***Instructions****: This template Memorandum of Understanding was prepared on March 19, 2020 by the Academic and Clinical Research Group (“ACRG”) of Verrill. The purpose of this template between health care providers and companies is to memorialize the parties’ mutual understandings with respect to the provision of certain investigational drugs for patient Expanded Access treatment of COVID-19 related diseases. This template is intentionally streamlined and balanced, to expedite agreement between the parties during this public health emergency. This template is drafted to focus on the provision of investigational drugs, as we understand drugs to be the primary expanded access treatment option at this stage of the pandemic. This template does not, and is not intended to, constitute legal advice or create an attorney-client relationship. Users of this template should consult their Verrill attorney to obtain advice with respect to any particular legal matter.*

*Before using this template, fill in the information highlighted in yellow and delete these instructions.*

Memorandum of Understanding

Provision of Investigational Drug Through Expanded Access – Treatment of COVID-19 Related Diseases

This Memorandum of Understanding (this “MOU”) by and between <Name of Manufacturer of Investigational Drug> (“Company”) and <Name of Institution> (“Institution”) is effective as of [ \_\_\_\_\_ ], 2020 (the “Effective Date”). The purpose of this MOU is to memorialize the parties’ mutual understandings with respect to the provision of <Investigational Drug> (the “Investigational Drug”) by Company to Institution for patient treatment of COVID-19 related diseases pursuant to the attached treatment plan or protocol (the “Plan”).

Accordingly, the parties agree as follows:

* Company shall provide the Investigational Drug to Institution or to Dr. <Physician Last Name> (the “Treating Physician”), an employee or agent of Institution and a licensed physician in good standing who is qualified to administer the Investigational Drug for the purpose set forth in the Plan.
* Company shall provide (i) <quantity and dose of drug (e.g., twenty 50 mg tablets)> of the Investigational Drug on a <timeframe (e.g., one time, weekly, monthly)> basis, and (ii) the information needed to minimize the risk and maximize the potential benefits of the Investigational Drug (e.g., an investigator’s brochure, if one exists) and any new safety information that may be relevant to the treatment use. Company shall immediately notify Institution and the Treating Physician if during the term of this MOU, despite reasonable efforts to do so, Company is no longer able to provide the Investigational Drug.
* Company shall provide the Investigational Drug at its own expense and at no charge to Institution, the Treating Physician, or the patient(s). The Treating Physician and Institution will not seek reimbursement from the patient(s) or from any third party payor for the Investigational Drug provided by Company hereunder.
* Institution and the Treating Physician shall (i) use the Investigational Drug solely for the treatment of the patient(s), (ii) obtain prior Institutional Review Board (“IRB”) approval for such treatment in accordance with 21 C.F.R. § 312.305(c)(4) and 21 C.F.R. Part 56, (iii) obtain prior informed consent from the patient(s) in accordance with 21 C.F.R. § 312.305(c)(4) and 21 C.F.R. Part 50, and in accordance with any requirements of the IRB, (iv) maintain accurate treatment case histories and Investigational Drug disposition records, (v) retain treatment records in a manner consistent with the requirements of 21 C.F.R. § 312.62, (vi) treat the patient(s) with the Investigational Drug in compliance with all other applicable federal and state laws and regulations, and (vii) make reasonable efforts to communicate to Company information Company requests regarding the progress of the patient(s) treated under the Plan.
* The sponsor of the expanded access investigational new drug application (“IND”), whichever party that may be, shall (i) maintain an effective IND for the treatment use, (ii) submit IND safety reports and annual reports as may be required to the U.S. Food and Drug Administration (“FDA”) under 21 C.F.R. § 312.32 and § 312.33, (iii) retain records in a manner consistent with the requirements of 21 C.F.R. § 312.57, and (iv) comply with all other sponsor responsibilities in accordance with applicable FDA regulations.
* When Institution/Treating Physician are the sponsor, they shall provide Company with copies of IND safety reports and annual reports made to the FDA. When Company is the sponsor, Institution/Treating Physician shall make the safety reports to Company as required by 21 C.F.R. § 312.64(b).
* In connection with the Plan, the parties may disclose to one another certain non-public proprietary scientific, financial, operational or other business information, including, in the case of Company, information concerning the Investigational Drug or other intellectual property of Company, and in the case of the Treating Physician and Institution, patient information (“Confidential Information”). Neither party will, without the prior written consent of the other party, use or disclose to a third party the Confidential Information of the other party for any purpose other than to carry out the Plan and meet their obligations under this MOU or to the extent required by applicable law.
* This MOU will expire upon the completion of the treatment of the patient(s), unless terminated earlier by (i) Institution upon written notice to Company, (ii) Company upon written notice to Institution in the event that the Investigational Drug is no longer available, or (iii) either party upon written notice to the other party in the event the conduct of the treatment is no longer in compliance with applicable laws.

IN WITNESS WHEREOF, each of the parties has caused this MOU to be executed by its duly authorized representative as of the first date written above.

[COMPANY] [INSTITUTION]

By:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature Signature

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Date Date

Read and Acknowledged

[TREATING PHYSICIAN]

By:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name

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Date