This document is a template memorandum of understanding ("MOU") between the National Institutes of Health ("NIH") and collaborating pharmaceutical companies in the NIH-Industry Pilot Program: Discovering New Therapeutic Uses for Existing Molecules. While there may be minor variations in the MOUs between the NIH and the specific collaborating pharmaceutical companies, this template MOU expresses the general intentions and expectations of the NIH and the collaborating pharmaceutical companies regarding their participation in the NIH-Industry Pilot Program: Discovering New Therapeutic Uses for Existing Molecules.

MEMORANDUM OF UNDERSTANDING
BETWEEN
NATIONAL INSTITUTES OF HEALTH
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
COMPANY
CONCERNING
NIH-INDUSTRY PROGRAM: DISCOVERING NEW THERAPEUTIC USES FOR EXISTING MOLECULES

This Memorandum of Understanding ("MOU") is between the National Institutes of Health ("NIH"), part of the U.S. Department of Health & Human Services, and [Pharmaceutical Company] ("COMPANY"). NIH and COMPANY are referred to herein individually as a Party and collectively as the Parties.

WHEREAS industry, academic, and government partnerships have always been important to the process of developing new medicines, and the need for partnerships is growing because many areas of unmet medical need are in complex or poorly understood disease areas;

WHEREAS NIH has established a new National Center for Advancing Translational Sciences ("NCATS") to catalyze the development of innovative methods and technologies that will enhance the development, testing, and implementation of diagnostics and therapeutics across a wide range of human diseases and conditions;

WHEREAS NCATS intends to work with experts in academia and the biotechnology and pharmaceutical industries to consider how extant technologies, knowhow, and materials can be used to better understand human biology, mechanisms of disease, and novel therapeutic indications; ("NIH-Industry Program: Discovering New Therapeutic Uses for Existing Molecules");

WHEREAS COMPANY, a global corporation dedicated to the discovery, development, and manufacturing of biological and small molecule therapeutics and diagnostics to improve health and well-being, owns or controls certain small

molecules and biologics (as more specifically defined below, the "COMPANY Materials") that have been advanced to clinical studies;

WHEREAS the COMPANY Materials, because of their potential as therapeutics, have been the subject, collectively, of extensive research and development efforts funded by COMPANY, which provide an extensive base of knowledge regarding their safety profiles, pharmacology, pharmacokinetics and mechanism of action;

WHEREAS COMPANY seeks to develop novel partnerships with the public sector that include a robust and rigorous process to jointly assess the feasibility of new ideas, identify and fill critical knowledge gaps, and thereby enable the best to be pursued;

WHEREAS COMPANY, to support public health by advancing science and potential new therapeutic understanding, approaches, and indications, is willing to make the COMPANY Materials available for translational research through the Project Plan provided for in, and subject to the terms and conditions of, this Memorandum of Understanding;

WHEREAS the discovery of new therapeutic indications for, or new human biology and disease insights regarding, any of the COMPANY Materials could facilitate the development of novel therapeutics and/or diagnostics to benefit public health;

WHEREAS NIH is uniquely able to: i) solicit and receive proposals for investigator-initiated research that will explore new, unanticipated therapeutic uses of the COMPANY Materials, ii) evaluate such proposals for scientific merit using its peer review system, iii) distinguish and determine projects of high public health relevance and benefit, and iv) fund research of high scientific merit and public health relevance;

WHEREAS COMPANY, in support of public health and academic research goals, expects to structure Collaborative Research Agreements ("CRA") (as defined below) under the NIH-Industry Pilot Program: Discovering New Therapeutic Uses for Existing Molecules (as defined below) to permit dissemination of research results and the right of the participants to grant non-exclusive research use licenses to non-profit and government entities, as more fully provided under such agreements;

WHEREAS the NIH and COMPANY agree that a public-private collaboration using drug candidates currently owned or controlled by private pharmaceutical companies and involving government, academia and industry for the purpose of advancing science and identifying new therapeutic indications would serve the best interests of the public, and that this pilot program could serve as a model for other similar collaborations;

WHEREAS, on the terms and conditions defined below, NIH and COMPANY expect that a collaboration between the Parties will take the form of an opportunity for research funding, the NIH-Industry Pilot Program: Discovering New Therapeutic Uses for Existing Molecules, that will be funded and administered by NIH and for which COMPANY will provide COMPANY Materials to the NIH funding recipients ("NIH Grantees") under separate agreements between COMPANY and prospective NIH Grantees;

NOW, THEREFORE, the Parties agree as follows:

A. Activities

1. NCATS Activities

a. NIH-Industry Pilot Program: Discovering New Therapeutic Uses for Existing Molecules. NIH intends to develop, fund and administer the NIH-Industry Program: Discovering New Therapeutic Uses for Existing Molecules, beginning under this MOU with a pilot grant program, NIH-Industry Pilot Program: Discovering New Therapeutic Uses for Existing Molecules ("Pilot Grant Program"), of cooperative agreements focusing on COMPANY Materials. This Pilot Grant Program will be for the purpose of discovering new therapeutic uses for or information regarding COMPANY Materials in order to develop new treatments for significant public health problems. If the Pilot Grant Program is successful, NIH and COMPANY may (subject to each Party's consent) expand the program to include additional COMPANY drug candidates. Under the NIH-Industry Program: Discovering New Therapeutic Uses for Existing Molecules, NIH intends to seek additional drug candidates from other sources, including other pharmaceutical companies. Regarding the additional drug candidates potentially received from other pharmaceutical companies, NIH intends to negotiate separate MOUs with said companies, which may be managed in a similar manner as this NIH-COMPANY MOU but not requiring any COMPANY participation.

b. Procedures to be followed. NIH intends to publish a Request for Information ("RFI") to invite public input, including input from COMPANY, outside experts and other stakeholders on the Pilot Grant Program. NIH intends to issue a Request for Applications ("RFA") to initiate the Pilot Grant Program and will include information with respect to each COMPANY Material so as to allow potential investigators to construct meaningful applications. The type of information COMPANY will provide includes: the targets/pathways affected by each drug candidate, whether the drug candidate is a small molecule or a biologic, its route of administration, and prominent safety and tolerability properties that may limit its utility, provided, however, that COMPANY may determine at its sole discretion what additional information will be provided in the case of any specific COMPANY Material.

The NIH expects to conduct its activities under the Pilot Grant Program in two phases as follows:

i. Pre-proposals. Pre-proposals submitted by applicants ("pre-applications") in response to a Funding Opportunity Announcement will be reviewed for scientific merit by NIH peer review. Applicants whose pre-applications are in the top tier of the initial phase of peer review will be invited to submit a full application to the Pilot Grant Program subject to obtaining access to the relevant COMPANY Material and confidential information from COMPANY and other program requirements. These applicants will be notified to engage with COMPANY to develop and submit a full proposal, which will include documentation of access to the relevant COMPANY Materials and confidential information pursuant to a CRA and related Project Plan, as specified below. No formulated molecule or Good Manufacturing Practice ("GMP") biopharmaceutical/biologic for the selected COMPANY Materials will be transferred to the applicants unless and until the applicant is awarded the NIH grant.

ii. NIH Review of Full Proposals and Grant Award. Each full application submitted in response to the RFA will undergo NIH peer review. After a second level of review by the appropriate NCATS Advisory Council, applications will be selected for funding based on scientific merit, program priorities, the availability of funds, and whether a CRA (including a Project Plan) has been executed with COMPANY. Any revisions in go/no go milestones (the "Go-Forward Decision Criteria"), based on feedback from peer review, and the Terms and Conditions of the cooperative agreement will be incorporated into the NIH Notice of Award.

c. Administration in accordance with Law. NIH intends to administer the Pilot Grant Program in accordance with applicable law and agency policy, including the use of peer review to determine and ensure scientific excellence. NIH will not disclose confidential COMPANY or applicant information without appropriate permission.

2. COMPANY Activities

a. Forms of Confidential Disclosure Agreement ("CDA") and CRA. Forms of the CDA and the CRA are attached as Exhibits A and B, respectively. The Parties agree that NIH will publish Exhibits A & B in the RFI in order to seek public comment on these agreements. In order to efficiently operate the Pilot Grant Program, applicants invited to submit a full application will agree to enter into the standard form CDA and CRA. Financial terms applicable to a specific CRA may be specified in the related Project Plan. Changes may be made to the standard form of CDA or CRA by mutual agreement of COMPANY, the applicant, and the NIH. A copy of any revised form shall be substituted for the respective Exhibit. Following the award of any grant, COMPANY and the NIH Grantee may modify or amend the Project Plan of the CRA upon written agreement of the NIH Grantee and COMPANY and the approval of NIH as specified in the NIH Notice of Award.

b. COMPANY Materials. COMPANY Materials will consist of those particular drug candidates listed on Schedule 1 (and no others). Schedule 1 may be amended from time to time by COMPANY to add or remove candidates, except that COMPANY will not remove any candidates during any given RFA or award cycle.

c. Execution of CDA. COMPANY and each applicant will execute the standard CDA prior to COMPANY reviewing any confidential information of the applicant or providing any COMPANY Material or COMPANY confidential information to the applicant.

d. Preparing Full Proposal. Under the CDA, COMPANY and applicants will share such information as they each deem necessary to provide in order for the applicant to prepare, with the Company's advice if the Company so provides, a full proposal. COMPANY or the applicant may determine at any time prior to submission of a full proposal to the NIH not to proceed with the full proposal and COMPANY shall have no further obligations with respect to such application. Each full proposal will include:

   i. An executed CRA providing for the Project Plan to be conducted under the Grant requested by the full proposal, to become effective upon award of the Grant, containing as an exhibit of the Project Plan described below.

   ii. A Project Plan describing the proposed research, the specific activities to be undertaken by each of COMPANY and the applicant, and support to be provided by the applicant and COMPANY under the Project Plan, including the COMPANY Materials and any of the other support that may be provided by COMPANY, the funding to be provided by the NIH, and any specific Go-Forward Decision Criteria applicable to the Project Plan.

e. COMPANY Support for Research Programs. COMPANY's support for any research program will be described in the Project Plan covered by a CRA. The types of support which may be included in Project Plans include those listed below. Not all forms of support may be provided in regard to any particular Project Plan. COMPANY's support will generally be provided by COMPANY directly to the NIH Grantee and, except as otherwise provided in any CRA or Project Plan, will generally be provided on an "in kind" basis at no cost to NIH or the NIH Grantee. In some circumstances, COMPANY may determine to provide additional support for the Project Plan, beyond the categories of support listed below, including additional in-kind support or direct funding. In regard to any particular Project Plan, COMPANY may provide, as and to the extent provided in the applicable Project Plan:

   i. Supplies of formulated molecule or GMP biopharmaceutical/biologic for the selected COMPANY Materials and placebo;

   ii. COMPANY data regarding the COMPANY Material for inclusion in regulatory data packages for the selected COMPANY Material, including if applicable data for inclusion in an Investigational New Drug ("IND") application for a drug or biological that uses the COMPANY Material;

   iii. Appropriate research and drug development expertise and enabling technologies for the selected COMPANY Material; and

v. Pharmacokinetics data analysis, pharmacokinetics modeling to calculate bioequivalence and drug exposure data, and biomarker Standard Operating Procedures information for the selected COMPANY Material to support any pre-clinical and clinical studies that the NIH Grantee conducts in accordance with the Project Plan.

B. General Provisions

1. **Effective Date.** This MOU becomes effective on the date of the last signature and shall remain in full force and effect for five (5) years, unless modified or terminated. Either Party may terminate this MOU by providing written notice to the other Party of its intent to terminate the MOU, not later than sixty (60) days before the proposed effective date of termination.

2. **Effect of Termination**. Termination of this MOU shall not terminate any grant, CDA or CRA entered into prior to the termination of this Agreement. The terms of the applicable grant or CRA, as appropriate, shall govern the rights of the NIH Grantee and COMPANY under such circumstances.

3. **No Prohibition on Similar Arrangements**. Nothing in this MOU restricts, in any way, the United States, the U.S. Department of Health & Human Services, or NIH from participating in similar activities or arrangements with other public or private agencies, organizations, or individuals. Nothing in this MOU restricts, in any way, COMPANY or its affiliates from participating in similar activities or arrangements with other public or private agencies, organizations or individuals.

4. **No Endorsement by NIH**. Nothing in this MOU may be interpreted to imply that the United States, the U.S. Department of Health & Human Services, or NIH endorses COMPANY, COMPANY Materials, COMPANY's products, or COMPANY's services. COMPANY will not take any action or make any statement that suggests or implies such an endorsement.

5. **Contingent on Availability of Funds**. It is understood that the award of any NIH grant under the Pilot Grant Program is contingent upon the availability of funds and the discretion of the NIH to engage in the activities enumerated herein. It is understood and agreed that NIH has no obligation under this MOU to award any grant. Any monies allocated by the NIH for purposes covered by this MOU shall be obligated and expended by the NIH in accordance with the terms and the manner prescribed by the fiscal regulations and/or administrative policies of the NIH. Transfers of funds, goods or services from NIH to COMPANY are not authorized by this MOU.

6. **Governing Law**. This Agreement shall be governed by U.S. Federal Law as applied in the Federal Courts of the District of Columbia.

7. **Entire Agreement; Amendment**. This MOU incorporates all Exhibits and Schedules (if any) hereto and constitutes the entire agreement and understanding between the Parties in respect of the subject matter hereof and replaces in its entirety any prior discussions, negotiations, agreements or other arrangements in relation to the subject matter, whether written or oral, all of which are replaced by the terms of this Agreement. No amendment or modification of this Agreement shall be valid or binding unless made in writing and signed by authorized representatives of both parties.

8. **Counterparts**. This MOU may be executed in counterparts, each of which shall be deemed to be an original and all of which together shall constitute a single document. The Parties acknowledge and agree that the exchange of electronic or fax signatures will have the same legal validity as the Parties' signatures would have if signed in hard copy form.

9. **Authority**. Section 479 of the Public Health Service (PHS) Act (42 U.S.C. § 287); Section 301 of the PHS Act, 42 U.S.C. § 241.

10. **Notices and Meetings**. All notices pertaining to or required by this MOU will be in writing, signed by an authorized representative of the notifying Party, and delivered by registered, certified or by an express/overnight delivery service and sent to the other Party at the address designated below. The contacts listed below will establish a schedule of periodic meetings for the Parties to discuss the administration of this MOU and the progress and coordination of the Pilot Grant Program.

COMPANY Contact.

Name:
Title:
Address:
Phone number:
Fax number:

NIH Contact.

Name: Kathy Hudson, Ph.D.
Title: Acting Deputy Director, NCATS
Address: 6701 Democracy Blvd., Bethesda, MD 20892-4874
Phone number: 301-435-0877
Fax number: 310-480-3658
Email address: Kathy.hudson@nih.gov

SIGNATURES BEGIN ON NEXT PAGE

In witness whereof each Party has caused this MOU to be executed by its duly authorized representative, as of the dates set forth below.

COMPANY	**THE NATIONAL INSTITUTES OF HEALTH**
By: _____	**By: _____**
Printed Name:	**Printed Name: Thomas Insel, M.D.**
Title:	**Title: Acting Director, National Center for Advancing Translational Sciences**
Date: _____	**Date: _____**