsor:	Inovio Pharmaceuticals, Inc. 660 W. Germantown Pike, Suite 110 Plymouth Meeting, PA 19462 Tel: (267) 440-4200 Fax: (267) 440-4242
Sponsor Representative:	[redacted]
Protocol Title:	Study to Evaluate the Safety, Tolerability, and Immunogenicity of INO-4700 for MERS-CoV in Healthy Volunteers
Protocol Number:	MERS-201
Protocol Version and Date:	Amendment 1: 12FEB2021 Original: 23MAR2020
Name of Test Drug:	INO-4700
Phase:	Phase 2a
Methodology:	Randomized, Blinded, Placebo-controlled
Analysis Plan Date:	12 August 2021
Analysis Plan Version:	Version 2.0

APPROVAL SIGNATURE PAGE

Protocol Title: Study to Evaluate the Safety, Tolerability, and Immunogenicity of INO-4700 for Middle East Respiratory Syndrome Coronavirus (MERS-CoV) in Healthy Volunteers

Protocol Number: MERS-201

Sponsor: Inovio Pharmaceuticals, Inc.
660 W. Germantown Pike, Suite 110
Plymouth Meeting, PA 19462

Veristat, Inc. Author: [redacted]
Veristat, LLC
118 Turnpike Road
Southborough, MA 01772

Approval Signature	Job Title
DocuSigned by: [redacted] Signer Name: [redacted] Signing Reason: I approve this document Signing Time: 11-Aug-2021 | 10:52:17 AM EDT [redacted]	[redacted]

Sponsor Signatory: [redacted]
660 W. Germantown Pike, Suite 110
Plymouth Meeting, PA 19462

Sponsor Approval

By signing this document, I acknowledge that I have read the document and approve of the planned statistical analyses described herein. I agree that the planned statistical analyses are appropriate for this study, are in accordance with the study objectives, and are consistent with the statistical methodology described in the protocol, clinical development plan, and all applicable regulatory guidance and guidelines.

I have discussed any questions I have regarding the contents of this document with the biostatistical author.

I also understand that any subsequent changes to the planned statistical analyses, as described herein, may have a regulatory impact and/or result in timeline adjustments. All changes to the planned analyses will be described in the clinical study report.

Approval Signature	Job Title
DocuSigned by: [redacted] Signer Name: [redacted] Signing Reason: I approve this document Signing Time: 11-Aug-2021 | 11:10:23 AM EDT [redacted]	[redacted]

TABLE OF CONTENTS

Section **Page**

Section **Page**

TABLES INCLUDED IN THE TEXT

Page

LIST OF ABBREVIATIONS AND DEFINITION OF TERMS

Abbreviation	Definition
AE	Adverse event
AESI	Adverse events of special interest
ATC	Anatomic therapeutic class
CI	Confidence Interval
CO_2	Carbon Dioxide
CSR	Clinical Study Report
DSMB	Data Safety Monitoring Board
ECG	Electrocardiogram
EOS	End of Study
EP	Electroporation
ICH	International Conference on Harmonisation
ID	Intradermal
IRB	Institutional Review Board
IP	Investigational Product
MedDRA	Medical Dictionary for Regulatory Activities
MERS-CoV	Middle East Respiratory Syndrome Coronavirus
mITT	Modified intention to treat
PP	Per-protocol
PT	Preferred term
Rel Day	Relative study day
SAP	Statistical Analysis Plan
SARS	Severe Acute Respiratory Syndrome
SD	Standard Deviation
SOC	System organ class
SP	Safety Population
TEAE	Treatment-emergent adverse events

1. INFORMATION FROM THE STUDY PROTOCOL

1.1. Introduction and Objectives

1.1.1. Introduction

First reported in 2012 in a patient from Saudi Arabia presenting with pneumonia and acute kidney injury, Middle East Respiratory Syndrome Coronavirus (MERS-CoV) has existed in central and east Africa for decades [2]. MERS-CoV belongs to the family *Coronaviridae*, which includes four major groups: alpha, beta, gamma, and delta. Although genomically related to the subgroup B beta-coronavirus severe acute respiratory syndrome (SARS) virus, MERS-CoV belongs to the subgroup C beta-coronavirus lineage. As a novel beta-coronavirus with high pathogenicity, significant morbidity and mortality is associated with infection of this subgroup, in contrast to less severe illness with another coronavirus infection [3].

Those in either a healthcare setting or who have come in contact with camels constitute the majority of known exposure routes and potential source of transmission [4]. Indeed, nosocomial transmission due to inadequate infection control has been established as a major driver of MERS-CoV infections in humans [5, 6], and contributed to the 2014 outbreak in Saudi Arabia and 2015 outbreak in South Korea. Primary cases tend to be middle-aged males and those with occupational exposure to animal hosts, while secondary cases include younger men and women and those in contact with confirmed patients.

The overall purpose of this clinical trial is to evaluate the DNA vaccine, INO-4700, in a demographically relevant population with the eventual goal of preparation for both routine prophylaxis and use during an outbreak situation. The hypothesis is that the optimal dose of INO-4700 delivered intradermally (ID) followed by electroporation (EP) using CELLECTRA^{TM} 2000 in healthy volunteers will be well tolerated and exhibit an acceptable safety profile, eventually to result in the generation of immune response to MERS-CoV.

1.1.2. Study Objectives

This statistical analysis plan (SAP) is designed to outline the methods to be used in the analysis of study data to answer the study objectives. Populations for analysis, data handling rules, statistical methods, and formats for data presentation are provided. The statistical analyses and summary tabulations described in this SAP will provide the basis for the results sections of the clinical study report (CSR) for this trial. Any differences in the currently planned analytical objectives relative to those planned in the study protocol will also be outlined in this document.

1.1.2.1. Primary Objectives

There are three primary objectives for this trial:

- To evaluate the tolerability and safety of INO-4700 administered by ID injection, and followed by EP, in healthy adult volunteers
- To evaluate the cellular (T cell) and humoral immune responses to INO-4700 administered by ID injection followed by EP for identification and confirmation of an optimal dose and regimen
- To evaluate selected optimal dose for safety and immunogenicity

1.1.2.2. Exploratory Objectives

The exploratory objectives include the following:

- To evaluate the expanded immunological profile by assessing both T and B cell immune responses
- To evaluate the cellular (T cell) and humoral immune response to INO-4700 administered by ID injection followed by EP for impact of boosting with a third dose
- Evaluate humoral immune response cross reactivity to other coronaviruses

1.2. Study Design

1.2.1. Synopsis of Study Design

MERS-201 is a Phase 2a, randomized, blinded, placebo-controlled, multi-center trial, designed to evaluate the safety, tolerability, and immunological profile of INO-4700. The study drug will be administered by ID injection followed by EP using the CELLECTRA™ 2000 device in healthy adult volunteers. The primary objectives of this trial are to evaluate the tolerability, safety, and immunogenicity of INO-4700 administered by ID injection followed by EP in healthy adult volunteers according to the regimens outlined in Table 1-1, Table 1-2, Table 1-3 and Figure 1 of the MERS-201 Protocol.

Approximately 542 healthy volunteers will be evaluated across two (2) parts of this study, Part 1 and Part 2. Participation is exclusive to Part 1 or Part 2; participants from Part 1 do not roll over to Part 2. INO-4700 or placebo (SSC-0001) will be administered ID in ~0.1 mL dose volume followed immediately by EP.

Part 1 – Dose Finding

In Part 1, approximately 192 participants ages 18-50 years will be assessed through five (5) dose levels and regimens. These five (5) dosage levels and regimens will be evaluated across nine (9) groups designated Study Groups A, B, C, D, E, F, G, H, and I.

- Study Groups A, B, C, D, and E will receive INO-4700 and enroll approximately 32 participants per group.
- Study Groups F, G, H, and I will receive placebo and enroll approximately 8 participants per group.

Following the Data Safety Monitoring Board (DSMB) evaluation and the completion of the Week 10 visit, Part 1 will be unblinded. The optimal regimen will be chosen based on optimal immune response, acceptable safety profile, and dose tolerance. Part 1 participants will be followed for the full 48 weeks, until the planned end of study visit.

Part 2 – Expansion

In Part 2A, approximately 350 participants will be evaluated across the one (1) dose level determined in Part 1. Enrollment into Part 2 may begin following completion of the Week 10 visit. Participants will be randomized to receive active treatment (n=300) or placebo (n=50).

In Part 2B, a booster dose will be administered to a subset of the participants from Part 2A. The first 200 participants from the Active treatment group will be randomized to receive either a booster dose or placebo at Week 48 (in addition to the first 2 doses at Day 0 and Week 4 or 8). Similarly, the first 25 participants from the Part 2A Placebo group will receive placebo at Week 48 as a control for Part 2B. All participants receiving a third dose at Week 48 (collectively 225 participants) will be followed for 68 weeks from the Day 0 dosing (i.e., Week 68 will be the planned End of Study [EOS] visit). These 225 patients will be enrolled first. The remaining 125 participants in Part 2A (i.e., those receiving only 2 doses) will be followed for 48 weeks from the Day 0 dosing (i.e., Week 48 will be the planned EOS visit).

1.2.2. Randomization Methodology

Part 1 of this study will be randomized across Study Groups A through I. Part 2 of this study will be randomized between the selected optimal active dose from Part 1 and placebo groups. The study is investigator-and-participant blinded except for the site pharmacy across all study groups for both parts of the study. The Sponsor will be blinded in Part 1 until Week 10 and blinded for the entire duration of Part 2 of the study.

Part 2 of the study includes an analysis at Week 12 to produce group-level, unblinded summaries of immunogenicity and safety. The first 225 subjects in Part 2 will be randomized to booster dose regimens and followed for 68 weeks; the remaining 125 subjects will be randomized to two dose regimens and followed for 48 weeks. The Sponsor will continue to remain blinded to subject-level treatment allocation for the remainder of the trial.

For details, see the randomization plan found in Appendix B of this SAP.

1.2.3. Stopping Rules and Unblinding

The trial will be stopped for any of the following criteria:

- Any treatment-related serious adverse event
- Any Grade 4 toxicities related to study treatment
- Any report of anaphylaxis from study treatment.

Should any of these criteria be met, at any time point in the study, the DSMB will be notified immediately. The study may be paused or stopped if the DSMB consider the safety data unsatisfactory. In this case, further enrollment of participants and further administration of INO-4700 or placebo to participants will be paused for further evaluation. An investigation will be undertaken by the Sponsor in consultation with the DSMB, and other experts if needed, to determine whether to resume randomization and/or dosing of the remainder of enrolled participants.

1.2.4. Study Procedures

The schedule of assessments, as outlined in the study protocol, are provided in

Table 1-1, 1-2, and 1-3.

Table 1-1 Part 1 Schedule of Assessments

Tests and assessments	Screen[a]	Day 0		Week 2 (± 3d)	Week 4 (± 5d)		Week 6 (± 5d)	Week 8 (± 5d)		Week 10 (± 5d)	Week 12[b] (± 5d)	Week 30[b] (± 10d)	Week 48 (± 5d)
		Pre	Post		Pre	Post		Pre	Post				
Informed Consent	X												
Inclusion/Exclusion Criteria	X												
Medical History	X	X[a]											
Demographics	X												
Concomitant Medications	X	X		X	X		X	X		X			X
Physical Exam[c]	X	X		X	X		X	X		X			X
Vital Signs	X	X		X	X		X	X		X			X
Height and Weight	X												
CBC with Differential	X			X			X			X			X
Chemistry and Liver Function[d]	X			X			X			X			X
Serology[e]	X												
12-lead ECG	X												
Urinalysis Routine[f]	X			X			X			X			X
Pregnancy Test[g]	X	X			X[k]			X[l]					
INO-4700 or placebo + EP[h]		X[i,j]			X[i,k]			X[j,l]					
Download EP Data[m]			X			X[k]			X[l]				
Adverse Events[n]	X	X	X	X	X	X	X	X	X	X	X	X	X
Immunology 1y (Whole blood)[o]	X	X					X			X			X
Immunology (Serum)[p]	X	X					X			X			X

a. Screening assessment occurs from -60 days to -1 day prior to Day 0. If screening occurs within 14 days prior to Day 0, then do not repeat medical history prior to dosing.
b. Follow-up phone call to collect AEs
c. Full physical examination at screening and Week 48 (or any other study discontinuation visit) only. Targeted physical exam at all other visits.
d. Includes Na, K, Cl, HCO_3 or CO_2, Ca, PO_4, glucose, BUN, Cr, AST and ALT.
e. MERS-CoV antibody (per PI discretion), HIV antibody or rapid test, HBsAg, HCV antibody.
f. Dipstick for glucose, protein, and hematuria. Microscopic examination should be performed if dipstick is abnormal.
g. Serum pregnancy test at screening. Urine pregnancy test at other visits.
h. INO-4700 or placebo is prepared by unblinded pharmacy personnel. All doses delivered via ID injection followed by EP.
i. For Study Groups A, B and F, one injection preferably over deltiod muscle at Day 0 and Week 4. For Study Groups E and I, two injections with each injection over a different deltoid or lateral quadriceps, preferably over the deltoid muscles, at Day 0 and Week 4.
j. For Study Groups C and G, one injection preferably over deltoid muscle at Day 0 and Week 8. For Study Groups D and H, two injections with each injection over a different deltoid or lateral quadriceps, preferably over the deltoid muscles, at Day 0 and Week 8.

k. Complete only for Study Groups A, B, E, F and I.
l. Complete for Study Groups C, D, G and H.
m. Following administration of INO-4700 or placebo, EP data will be downloaded from the CELLECTRA™ 2000 device and provided to Inovio.
n. Includes AEs from the time of consent and all injection site reactions that qualify as an AE. All AEs collected until study discharge.
o. 4 x 8.0 mL (32 mL) whole blood in Cell Preparation Tubes (CPT) tubes per time point. Note: At the investigator's discretion, rather than collecting a sample at screening, 64 mL (8 x 8.0 mL whole blood in CPT tubes) may be collected prior to dosing on Day 0).
p. 1 x 8 mL blood in 10 mL red top serum collection tube per time point. Note: Collect four aliquots of 1 mL each (total 4 mL) serum at each time point prior to 1st dose. At the investigator's discretion, rather than collecting a sample at screening, 2 x 8 mL blood in two (2) 10 mL red top serum collection tubes (for eight aliquots of 1 mL each) may be collected prior to dosing on Day 0.

Table 1-2 Part 2 Schedule of Assessments (Day 0 & Week 4 Optimal Regimen)

Tests and assessments	Screen[a]	Day 0		Week 2 (± 3d)	Week 4 (± 5d)		Week 6 (± 5d)	Week 8[b] (± 5d)	Week 12 (± 5d)	Week 30[b] (± 10d)	Week 48 (± 5d)		Week 50[i] (± 5d)	Week 68[i] (± 10d)
		Pre	Post		Pre	Post					Pre	Post		
Informed Consent	X													
Inclusion/Exclusion Criteria	X													
Medical history	X	X[a]												
Demographics	X													
Concomitant Medications	X	X		X	X		X				X		X	X
Physical Exam[c]	X	X		X	X		X				X		X	X
Vital Signs	X	X		X	X		X				X		X	X
Height and Weight	X													
CBC with differential	X			X			X				X		X	X
Chemistry and Liver Function[d]	X			X			X				X		X	X
Serology[e]	X													
12-lead ECG	X													
Urinalysis Routine[f]	X			X			X				X		X	X
Pregnancy Test[g]	X	X			X						X[i]			
INO-4700 or placebo + EP[h]		X			X						X[i]			
Download EP Data[j]			X			X						X[i]		
Adverse Events[k]	X	X	X	X	X	X	X	X	X	X	X	X[i]	X	X
Immunology (Whole blood)[l]	X	X					X		X		X		X	X
Immunology (Serum)[m]	X	X					X		X		X		X	X

a. Screening assessment occurs from -60 days to -1 day prior to Day 0. If screening occurs within 14 days prior to Day 0, then do not repeat medical history prior to dosing.
b. Follow-up phone call to collect AEs.
c. Full physical examination at screening and Week 48 (participants receiving only two doses) or Week 68 (participants receiving three doses), as well as any other study discontinuation visit. Targeted physical exam at all other visits.
d. Includes Na, K, Cl, HCO_3 or CO_2, Ca, PO_4, glucose, BUN, Cr, AST, and ALT.
e. MERS-CoV antibody (per PI discretion), HIV antibody or rapid test, HBsAg, HCV antibody.
f. Dipstick for glucose, protein, and hematuria. Microscopic examination should be performed if dipstick is abnormal.
g. Serum pregnancy test at screening. Urine pregnancy test prior to dosing at other visits.
h. INO-4700 or placebo is prepared by unblinded pharmacy personnel. All doses delivered via ID injection followed by EP.
i. Complete only for participants receiving a third dose of either INO-4700 or placebo (Part 2B).
j. Following administration of INO-4700 or placebo, EP data will be downloaded from the CELLECTRA™ 2000 device and provided to Inovio.
k. Includes AEs from the time of consent and all injection site reactions that qualify as an AE. All AEs collected until study discharge.

l. 4 x 8.0 mL (32 mL) whole blood in Cell Preparation Tubes (CPT) tubes per time point. Note: At the investigator's discretion, rather than collecting a sample at screening, 64 mL (8 x 8.0 mL whole blood in CPT) may be collected prior to dosing on Day 0).

m. 1 x 8 mL blood in 10 mL red top serum collection tube per time point. Note: Collect four aliquots of 1 mL each (total 4 mL) serum at each time point prior to 1st dose. At the investigator's discretion, rather than collecting a sample at screening, 2 x 8 mL blood in two (2) 10 mL red top serum collection tubes (for eight aliquots of 1 mL each) may be collected prior to dosing on Day 0).

Table 1-3 Part 2 Schedule of Assessments (Day 0 & Week 8 Optimal Regimen)

Tests and assessments	Screen[a]	Day 0		Week 2 (± 3d)	Week 4[b] (± 5d)	Week 8 (± 5d)		Week 10 (± 5d)	Week 12[b] (± 5d)	Week 30[b] (± 10d)	Week 48 (± 5d)		Week 50[i] (± 5d)	Week 68[i] (± 10d)
		Pre	Post			Pre	Post				Pre	Post		
Informed Consent	X													
Inclusion/Exclusion Criteria	X													
Medical history	X	X[a]												
Demographics	X													
Concomitant Medications	X	X		X		X		X			X		X	X
Physical Exam[c]	X	X		X		X		X			X		X	X
Vital Signs	X	X		X		X		X			X		X	X
Height and Weight	X													
CBC with differential	X			X				X			X		X	X
Chemistry and Liver Function[d]	X			X				X			X		X	X
Serology[e]	X													
12-lead ECG	X													
Urinalysis Routine[f]	X			X				X			X		X	X
Pregnancy Test[g]	X	X				X					X[i]			
INO-4700 or placebo + EP[h]	X	X				X					X[i]			
Download EP Data[j]			X				X					X[i]		
Adverse Events[k]	X	X	X	X	X	X	X	X	X	X	X	X[i]	X	X
Immunology (Whole blood)[l]	X	X				X		X			X		X	X
Immunology (Serum)[m]	X	X				X		X			X		X	X

a. Screening assessment occurs from -60 days to -1 day prior to Day 0. If screening occurs within 14 days prior to Day 0, then do not repeat medical history prior to dosing.
b. Follow-up phone call to collect AEs.
c. Full physical examination at screening and Week 48 (participants receiving only two doses) or Week 68 (participants receiving three doses), as well as any other study discontinuation visit. Targeted physical exam at all other visits.
d. Includes Na, K, Cl, HCO_3 or CO_2, Ca, PO_4, glucose, BUN, Cr, AST and ALT.
e. MERS-CoV antibody (per PI discretion), HIV antibody or rapid test, HBsAg, HCV antibody.
f. Dipstick for glucose, protein, and hematuria. Microscopic examination should be performed if dipstick is abnormal.
g. Serum pregnancy test at screening. Urine pregnancy test prior to dosing at other visits.
h. INO-4700 or placebo is prepared by unblinded pharmacy personnel. All doses delivered via ID injection followed by EP.
i. Complete only for participants receiving a third dose of either INO-4700 or placebo (Part 2B).
j. Following administration of INO-4700 or placebo, EP data will be downloaded from the CELLECTRA™ 2000 device and provided to Inovio.
k. Includes AEs from the time of consent and all injection site reactions that qualify as an AE. All AEs collected until study discharge.

l. 4 x 8.0 mL (32 mL) whole blood in 10 mL Cell Preparation Tubes (CPT) per time point. Note: At the investigators' discretion, rather than collecting a sample at screening, 64 mL (8 x 8.0 mL whole blood in CPT) may be collected prior to dosing on Day 0).

m. 1 x 8 mL blood in 10 mL red top serum collection tube per time point. Note: Collect four aliquots of 1 mL each (total 4 mL) serum at each time point prior to 1st dose. At the investigator's discretion, rather than collecting a sample at screening, 2 x 8 mL blood in two (2) 10 mL red top serum collection tubes (for eight aliquots of 1 mL each) may be collected prior to dosing on Day 0.

1.2.5. Safety, Immunology, and Exploratory Parameters

1.2.5.1. Safety Parameters

- Incidence of adverse events (AEs) summarized by system organ class (SOC), preferred term (PT), and grouped by severity and relationship to investigational product.
- Frequency and severity of injection site reactions.
- Incidence of adverse events of special interest (AESIs).

Details and definitions of AEs are provided in the Section 4.3.2.2.

1.2.5.2. Immunology Parameters

- Overall Immune Response
    - MERS-CoV antigen specific antibodies
    - Antigen-specific cytokine-producing T cell responses

1.2.5.3. Exploratory Parameters

The exploratory endpoint of expanded immune response parameters will include (provided there are available samples):

- Change in T and B cell immunologic proteins levels
- Change in levels of mRNA for genes of interest
- Antibodies to other coronaviruses

In addition to the overall immune response, endpoints to determine the response to the booster dose response for selected participants will be measured, including

- MERS-CoV antigen specific antibodies
- Antigen-specific cytokine-producing T cell responses
- T and B cell responses from immunogenicity assays

2. PARTICIPANT POPULATION

2.1. Population Definitions

The following participant populations will be used for presentation and analysis of the data:

- The modified intention to treat (mITT) population - includes all participants who receive at least one dose of the INO-4700 or placebo. Participants in this sample will be analyzed by their original assigned dose of INO-4700 or placebo. The mITT population will be used to analyze co-primary and exploratory immunological endpoints.

- The per-protocol (PP) population - comprises mITT participants who receive all their planned administrations and who have no Medical Monitor-assessed important protocol violations. Analyses on the PP population will be considered supportive of the corresponding mITT analyses. Participants excluded from the PP population will be identified and documented prior to locking the study database.

- The safety population (SP) - includes all participants who receive at least one dose of INO-4700 or placebo administered by ID injection. Participants for this population will be grouped in accordance with the dose of INO-4700 or placebo that they received. This population will be used for all safety analyses in the study.

2.2. Protocol Violations

Participants are not required to follow special instructions specific to the Investigational Product (IP) used in this clinical trial. Participants will be provided with Investigator emergency contact information and advised to report all AEs. While every effort should be made to avoid protocol deviations, should an important deviation be discovered, the Sponsor must be informed immediately. Any protocol deviation impacting participant safety must be reported to the Medical Monitor immediately.

At the discretion of the Sponsor, major protocol violations, as determined by a review of the data prior to unblinding of the study results and the conduct of statistical analyses, may result in the remove of a participant's data from the PP population. The Sponsor or designee will be responsible for producing the final protocol violation file (formatted as a Microsoft Excel file), in collaboration with Veristat and the data monitoring group as applicable; this file will include a description of the protocol violation and clearly identify whether or not this violation warrants exclusion from the PP population. This file will be finalized prior to hard database lock.

All protocol violations will be presented in a data listing.

3. GENERAL STATISTICAL METHODS

3.1. Sample Size Justification

The study is to be conducted in two parts. No formal power analysis is applicable to Part 1 of this trial, as descriptive statistics will be used to summarize the data.

For Part 1 of the trial with 32 INO-4700 administered participants per study group, the study provides 95% confidence that the true incidence of serious adverse events (SAEs) is <11% if no SAEs are observed in a study group. For all the study groups combined in Part 1 of the trial with 160 INO-4700 administered participants, the study provides 95% confidence that the true incidence of SAEs is <3% if no SAEs are observed in this study phase. For all study groups combined across Parts 1 and 2 of the trial with 460 INO-4700 administered participants, the study provides 95% confidence that the true incidence of SAEs is <1% if no SAEs are observed.

For Part 2 of this trial, an evaluable sample of 260 active participants treated with INO-4700, which will be used for formal hypothesis testing, provides >90% power to detect an INO-4700 overall immunological response rate of 70% or higher should this overall response rate truly be 80%, using a one-sided type 1 error rate of 0.025.

3.2. General Methods

All data listings that contain an evaluation date will have a relative study day (Rel Day). Pre-treatment and on-treatment study days are numbered relative to the day of the first dose of study medication (Day 0) which is designated as Rel Day 1. The preceding day is Rel Day -1, the day before that is Rel Day -2, etc. There is no Rel Day 0.

All output will be incorporated into Microsoft Word or Excel files, or Adobe Acrobat PDF files, sorted and labeled according to the International Council on Harmonisation (ICH) recommendations, and formatted to the appropriate page size(s).

Tabulations will be produced for appropriate demographic, baseline, immunogenicity, and safety parameters. For categorical variables, summary tabulations of the number and percentage of participants within each category of the parameter will be presented. For continuous variables, the number of participants, mean, median, standard deviation (SD), minimum, and maximum values will be presented. Summarizations will be presented by study group and overall as applicable for Part 1, and by treatment groups (randomized to active, randomized to placebo, randomized to an active booster with previous active dose, to placebo booster dose who had previously 2 active doses, and the number randomized to three placebo doses) and overall as applicable for Part 2. All data from active vs. placebo treatments will be pooled and summarized.

Formal statistical hypothesis testing will be performed on the primary immunogenicity endpoint (see Section 1.2.5.1.) with all tests conducted at the 1-sided, 0.025 level of significance. Summary statistics will be presented, as well as confidence intervals (CIs) on selected parameters, as described in the sections below.

3.3. Computing Environment

All statistical analyses will be performed using SAS statistical software Version 9.4. Adverse events will be coded using the current Medical Dictionary for Regulatory Activities (MedDRA) Version 22.1 or higher.

All output will be incorporated into Microsoft Word or Excel files, or Adobe Acrobat PDF files, sorted and labeled according to the ICH recommendations, and formatted to the appropriate page sizes.

3.4. Baseline Definitions

For all analyses, baseline will be defined as the most recent measurement prior to the first administration of study drug.

3.5. Methods of Pooling Data

Data will be pooled across study sites.

3.6. Adjustments for Covariates

Exploratory Analysis of Covariance (ANCOVA) and logistic regression models may be fitted to study the relationship between study group and different immune response variables. Possible covariates may include baseline values, age, antibodies, gender, and other covariates to test the relationship between study group and different immune response variables. The relationship between antibodies to other coronaviruses and humoral immune responses will be explored using regression methods such as linear regression.

3.7. Multiple Comparisons/Multiplicity

No adjustments for multiplicity will be conducted for this trial.

3.8. Subpopulations

No analyses of participant subgroups are planned.

3.9. Withdrawals, Dropouts, Loss to Follow-up

Participants who are withdrawn or discontinued from the study will not be replaced.

3.10. Missing, Unused, and Spurious Data

In general, other than for AE and concomitant treatments, missing data will not be imputed or replaced, and calculations will be done on reported values.

When summarizing adverse event data, partial dates will be handled as follows. If any of the day, month, or year is missing, the onset date will be set to the earliest date that is consistent with any non-missing date information, unless the non-missing date information is the same as study treatment start. In this case, to conservatively report the event as treatment-emergent, the

onset date will be assumed to be the date of start of treatment. A completely missing onset date will be coded as the day of start of treatment. If the resulting imputed start date is later than a reported stop date, the start date will be imputed as the stop date. Date imputation is used only to determine treatment emergence; in by-patient listings, partial dates will be presented as recorded.

A prior medication is defined as any medication that has a stop date before the start of the trial (prior to Dose #1 on Day 0). A concomitant medication is defined as any medication that has a stop date that is on or after the date of first dose of study drug. For prior and concomitant medications, partial start dates will not be imputed, as stop dates determine prior versus concomitant. Partial stop dates will be assumed to be the latest possible date consistent with the partial date.

Partial stop dates of prior and concomitant medications will be assumed to be the latest possible date consistent with the partial date. Data for all prior and concomitant medications will be summarized with percentages for participants in the safety and mITT populations.

3.11. Visit Windows

It is expected that all visits should occur according to the protocol schedule. All data will be tabulated per the evaluation visit as recorded on the clinical report form (CRF) even if the assessment is outside of the visit window. In data listings, the relative day of all dates will be presented.

3.12. Interim Analyses

No formal interim analyses are planned for this study. However, safety and tolerability will be assessed by the DSMB for the participants in each study group.

A Sponsor unblinded review of the Week 10 immunogenicity and safety data will be made during Part 1, when all evaluable data observations are available for determination of the optimal dose for Part 2.

Additionally, upon completion of the Week 12 visit and availability of immunological data, group-level (INO-4700 or placebo) unblinded summaries of immunogenicity and safety will be produced.

4. STUDY ANALYSES

4.1. Participant Disposition

Participant disposition will be tabulated by study group (A-I) for Part 1 and by treatment group for Part 2, and will include the number screened, the number of screen failures, the number randomized, the number in each population for analysis, the number treated by the highest number of doses received, the number that completed all study treatments and follow-up visits, the number who discontinued prior to completing the study treatment, the number who withdrew prior to completing all follow-up visits, and reason(s) for withdrawal.

A by-participant data listing of study completion information including the reason for premature study withdrawal, if applicable, will be presented.

4.2. Demographics and Baseline Characteristics

Demographics and baseline characteristics will be summarized and presented by study group for Part 1 and treatment group for Part 2. Age, height, weight, and body mass index (BMI) will be summarized using descriptive statistics (number of participants, mean, SD, median, minimum, and maximum). The number and percentage of participants in each sex, race, and ethnicity category also will be presented. These analyses will be conducted on the mITT and PP populations.

No formal statistical comparisons between groups will be performed for demographics, baseline data, or medical history data. Data for each participant will also be provided in data listings.

4.3. Immunology, Safety, and Exploratory Evaluations

4.3.1. Immunology Evaluations

The following immunogenicity analyses will be conducted on participants in the PP and mITT study populations.

In Part 1, the difference in percentage of overall immune responders including seroconverters (i.e. positive titer) between all pairs of INO-4700 study groups will be calculated along with corresponding exact (Clopper-Pearson) 95% CIs. The T and B cell immune responses to INO-4700 will be measured using assays that include ELISA, neutralization, assessment of immunological gene expression, assessment of immunological protein expression, flow cytometry, and ELISPOT.

In Part 2, the primary hypothesis of H_0: $p \leq 70\%$ versus H_1: $p > 70\%$ will be tested with an exact test of a binomial proportion. In addition, the binding antibody titer difference between INO-4700 and placebo will be analyzed using the geometric mean fold ratio and associated 95% confidence interval. Percent neutralizing antibodies and antigen specific cellular immune response differences between INO-4700 and placebo will be analyzed using the difference in medians and associated 95% CIs.

For both Part 1 and Part 2, antigen specific binding antibody titers, MERS-CoV neutralizing antibody titers, antibodies to other coronaviruses, and specific cellular immune responses will

be analyzed by study group and treatment group, respectively. Time to peak post-baseline titers will be summarized using descriptive statistics. Binding antibody titer will be analyzed for each study group using the geometric mean and associated 95% CIs. Percent neutralizing antibodies and antigen specific cellular immune response increases will be analyzed for each study group using medians, inter-quartile range and 95% CIs. Percentage with overall immune response, inclusive of seroconversion and corresponding 95% Clopper-Pearson CIs will be analyzed within each study and treatment group.

All immunologic data will be presented in data listings.

4.3.2. Safety Analyses

All safety analyses will be conducted using the Safety Population. For analyses on Part 1, tabulations will be provided by study group. For analyses on Part 2, tabulations will be provided by treatment group.

Incidences of medical history events will be presented by MedDRA SOC and PT v. 22.1 or higher using the Safety Population.

4.3.2.1. Study Drug Exposure

Study drug information for each participant will be presented in a data listing and will include the date and time of administration, the study part, treatment group, dose, and the location of the injection site. Number of applications of the electroporation and the CELLECTRA™ used will also be presented in the same listing.

4.3.2.2. Adverse Events

All AEs will be coded using the MedDRA SOC and PT coding system (v. 23.0) and displayed in tables by study and treatment groups and by subject in data listings.

Analyses of AEs will be performed for those events that are considered treatment-emergent, where treatment-emergent adverse events (TEAEs) are defined per protocol as any adverse event with onset after the administration of study medication through the end of the study (Week 68), or any event that was present at baseline but worsened in intensity or was subsequently considered drug-related (definite, probable, or possible relationship) by the Investigator through the end of the study.

Laboratory AEs will be assessed and graded in accordance with the "Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials", issued in September 2007 (see Protocol Appendix A).

Adverse events will be summarized by participant incidence rates; therefore, in any tabulation, a participant contributes only once (i.e., the most related occurrence or the most intense occurrence) to each of the incidence rates in the descriptive analysis, regardless of the number of episodes.

All TEAEs will be summarized by frequency, percentage, and, in Part 2, by the difference in the percentage between those who received INO-4700 and their corresponding regimen placebo.

Related SAEs and related Grade 3 or higher AEs will also be analyzed as described above within and between associated placebo in Part 1. The frequencies will also be presented separately by dose number and will be depicted by SOC and PT. Additional frequencies will be presented with respect to maximum severity and relationship to IP. Multiple occurrences of the same AE in a single participant will be counted only once following a worst-case approach with respect to severity and relationship to INO-4700. All serious TEAEs will also be summarized as above.

No formal hypothesis-testing analysis of adverse event incidence rates will be performed.

By-participant listings will be provided for all AEs, participant deaths, SAEs, and AEs leading to withdrawal.

4.3.2.2.1. Adverse Events of Special Interest

Adverse events of special interest (AESIs) will be analyzed in a similar fashion as standard TEAEs (see Appendix B in the MERS-201 Protocol v 2.0 12FEB2021). These include respiratory distress syndrome, pneumonia, neurologic, hematologic, immunologic, and other events (including local or systemic SAEs, acute renal failure, SARS-CoV-2 infection, or death). In addition, anxiety and pain related to the EP procedure will be monitored.

4.3.2.3. Laboratory Data

Clinical laboratory values will be expressed in International System (SI) units. The actual value and changes from baseline to each on-study evaluation will be summarized using descriptive statistics and 95% CIs for hematology, chemistry, and urinalysis laboratory parameters. In the event of repeat values, the average value per study day/time will be used. Tabulations will be provided by study group for Part 1 and treatment group for Part 2.

Serum pregnancy at screening and urine pregnancy at each post baseline time point will also be descriptively summarized for participants in the safety population.

All laboratory data will be presented in data listings. Laboratory values considered clinically significant will also be presented in a distinct listing.

4.3.2.4. Vital Signs and Physical Examination

Measurements for vital signs as well as changes from baseline will be descriptively summarized by time point for participants in the safety population. Tabulations will be provided by study group for Part 1 and treatment group for Part 2.

Vital sign measurements will be presented for each participant in a data listing.

Physical examination results will be presented in a data listing.

4.3.2.5. Electrocardiogram

Results and changes from baseline from 12-lead electrocardiogram (ECG) performed at all visits, including measurements of ventricular rate, PR, QRS, QT, QTcB or QTcF, as well as an assessment of whether the ECG is normal or abnormal will be summarized using descriptive statistics. Tabulations will be provided by study group for Part 1 and treatment group for Part 2.

Electrocardiogram data for each participant, including interpretation of abnormal ECGs will be collected and analyzed as a dichotomous variable, as clinically significant or not clinically significant. These results will be provided in data listings.

4.3.2.6. Concomitant Medications

Concomitant medications will be coded using the WHO Drug Dictionary. Results will be tabulated by anatomic therapeutic class (ATC) and PT.

Prior medications are defined as those that were used and stopped before the start of the trial (prior to Day 0/ Rel Day 1) and concomitant medications are defined as those used during the trial (on or after Day 0/ Rel Day 1). Data for all prior and concomitant medications will be summarized with percentages for participants in the safety, mITT, and PP populations.

The use of concomitant medications will be included in a by-participant data listing.

5. CHANGES TO PLANNED ANALYSES

1. Updated analysis population to include Per Protocol (PP) for:
    - Demographics and Baseline Characteristics (Section 4.2)
    - Concomitant Medication (Section 4.3.2.6.)
2. Key analysis population has been changed to PP for Immunogenicity (Section 4.3.1.).

6. REFERENCES

1. Zaki AM, van Boheemen S, Bestebroer TM, Osterhaus AD, Fouchier RA. Isolation of a novel coronavirus from a man with pneumonia in Saudi Arabia. *N Engl J Med* 2012,**367**:1814-1820.

2. Muller MA, Corman VM, Jores J, Meyer B, Younan M, Liljander A*, et al.* MERS coronavirus neutralizing antibodies in camels, Eastern Africa, 1983-1997. *Emerg Infect Dis* 2014,**20**:2093-2095.

3. Fehr AR, Perlman S. Coronaviruses: an overview of their replication and pathogenesis. *Methods Mol Biol* 2015,**1282**:1-23.

4. Dawson P, Malik MR, Parvez F, Morse SS. What Have We Learned About Middle East Respiratory Syndrome Coronavirus Emergence in Humans? A Systematic Literature Review. *Vector Borne Zoonotic Dis* 2019,**19**:174-192.

5. Maltezou HC, Tsiodras S. Middle East respiratory syndrome coronavirus: implications for health care facilities. *Am J Infect Control* 2014,**42**:1261-1265

6. Alraddadi BM, Al-Salmi HS, Jacobs-Slifka K, Slayton RB, Estivariz CF, Geller AI*, et al.* Risk Factors for Middle East Respiratory Syndrome Coronavirus Infection among Healthcare Personnel. *Emerg Infect Dis* 2016,**22**:1915-1920.

7. REVISION HISTORY

Statistical Analysis Plan Version 2.0: 12 August 2021

Statistical Analysis Plan Version 1.0: 04 December 2020

8. APPENDICES

8.1. Appendix A: Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trial

Table for Clinical Abnormalities

Local Reaction to Injectable Product	**Mild (Grade 1)**	**Moderate (Grade 2)**	**Severe (Grade 3)**	**Potentially Life Threatening (Grade 4)**
Pain	Does not interfere with activity	Repeated use of non-narcotic pain reliever > 24 hours or interferes with activity	Any use of narcotic pain reliever or prevents daily activity	Emergency room (ER) visit or hospitalization
Tenderness	Mild discomfort to touch	Discomfort with movement	Significant discomfort at rest	ER visit or hospitalization
Erythema/Redness[a]	2.5-5 cm	5.1-10 cm	> 10 cm	Necrosis or exfoliative dermatitis
Induration/Swelling[b]	2.5-5 cm and does not interfere with activity	5.1-10 cm or interferes with activity	> 10 cm or prevents daily activity	Necrosis
Vital Signs[c]	**Mild (Grade 1)**	**Moderate (Grade 2)**	**Severe (Grade 3)**	**Potentially Life Threatening (Grade 4)**
Fever (°C)[d] (°F)[d]	38.0-38.4 100.4-101.1	38.5-38.9 101.2-102.0	39.0-40.0 102.1-104.0	> 40.0 > 104.0
Tachycardia - beats per minute	101-115	116-130	> 130	ER visit or hospitalization for arrhythmia
Bradycardia - beats per minute[e]	50-54	45-49	< 45	ER visit or hospitalization for arrhythmia
Hypertension (systolic) - mm Hg	141-150	151-155	> 155	ER visit or hospitalization for malignant hypertension
Hypertension (diastolic) - mm Hg	91-95	96-100	> 100	ER visit or hospitalization for malignant hypertension
Hypotension (systolic) - mm Hg	85-89	80-84	< 80	ER visit or hospitalization for hypotensive shock
Respiratory Rate - breaths per minute	17-20	21-25	> 25	Intubation

[a] In addition to grading the measured local reaction at the greatest single diameter, the measurement should be recorded as a continuous variable.
[b] Induration/Swelling should be evaluated and graded using the functional scale as well as the actual measurement.
[c] Subject should be at rest for all vital sign measurements.
[d] Oral temperature; no recent hot or cold beverages or smoking.
[e] When resting heart rate is between 60-100 beats per minute. Use clinical judgement when characterizing bradycardia among some healthy subject populations, for example, conditioned athletes.

Systemic (General)	**Mild (Grade 1)**	**Moderate (Grade 2)**	**Severe (Grade 3)**	**Potentially Life Threatening (Grade 4)**
Nausea/Vomiting	No interference with activity or 1-2 episodes/24 hours	Some interference with activity or > 2 episodes/24 hours	Prevents daily activity, requires outpatient IV hydration	ER visit or hospitalization for hypotensive shock
Diarrhea	2-3 loose stools or < 400 gms/24 hours	4-5 loose stools or 400-800 gms/24 hours	6 or more watery stools or > 800 gms/24 hours or requires outpatient IV hydration	ER visit or hospitalization
Headache	No interference with activity	Repeated use of non-narcotic pain reliever > 24 hours or some interference with activity	Significant; any use of narcotic pain reliever or prevents daily activity	ER visit or hospitalization
Fatigue	No interference with activity	Some interference with activity	Significant; prevents daily activity	ER visit or hospitalization
Myalgia	No interference with activity	Some interference with activity	Significant; prevents daily activity	ER visit or hospitalization
Systemic Illness	**Mild (Grade 1)**	**Moderate (Grade 2)**	**Severe (Grade 3)**	**Potentially Life Threatening (Grade 4)**
Illness or clinical adverse event (as defined according to applicable regulations)	No interference with activity	Some interference with activity not requiring medical intervention	Prevents daily activity and requires medical intervention	ER visit or hospitalization

U.S. Department of Health and Human Services, Food and Drug Administration, and Center for Biologics Evaluation and Research. Guidance for industry: Toxicity grading scale for healthy adult and adolescent volunteers enrolled in preventive vaccine clinical trials. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/toxicity-grading-scale-healthy-adult-and-adolescent-volunteers-enrolled-preventive-vaccine-clinical 2007 Sep; 3-5

8.2. Appendix B: Randomization Plan

See most recent version in Veeva Vault.

DocuSign

Certificate Of Completion

Envelope Id: A7D1F99E6C8D437C8224A07E04B985E7
Status: Completed
Subject: Please DocuSign: MERS-201_Statistical_Analysis_Plan_Final_v2.0_12AUG2021.docx
Source Envelope:
Document Pages: 32
Signatures: 2
Certificate Pages: 5
Initials: 0
AutoNav: Enabled
EnvelopeId Stamping: Disabled
Time Zone: (UTC-05:00) Eastern Time (US & Canada)

Envelope Originator:
[redacted]
134 Turnpike Road
Southborough, MA 01772
[redacted]
IP Address: [redacted]

Record Tracking

Status: Original
8/11/2021 10:49:17 AM

Holder: [redacted]

Location: DocuSign

Signer Events	Signature	Timestamp
[redacted] Veristat Security Level: Email, Account Authentication (Required)	[redacted] Signature Adoption: Pre-selected Style Signature ID: [redacted] Using IP Address: [redacted] With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 8/11/2021 10:51:35 AM Viewed: 8/11/2021 10:52:01 AM Signed: 8/11/2021 10:52:23 AM
Electronic Record and Signature Disclosure: Not Offered via DocuSign		
[redacted] Security Level: Email, Account Authentication (Required)	[redacted] Signature Adoption: Pre-selected Style Signature ID: [redacted] Using IP Address: [redacted] With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 8/11/2021 10:51:35 AM Resent: 8/11/2021 10:52:45 AM Viewed: 8/11/2021 11:09:48 AM Signed: 8/11/2021 11:10:34 AM
Electronic Record and Signature Disclosure: Accepted: 8/11/2021 11:09:48 AM ID: [redacted]		

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	Hashed/Encrypted	8/11/2021 10:51:35 AM
Certified Delivered	Security Checked	8/11/2021 11:09:48 AM
Signing Complete	Security Checked	8/11/2021 11:10:34 AM
Completed	Security Checked	8/11/2021 11:10:34 AM

Payment Events	Status	Timestamps

Electronic Record and Signature Disclosure

ELECTRONIC RECORD AND SIGNATURE DISCLOSURE

From time to time, Veristat (we, us or Company) may be required by law to provide to you certain written notices or disclosures. Described below are the terms and conditions for providing to you such notices and disclosures electronically through the DocuSign system. Please read the information below carefully and thoroughly, and if you can access this information electronically to your satisfaction and agree to this Electronic Record and Signature Disclosure (ERSD), please confirm your agreement by selecting the check-box next to 'I agree to use electronic records and signatures' before clicking 'CONTINUE' within the DocuSign system.

Getting paper copies

At any time, you may request from us a paper copy of any record provided or made available electronically to you by us. You will have the ability to download and print documents we send to you through the DocuSign system during and immediately after the signing session and, if you elect to create a DocuSign account, you may access the documents for a limited period of time (usually 30 days) after such documents are first sent to you. After such time, if you wish for us to send you paper copies of any such documents from our office to you, you will be charged a $0.00 per-page fee. You may request delivery of such paper copies from us by following the procedure described below.

Withdrawing your consent

If you decide to receive notices and disclosures from us electronically, you may at any time change your mind and tell us that thereafter you want to receive required notices and disclosures only in paper format. How you must inform us of your decision to receive future notices and disclosure in paper format and withdraw your consent to receive notices and disclosures electronically is described below.

Consequences of changing your mind

If you elect to receive required notices and disclosures only in paper format, it will slow the speed at which we can complete certain steps in transactions with you and delivering services to you because we will need first to send the required notices or disclosures to you in paper format, and then wait until we receive back from you your acknowledgment of your receipt of such paper notices or disclosures. Further, you will no longer be able to use the DocuSign system to receive required notices and consents electronically from us or to sign electronically documents from us.

All notices and disclosures will be sent to you electronically

Unless you tell us otherwise in accordance with the procedures described herein, we will provide electronically to you through the DocuSign system all required notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you during the course of our relationship with you. To reduce the chance of you inadvertently not receiving any notice or disclosure, we prefer to provide all of the required notices and disclosures to you by the same method and to the same address that you have given us. Thus, you can receive all the disclosures and notices electronically or in paper format through the paper mail delivery system. If you do not agree with this process, please let us know as described below. Please also see the paragraph immediately above that describes the consequences of your electing not to receive delivery of the notices and disclosures electronically from us.

How to contact Veristat:

You may contact us to let us know of your changes as to how we may contact you electronically, to request paper copies of certain information from us, and to withdraw your prior consent to receive notices and disclosures electronically as follows:
To contact us by email send messages to: [redacted]

To advise Veristat of your new email address

To let us know of a change in your email address where we should send notices and disclosures electronically to you, you must send an email message to us at [redacted] and in the body of such request you must state: your previous email address, your new email address. We do not require any other information from you to change your email address.

If you created a DocuSign account, you may update it with your new email address through your account preferences.

To request paper copies from Veristat

To request delivery from us of paper copies of the notices and disclosures previously provided by us to you electronically, you must send us an email to [redacted] and in the body of such request you must state your email address, full name, mailing address, and telephone number. We will bill you for any fees at that time, if any.

To withdraw your consent with Veristat

To inform us that you no longer wish to receive future notices and disclosures in electronic format you may:

i. decline to sign a document from within your signing session, and on the subsequent page, select the check-box indicating you wish to withdraw your consent, or you may;

ii. send us an email to [redacted] and in the body of such request you must state your email, full name, mailing address, and telephone number. We do not need any other information from you to withdraw consent.. The consequences of your withdrawing consent for online documents will be that transactions may take a longer time to process..

Required hardware and software

The minimum system requirements for using the DocuSign system may change over time. The current system requirements are found here: https://support.docusign.com/guides/signer-guide-signing-system-requirements.

Acknowledging your access and consent to receive and sign documents electronically

To confirm to us that you can access this information electronically, which will be similar to other electronic notices and disclosures that we will provide to you, please confirm that you have read this ERSD, and (i) that you are able to print on paper or electronically save this ERSD for your future reference and access; or (ii) that you are able to email this ERSD to an email address where you will be able to print on paper or save it for your future reference and access. Further, if you consent to receiving notices and disclosures exclusively in electronic format as described herein, then select the check-box next to 'I agree to use electronic records and signatures' before clicking 'CONTINUE' within the DocuSign system.

By selecting the check-box next to 'I agree to use electronic records and signatures', you confirm that:

- You can access and read this Electronic Record and Signature Disclosure; and
- You can print on paper this Electronic Record and Signature Disclosure, or save or send this Electronic Record and Disclosure to a location where you can print it, for future reference and access; and
- Until or unless you notify Veristat as described above, you consent to receive exclusively through electronic means all notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you by Veristat during the course of your relationship with Veristat.