

RESEARCH COLLABORATION AGREEMENT

This Agreement is between the NIH Center for Translational Therapeutics, National Center for Advancing Translational Sciences (“NCATS”), which is a component of the National Institutes of Health (“NIH”), an agency of the U.S. Department of Health and Human Services, having offices located at 9800 Medical Center Drive, Room 300B, Bethesda, MD 20892, Bethesda, and **COLLABORATOR** (“Collaborator”), having a principal place of business at **ADDRESS** (collectively, the “Parties”). This Agreement is neither a funding agreement as defined in 35 U.S.C. § 201(b) nor a cooperative research and development agreement authorized under the Federal Technology Transfer Act of 1986, as amended, 15 U.S.C. §§ 3710a *et seq.*, and Executive Order 12591 of April 10, 1987. NCATS enters into this Agreement pursuant to the authority of the Public Health Services Act of 1944, as amended (42 U.S.C. § 241).

BACKGROUND

1. NCATS and Collaborator want to collaborate on a research project; and
2. NCATS and Collaborator want to transfer between the laboratories of their investigators, during the term of this Agreement, proprietary research materials required to conduct the research project.

TERMS AND CONDITIONS

Article 1 DEFINITIONS

- 1.1 “**Confidential Information**” includes scientific, business, or financial information pertaining to the Research Project (defined below) that is designated as confidential by Provider (defined below). Confidential Information does not include information that: (i) is in the public domain other than as a result of a disclosure by Recipient (defined below) or any of Recipient’s representatives in violation of this Agreement; (ii) was in the possession of Recipient before disclosure by the Provider; (iii) is acquired by Recipient from a third party having no obligation of confidentiality to Provider; (iv) is hereafter independently developed by Recipient, without reference to Confidential Information received from Provider; or (v) Provider expressly authorizes Recipient to disclose.
- 1.2 “**Invention**” means any invention or discovery that is or may be patentable or protectable under applicable laws.
- 1.3 “**Investigator**” means the principal researcher designated by a Party to direct the Research Project.
- 1.4 “**Material**” means _____.
- 1.5 “**Original Material**” means a material provided by one of the Parties and used in the Research Project.
- 1.6 “**Progeny**” means unmodified descendent from Material, such as virus from virus, cell from cell, or organism from organism.
- 1.7 “**Provider**” means the Party that provides Original Material or discloses Confidential Information to the other Party under this Agreement.

- 1.8 “**Recipient**” means the Party that receives Original Material or Confidential Information from the other Party under this Agreement.
- 1.9 “**Research Project**” means the collaborative research described in Appendix A.

Article 2 COLLABORATIVE RESEARCH

- 2.1 NCATS and Collaborator agree to collaborate on the Research Project. The Investigator for NCATS will be **NAME (&DEGREE)** and the Investigator for Collaborator will be **NAME (&DEGREE)**.
- 2.2 Nothing in this Agreement will be construed to limit the freedom of either Party from engaging in similar research with other parties, providing the research does not create a conflict with the Parties’ obligations under this Agreement, especially with regard to Article 3.
- 2.3 The Parties recognize that the Research Project describes the collaborative research to be conducted under this Agreement and that the goals set forth in Appendix A are good faith guidelines. If events occur that require substantial modification of the Research Project, the Parties may amend Appendix A according to Paragraph 6.2.1 of this Agreement.

Article 3 CONFIDENTIALITY; PUBLICATIONS

3.1 Confidential Information

- 3.1.1 Either Party may disclose or receive Confidential Information under this Agreement.
- 3.1.2 All Confidential Information exchanged between the Parties must conspicuously bear the words “Confidential Information” or “Confidential.” Confidential Information exchanged orally or through observation must be reduced to writing and marked “Confidential Information” or “Confidential” within 30 days after disclosure to be considered Confidential Information.
- 3.1.3 Recipient will maintain Confidential Information in confidence for a period of 3 years from the effective date of this Agreement and will protect Confidential Information with the same degree of care as Recipient uses to protect its own Confidential Information.
- 3.1.4 Recipient may disclose Confidential Information to its employees, consultants, or contractors to whom it is necessary to disclose this information for the purpose of the Research Project; Recipient may make these disclosures only under terms at least as restrictive as those specified in this Agreement. Recipient agrees that disclosure of Confidential Information may not be made to any party not listed herein unless Provider grants prior written approval to Recipient.
- 3.1.5 Recipient may disclose Provider’s Confidential Information if required to do so by law, regulation, or court order. If Recipient, or anyone to whom it discloses Confidential Information in accordance with Article 3, becomes legally required to disclose any Confidential Information, Recipient will provide timely notice to Provider and, to the extent practicable, consult with Provider prior to any disclosure.
- 3.1.6 Either Party may disclose the Abstract of the Research Project (in Appendix A) to the public.

3.2 Publications; Press Releases

- 3.2.1 Publications
- 3.2.1.1 In addition to the specific goals of the Research Project, the Parties view dissemination of research findings, both by publication and oral presentation, as

an essential objective of the Research Project. Authorship will be decided according to commonly accepted conventions for scientific publications.

3.2.1.2 The Parties are encouraged to make publicly available the results of the Research Project. Before either Party submits a paper or abstract for publication or otherwise intends to publicly disclose information about any Invention made in the course of the Research Project, the other Party will have 30 days to review proposed manuscripts and 3 days to review proposed abstracts to assure that its Confidential Information is protected. Either Party may request in writing that the proposed publication or other disclosure be delayed for up to 30 additional days as necessary to file a patent application.

3.2.2 Press Releases

Collaborator-issued press releases that reference or rely upon the work of NCATS under this Agreement will be made available to NCATS for review and comment at least 7 days prior to publication.

Article 4 INVENTIONS; DATA

4.1 Inventions

- 4.1.1 The Parties acknowledge the possibility that Inventions may be made in the course of the Research Project. Inventorship of those Inventions will be determined in accordance with applicable U.S. laws and regulations. The term made, as used in reference to any invention, means the conception or first actual reduction to practice of such invention.
- 4.1.2 Inventions made in the course of the Research Project will be owned by the Party employing the inventor or inventors. Inventions that are invented jointly by employees of both Parties will be owned jointly.
- 4.1.3 Each Party will report to the other Party, in writing, all Inventions made during the Research Project no later than 3 months from the time the invention is disclosed to a Party by its Investigator. The reports will be written in sufficient detail to determine inventorship and will be treated as Confidential Information in accordance with Article 3. The Parties will confer with each other regarding a patent filing strategy for jointly made Inventions. If either Party files a patent application on a jointly made Invention, then the filing Party will include a statement in the patent application that clearly identifies the Parties and states that the Invention was made jointly under this Agreement.

4.2 Data

Each Party will disclose to the other Party a summary of all data generated under this Agreement. Subject to the restrictions in Article 3, both Parties will have free access to and use of any data generated under this Agreement.

Article 5 THE TRANSFER AND USE OF MATERIAL

5.1 Mechanics of Transfer

Either Party may provide or receive Original Material under this Agreement. Provider will send Original Material to Recipient with a cover letter as described in Appendix B. The letter will refer to this Agreement and identify Original Material. If either Party transfers to the other Party a material not listed in Appendix A, the Parties will amend this Agreement to include the additional material.

5.2 **Conditions of Use**

- 5.2.1 RECIPIENT WILL NOT USE MATERIAL IN RESEARCH INVOLVING HUMAN SUBJECTS.
- 5.2.2 Recipient's Investigator will use Material solely in connection with the Research Project in the Investigator's laboratory. If Recipient wants to use Material for commercial purposes, Recipient agrees to first obtain the appropriate commercial use or commercialization license from Provider.
- 5.2.3 Recipient agrees that Recipient's Investigator will retain control over Material and further agrees that Recipient's Investigator will not transfer Material to people not under the Investigator's direct supervision without advance written approval of Provider.
- 5.2.4 Recipient will use Material in compliance with all applicable laws, regulations and policies.
- 5.2.5 Provider reserves the right to distribute its Material to others and to use its Material for its own purposes.
- 5.2.6 Upon termination of this Agreement, Recipient agrees that Recipient's Investigator will return any and all remaining Original Material unless Provider gives Recipient's Investigator directions for disposing of Original Material by another means.
- 5.2.7 Nothing in this Agreement will be construed as conferring on Recipient any implied license to Material, or option to license Material, any technology, or any patent or patent application owned by Provider and will not create any obligation, by implication or otherwise, of either Party to enter into any further agreement with the other Party.

Article 6 TERMINATION AND GOVERNANCE

6.1 **Effective Date**

This Agreement will be effective on the date of the last authorized signature below.

6.2 **Term and Termination**

- 6.2.1. The Parties agree that this Agreement will be effective for **1 year** from the date of the last authorized signature below and may be extended as mutually agreed by the Parties in a written amendment to this Agreement.
- 6.2.2 This Agreement will terminate immediately upon the mutual agreement of the Parties in writing.
- 6.2.3 This Agreement will terminate in 30 days after either Party receives written notice of the other Party's desire to terminate this Agreement.

6.3 **Representations, Warranties, and Liability**

- 6.3.1 Material is understood to be experimental in nature and may have hazardous properties. ORIGINAL MATERIAL IS BEING SUPPLIED TO RECIPIENT WITH NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. Provider makes no representations that the use of Material will not infringe any patent or other proprietary rights of third parties.
- 6.3.2 No indemnification for any loss, claim, damage, or liability is intended or provided by either Party under this Agreement. Each Party will be liable for any loss, claim, damage, or liability that the Party incurs as a result of its activities under this Agreement, except

that NCATS, as an agency of the U.S. Government, assumes liability only to the extent provided under the Federal Tort Claims Act, 28 U.S.C. §§ 2671 *et seq.*

6.4 Assignment

Neither this Agreement nor any rights or obligations of either Party hereunder may be assigned or otherwise transferred by either Party without the prior written consent of the other Party. This Agreement will be binding upon the Parties and their respective successors and permitted assigns.

6.5 Non-endorsement

By entering into this Agreement, NCATS does not directly or indirectly endorse any product or service that is or will be provided, whether directly or indirectly related to this Agreement, by Collaborator, its successors, permitted assigns, or licensees. Collaborator will not in any way state or imply that this Agreement is an endorsement of any such product or service by the U.S. Government or any of its organizational units or employees.

6.6 Survivability

Articles 3, 4, 6.3, 6.5, 6.6 and 6.8 will survive expiration or earlier termination of this Agreement.

6.7 Severability

The illegality or invalidity of any provisions of this Agreement will not impair, affect, or invalidate the other provisions of this Agreement.

6.8 Governing Law

The construction, validity, performance, and effect of this Agreement will be governed by federal law as applied by the federal courts in the District of Columbia. Federal law and regulations will preempt any conflicting or inconsistent provisions in this Agreement.

6.9 Entire Agreement

This Agreement, together with all appendices, constitutes the entire agreement between the Parties and supersedes any prior or contemporaneous oral or written agreements or communications between them with respect to the subject matter hereof. This Agreement may be amended only by written instrument signed by authorized representatives of NCATS and Collaborator.

6.10 Notices

All notices pertaining to or required by this Agreement shall be in writing, shall be signed by an authorized representative and shall be delivered to the addresses indicated on the signature page for each Party.

SIGNATURES BEGIN ON THE NEXT PAGE

FOR NCATS:

Lili M. Portilla, MPA
Director, Office of Strategic Alliances, NCATS

Date

Mailing Address for Notices:

Lili M, Portilla, MPA
National Center for Translational Therapeutics
National Center for Advancing Translational Sciences, NIH
9800 Medical Center Dr. Building B, Room B3005
Bethesda, MD 20892-3370
Phone: 301-217-2589
Fax: 301-217-5736
Email: Lilip@nih.gov

Note Rockville, MD 20850 should be used for Fedex, UPS, and other courier services.

Acknowledgment by NCATS's Investigator:

NAME, DEGREE
Title

Date

FOR COLLABORATOR:

Signature

Date

Printed Name and Title

Mailing Address for Notices:

Tel: _____

Fax: _____

Acknowledgment by COLLABORATOR's Investigator:

NAME, DEGREE
Title

Date

APPENDIX A

Research Project

- I. **Abstract of the Research Project – for Public Release**
EITHER PARTY MAY, WITHOUT FURTHER CONSULTATION OR PERMISSION,
RELEASE THIS ABSTRACT TO THE PUBLIC.

- II. **Goal(s) of Project**

- III. **Background**

- IV. **Respective Contributions of the Parties**

- V. **Material Contributed by NCATS**

- VI. **Material Contributed by Collaborator**

- VII. **Experimental Plan**

APPENDIX B

Sample Material Transfer Cover Letter

A sample letter follows.

Date

Provider Organization Name
Provider Organization Address
Tel:
Fax:

Recipient PI
Recipient Organization
Recipient Organization Address

**RE: TRANSFER OF MATERIAL(S) UNDER COLLABORATION AGREEMENT BETWEEN NCATS AND
[NAME OF COLLABORATOR] DATED [MONTH/YEAR]**

DEAR DR. [NAME OF NCATS PI OR COLLABORATOR PI]:

The [NCATS or Collaborator] is pleased to provide you with the following material: [Describe material]. The material developed by [insert name], are being shipped to you by [NCATS/ Collaborator].

The material may only be used for research conducted between NCATS and [Collaborator] under the Collaboration Agreement referenced above. In addition, you understand that any remaining material will be returned to [NCATS/ Collaborator] or disposed of according to the written instructions of [NCATS/ Collaborator] when the Collaboration Agreement expires, unless [NCATS/ Collaborator] obtains permission from [NCATS/ Collaborator] to continue using the materials.

Please acknowledge receipt of the material(s) by signing below. At your earliest convenience, please fax a copy of this letter to your technology transfer office at [NCATS/ Collaborator].

Sincerely,

NCATS/ Collaborator [Provider]
Title
cc:

Acknowledged by NCATS/ Collaborator PI [Recipient]

Signature

Date

Printed Name and Title