**Transfer of (IND) Regulatory Obligations**

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|---|---|
| Sponsor Name: | ModernaTx, Inc. |
| Sponsor Address: | 200 Technology Square<br>Cambridge, MA 02139 |
| IND#: | 19745 |
| Protocol Number: | mRNA-1273-P201 |
| Title of Study(ies): | A Phase 2, Randomized, Observer-Blind, Placebo-Controlled, Dose-Finding Trial to Evaluate the Safety, Reactogenicity, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older |

As allowed for under 21CFR 312.52, the Sponsor hereby transfers certain obligations pertaining to their clinical study to a contract research organization (CRO), PPD Development, LP, a Delaware limited partnership. The obligations transferred are as follows:

| Obligation and/or Task | Moderna | PPD |
|---|---|---|
| Responsible for all communications to and from the FDA | X | |
| Review all information relative to the safety of the drug, especially adverse event information derived from clinical investigations conducted under the IND | X | |
| Promptly prepare IND safety reports for all serious adverse experiences requiring expedited reporting | X | |
| Promptly submit IND safety reports for all serious adverse experiences requiring expedited reporting | X | |
| Notify promptly all participating investigators of all IND safety reports | | X |
| Maintain an effective IND with respect to the investigations to include timely submission of protocol amendments, information amendments, IND safety reports, and annual reports | X | |
| Regarding the conduct of clinical studies and obligations described in 21CFR Part 312, Subpart D.<br>Selection of qualified investigators | X | |
| Selection of qualified monitors | X | X |
| Ensuring proper monitoring of the clinical investigations | | X |
| Obtaining information from the Investigator before allowing the trial to begin, e.g., Signed and completed Form FDA-1572, CV of Principal Investigator | | X |
| Control of investigational drug to include:<br>• Shipping drug only to participating investigators<br>• Maintaining adequate records of receipt, shipment, or other disposition of drug<br>• Assuring return or any previously approved alternative disposition of drug upon the discontinuation or termination of a study | X | X |
| Providing investigators with appropriate information to properly conduct the investigation, e.g., protocol and investigator brochure | | X |
| Ensuring the investigation is conducted according to the investigational plan and protocol contained in the IND | X | X |
| Keeping each participating Investigator informed of new observations made known to the Sponsor and PPD Development about the drug, particularly with respect to safe use of the drug | | X |
| Retention of records showing receipt, shipment, or other disposition of the investigational drug to the | X | X |

| Obligation and/or Task | Moderna | PPD |
|---|---|---|
| Investigator for 2 years after a marketing application is approved, or if an application is not approved, until 2 years after shipment and delivery of the drug for investigational use is discontinued and FDA has been so notified.<br>Note: The Sponsor's obligation under 312.57 is separate and distinct from the Investigator's obligations, under 21CFR 312.62, to retain records of drug disposition and use in subjects for a 2 year period. PPD Development is not assuming responsibility for the Investigator's obligations under 312.62 | | |

PPD Contact: **PPD Development LLC**

Address of CRO: **PPD Development LLC**
929 North Front Street
Wilmington, NC 28401-3331

(b) (6)
PPD Development, LLC

ModernaTx, Inc.: Marjorie Hurley Digitally signed by Marjorie Hurley Date: 2020.04.13 12:09:37 -04'00' Date: _____

Title: _____

PPD Signature: (b) (6) Date: 08 APR 2020

Title: (b) (6)