	TITLE Transfer of Regulatory Obligations (TORO)	
	DOC NUMBER FRM-0757	VERSION NUMBER 1.0


Refer to SOP-1048 / Transfer of Regulatory Obligations (TORO)

Sponsor: ModernaTX, Inc.	IND Number: 19745
Product: mRNA-1273	Protocol Number: mRNA-1273-P203
CRO Name: PPD	CRO Address: 929 North Front Street Wilmington, NC 28401-3331

Per 21CFR §312.52, the Sponsor hereby transfers certain obligations pertaining to their clinical study to a Contract Research Organization (CRO): PPD. The obligations transferred are as follows:

Obligation and/or Task	Reference	Sponsor	CRO
A. Selecting investigators and monitors	21 CFR §312.53		
1. Select qualified investigators	21 CFR §312.53(a)	X	X
2. Control of drug Ship IP only to approved investigators	21 CFR §312.53(b)		X
3. Before permitting investigator participation obtain: <ul style="list-style-type: none"> Form FDA 1572 Curriculum vitae (CV) Financial Disclosure 	21 CFR §312.53(c)		X
4. Provide qualified monitors	21 CFR §312.53(d)		X
B. Informing investigators and FDA	21 CFR §312.55		
1. Deliver investigator's brochure to all participating investigators.	21 CFR §312.55(a)		X
2. Inform participating investigators of new safety information about the study drug.	21 CFR §312.55(b)		X
C. Review of ongoing investigations	21 CFR 312.56		
1. Monitoring this investigation	21 CFR §312.56(a)		X
2. Secure compliance or discontinue shipments of IP/investigator participation if not complying with signed Form FDA 1572, protocol, or regulations.	21 CFR §312.56(b) 21 CFR §312.59	X	X
3. If investigator participation has ended, <ul style="list-style-type: none"> a. notify FDA b. assure disposal or return of investigational drug 		X X	 X

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Obligation and/or Task	Reference	Sponsor	CRO
4. Provide medical expertise to evaluate safety information.	21 CFR §312.56(c)	X	
5. Report drug safety to FDA at required intervals.			
6. Upon discontinuation of study that presents an unreasonable and significant risk:	21 CFR §312.56(d)	X	X
a) Notify FDA			
b) Notify IRBs (or notify the investigators of their responsibility to notify their IRB)			
a) Notify investigators			
b) assure disposal or return of investigational drug		X	X
D. Recordkeeping and record retention	21 CFR §312.57		
1. Maintain sponsor records and reports, receipt, shipment, or other disposition of IP.	21 CFR §312.57(a)	X	X
2. Maintain records of financial interest paid to clinical investigators.	21 CFR §312.57(b)	X	X
3. Archive sponsor records and reports according to applicable regulatory requirements.	21 CFR §312.57(c)	X	
4. Retain reserve samples of test articles and reference standards used in bioequivalence or bioavailability studies.	21 CFR §312.57(d)	X	

Sponsor Signature: Carlota (Carla) Vinals

Date: 04DEC2020

Title: Head Regulatory Strategy ID


 Digitally signed
by Carla Vinals
Date:
2020.12.04
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