

Use PI Institutional Letterhead

COLLABORATION AGREEMENT

Agreement Number _____

THIS AGREEMENT, effective as of the date of last signature (the “Effective Date”), by and between Name of PI institution, a non-profit, educational and research institution, having a principal place of business at Address of PI Institution (hereinafter referred to as “University”) and Company Name of collaborating industry, a State of corporation for Collaborating Industry corporation, with its principal place of business at Address of Collaborating industry (such entity, along with Any affiliate company names and its other affiliates, are hereinafter referred to as “COMPANY ACRONYM” [Company name used throughout agreement]).

RECITALS:

1. The collaboration contemplated by this Agreement is of mutual interest and benefit to University and COMPANY ACRONYM, will further the multiple missions of University (Instruction, Research and Public Service) in a manner consistent with its status as a non-profit, tax-exempt, educational institution, and may derive benefits for COMPANY ACRONYM, University and society by the advancement of science and engineering through discovery;
2. COMPANY ACRONYM is willing to perform certain specific work to be done [e.g., NMR testing, serum assays] of samples for University and provide data for End product from company [e.g., NMR-measured biomarkers] for University and its principal investigator, Name of PI (“Principal Investigator”), to conduct a study entitled “Name of study” described in Exhibit A {*if applicable*, and a study entitled “additional study name” described in Exhibit specify}. For purposes of this Agreement, Exhibit A {*if applicable*, and Exhibit B are each} referred to hereinafter as a “Scope of Work,” and each study described therein is referred to hereinafter as a “Project.”
3. University’s capabilities reflect a substantial public investment which University, as a part of its mission as a state educational institution, wishes to utilize in a cooperative and collaborative effort with COMPANY ACRONYM in order to meet the above stated needs;

NOW THEREFORE, in consideration of the premises and mutual covenants set forth below, the parties hereto agree to the following:

Article 1 – Delivery and Use of Samples

- 1.1 University shall arrange for The National Institute of Diabetes and Digestive and Kidney Disease (NIDDK) to package and ship NASH CRN study name samples as described on Exhibit A {*if applicable* and Exhibit B} (collectively, the “Samples”) at sample shipment cost or “no” depending on collaborative agreement cost to COMPANY ACRONYM, directly to COMPANY ACRONYM at the following address: Name and address of the company lab to ship the NASH CRN samples to. University represents to COMPANY ACRONYM that University has confirmed that (a) the Samples have been obtained and handled in compliance with all applicable laws and regulations, (b) NIDDK has the right, power and authority to provide the Samples to COMPANY ACRONYM for the purpose of the Projects, (c) all necessary third party approvals,

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consents and waivers have been obtained (including without limitation Institutional Review Board approvals and the informed consent of any applicable patients and physicians), and (d) University is not aware of any rights of third parties that would prevent COMPANY ACRONYM from using the Samples for the Projects.

- 1.2 COMPANY ACRONYM will conduct *testing* on the Samples as described in each Scope of Work (the “*Testing Services*”). The *Testing Services* will be conducted under the supervision and oversight of *Name of the company collaborating scientist* (the “COMPANY ACRONYM Collaborating Scientist”), or their replacements if designated by COMPANY ACRONYM. COMPANY ACRONYM agrees that the Samples shall be used only for the Projects in its laboratory under suitable conditions. COMPANY ACRONYM agrees to retain control over the Samples and further agree not to transfer the Samples to any party, except as otherwise stated herein.
- 1.3 THE *TESTING SERVICES ARE BEING PROVIDED BY COMPANY ACRONYM AT NO or agreed CHARGE TO UNIVERSITY, AND THEREFORE ARE BEING PROVIDED “AS IS.” NO EXPRESS OR IMPLIED WARRANTIES ARE MADE BY COMPANY ACRONYM. IN NO EVENT SHALL COMPANY ACRONYM BE RESPONSIBLE FOR ANY PUNITIVE DAMAGES OR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, OR SPECIAL DAMAGES OF UNIVERSITY OR OF ANY THIRD PARTY ARISING FROM OR RELATING TO THE TESTING SERVICES.*
- 1.4 COMPANY ACRONYM acknowledges that the Samples have the potential for carrying viruses, latent viral genomes, and other infectious agents in a dormant state. COMPANY ACRONYM agree to treat the Samples under laboratory conditions that afford adequate biohazard containment. By accepting the Samples, COMPANY ACRONYM assumes full responsibility for their safe and appropriate handling. COMPANY ACRONYM agrees that the Samples may not be used in humans.
- 1.5 University and Principal Investigator acknowledge that they are responsible for ensuring that the protocol for the Projects, and the use of the Samples for the Projects, are in compliance and consistent with Federal (including 45 CFR Part 46), state, and local laws. COMPANY ACRONYM acknowledges that it is responsible for ensuring the Samples are used in accordance with this Agreement, the applicable Scope of Work, and COMPANY ACRONYM policies.
- 1.6 Upon completion of the analysis, COMPANY ACRONYM shall, upon written instructions from University, return or destroy remaining Samples.

Article 2 – Results

- 2.1 COMPANY ACRONYM will send all data and all other results *or any other end product* generated in the performance of the analysis (“Results”) in a format as agreed upon between the parties. University shall have the unrestricted right to freely utilize all Results internally in support of its own academic, education, and non-commercial research and patient care mission, including, but not limited to publication of Results as described in Section 2.2. COMPANY ACRONYM shall have the perpetual right to retain and use Results for its internal research and development purposes only (including publication of Results as described in Section 2.2), provided that such use (i) does not preempt first publication of such Results by University without the Principal Investigator’s or University’s express written permission, and (ii) is not covered by any patent rights of the University that have not been licensed to COMPANY ACRONYM.
- 2.2 Since the Projects involve collaborative research activities by the University’s Principal Investigator and the COMPANY ACRONYM Collaborating Scientist, it is currently anticipated that the Results and/or findings based on the Projects will be jointly published or presented. In such case, University and COMPANY ACRONYM will jointly prepare, author, and submit for

publication one or more joint manuscripts for each Project. Either Party shall have the right to independently publish the Results or disclose in a public presentation in accordance with the review procedures contained in this Section 2.2 after the collaborative publication or presentation, if any. Regardless of whether any Results or findings from the Projects are published or presented jointly or by a single party, each party agrees to give the other party a reasonable opportunity (at least thirty (30) days) for prior review of the publication or presentation, and each party agrees to remove any confidential information of the other party upon written request (excluding Results). In addition, each party agrees to delay publication or presentation for an additional sixty (60) day period upon written request if the other party determines that the proposed publication or presentation contains patentable subject matter which requires protection.

Article 3 – Non-Endorsement, Non-Indemnification

- 3.1 Except as expressly stated in this Agreement, the Samples are supplied to COMPANY ACRONYM with NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. University makes no representation that the use of the Samples will not infringe any patent or proprietary rights of third parties.
- 3.2 To the extent allowed by law, each party shall be responsible for any loss, claim, damage, or liability that the party incurs as a result of its own activities under this Agreement, but a party shall not be responsible for any loss, claim, damage or liability that such party incurs as a result of the other party's breach of this Agreement, violation of applicable law, or negligence or intentional misconduct.

Article 4 – Publicity

Neither party to this Agreement will use the name of the other party, nor of any member of the other party's employees, in any publicity, advertising, or news release without the prior written approval of an authorized representative of that party. Parties may consider developing joint press releases upon successful completion of each Project. The parties agree that in order for University to satisfy its internal and governmental reporting obligations, including but not limited to disclosure required by its Conflict of Interest Committee, it may identify COMPANY ACRONYM as a collaborator of each Project, the name of the Principal Investigator, and a brief protocol title. Proper acknowledgement will be made for the contributions of COMPANY ACRONYM to each Project in University's publication.

Article 5 – Confidentiality

The parties agree that the terms of the Confidentiality Agreement entered into between the parties effective as of *date* (the "Confidentiality Agreement") shall apply to any information exchanged by the parties pursuant to this Agreement; provided, however, that the Confidentiality Agreement is hereby deemed amended as follows: ***{include bullet items as appropriate to specific collaboration}***

- a. the "Purpose," as defined in the recitals to the Confidentiality Agreement, is hereby expanded to include the purposes of fulfilling obligations or exercising rights under this Agreement; and
- b. the one (1) year period referenced in Section 5 of the Confidentiality Agreement is hereby extended for the duration of the term of this Agreement, if longer; and
- c. the three (3) year period referenced in Section 5 of the Confidentiality Agreement is hereby revised as to the information exchanged by the parties pursuant to this Agreement

to be a period of five (5) years from the date of expiration or termination of this Agreement.

Article 6 – Term and Termination

- 6.1 The term of this Agreement shall commence on the Effective Date and, unless earlier terminated as hereinafter provided, shall continue until completion of both Projects.
- 6.2 Either party may terminate this Agreement upon sixty (60) days prior written notice to the other.
- 6.3 In the event that either party hereto shall commit any material breach of or default in any terms or conditions of this Agreement, and also shall fail to reasonably remedy such default or breach within thirty (30) days after receipt of written notice thereof, the non-breaching party may, at its option and in addition to any other remedies which it may have at law or in equity, terminate this Agreement by sending notice of termination in writing to the other party to such effect. Termination shall be effective as of the day of the receipt of such notice.
- 6.4 Termination of this Agreement by either party for any reason shall not affect the rights and obligations of the parties accrued prior to the effective date of termination of this Agreement. The rights and obligations of Articles 2-7 and 11-13 of this Agreement shall survive termination.

Article 7 – Intellectual Property

- 7.1 For the avoidance of doubt, all intellectual property and know-how existing as of the Effective Date, or developed or acquired outside of the scope of this Agreement (“Background Intellectual Property”), that is used in connection with the Projects shall remain the property of the party originally owning the same. Nothing in this Agreement shall transfer any rights in such Background Intellectual Property to the other party.
- 7.2 In the event University solely or jointly invents, creates, develops or otherwise makes any Intellectual Property (defined below) based on the Results (“Applicable IP”), then University shall promptly notify COMPANY ACRONYM in writing of such Applicable IP (a “University IP Notice”). University hereby grants COMPANY ACRONYM and its affiliates a non-exclusive, worldwide, fully-paid, royalty-free perpetual right and license to use the Applicable IP for internal research and development purposes. In addition, COMPANY ACRONYM shall have sixty (60) days from the date of receipt of a University IP Notice to notify University (a “COMPANY ACRONYM IP Notice”) of its desire to enter into a license agreement for more comprehensive, exclusive rights, as described below, and for a period of *six (6) months* after the date of the COMPANY ACRONYM IP Notice, or such additional period of time as to which the parties shall mutually agree (collectively, the “Option Period”), the parties shall use good faith efforts to enter into a license agreement granting COMPANY ACRONYM and its affiliates an exclusive, worldwide, royalty-bearing license to (a) use the Applicable IP to develop, import, make, market, offer for sale, sell or otherwise commercialize products or services of any nature; (b) sublicense, disclose, display, distribute, publish, or otherwise provide the Applicable IP to third parties (notwithstanding any other terms of this Agreement); and (c) copy, modify, and create derivative works and improvements based on the Applicable IP. University agrees not to negotiate with any third parties or license, assign, or otherwise provide any Applicable IP to any third parties prior to expiration of the Option Period. “Intellectual Property” means any (i) invention (whether or not patentable), know-how, works of authorship, technology, software, techniques, developments, discoveries, designs, algorithms, models, formulations, improvements, protocols, data and proprietary information; and (ii) patents, copyrights, trademarks, service marks, trade secrets, or other intellectual property rights associated with the foregoing. If the University owns or controls any Intellectual Property other than Applicable IP that is necessary for COMPANY ACRONYM and its affiliates to utilize any Applicable IP (“Necessary Background IP”), then upon request by

- COMPANY ACRONYM, University, if free to do so, agrees to negotiate in good faith with COMPANY ACRONYM for a non-exclusive license to use such Necessary Background IP.
- 7.3 If COMPANY ACRONYM provides a COMPANY ACRONYM IP Notice but COMPANY ACRONYM and University fail to enter into an agreement during the Option Period with respect to any Applicable IP owned solely by the University, University shall be permitted to negotiate with third parties and enter into agreements with third parties relating to the Applicable IP, but for the period of *one (1) year* the terms will be equivalent with terms that are no more favorable to such third parties than those offered to COMPANY ACRONYM.
- 7.4 If COMPANY ACRONYM provides a COMPANY ACRONYM IP Notice but COMPANY ACRONYM and University fail to enter into any agreement during the Option Period with respect to any Applicable IP owned jointly by COMPANY ACRONYM and University (“Joint IP”), then each party and its affiliates shall have a royalty-free, non-transferable, non-exclusive, perpetual right to use and license their rights to such Joint IP in any manner and for any purpose, without any obligation to obtain the other party’s consent and without any obligation to share with the other party any revenue or other benefits received, but at such party’s own risk. Without limiting the foregoing and for illustrative purposes only, each party and its affiliates shall be permitted, royalty-free, to use and license their rights to the applicable Joint IP to develop, import, make, market, offer for sale, sell or otherwise commercialize products or services of any nature.
- 7.5 COMPANY ACRONYM has no proprietary interest in the drugs whose effects were evaluated in the *name of the NASH CRN trial and/or study of the samples*.
- 7.6 The parties acknowledge that the United States Government, as a matter of statutory right under 35 USC Sections 200-212, holds or may hold a non-exclusive license and certain other rights under patents on inventions made as a consequence of investigation whose funding includes funds supplied by the United States Government. In the event the United States Government has such rights or in the future is found to have such rights with respect to all or any Intellectual Property, any license contemplated under this Agreement, even if termed an "exclusive" license, shall be understood to be subject to the rights of the United States Government, without any effect on the parties' remaining obligation, as set forth in the license or in this Agreement.

Article 8 – Changes in Laws

The terms of this Agreement are intended to be in compliance with all federal, state and local statutes, regulations and ordinances applicable on the date this Agreement takes effect including but not limited to, the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), and applicable State False Claims Acts (“SFCA”). The parties agree to execute amendments as may be necessary for the continuing compliance with the aforementioned Acts, as additional regulations are promulgated or become final and effective. Should either party reasonably conclude that any portion of this Agreement is or may be in violation of such requirements or subsequent enactments by federal, state or local authorities, or if any such change or proposed change would materially increase the cost of COMPANY ACRONYM’s performance hereunder, the parties agree to negotiate written modifications to this Agreement as may be necessary to establish compliance with such authorities or to reflect applicable changes.

Article 9 – Force Majeure

Neither party shall be liable for any claims or damages and each party shall be excused for such claims, damages, failures and delays in the performance of its obligations under this Agreement, in each case if due to any act or cause beyond the reasonable control and without the fault of that party, including, without limitation, acts of God such as fire, flood, tornado, earthquake; acts of government (i.e., civil injunctions or enacted statutes and regulations); or acts or events caused by third parties such as riot, strike, power outage or explosion; or the inability due to any of the aforementioned causes to obtain necessary labor or materials.

Article 10 – Independent Contractor

- 10.1 In the performance of the services under this Agreement, COMPANY ACRONYM shall be deemed to be and shall be an independent contractor.
- 10.2 Neither party hereto is authorized or empowered to act as agent for the other for any purpose and shall not on behalf of the other enter into any contract, warranty, or representation as to any matter. Neither party shall be bound by the acts or conduct of the other.

Article 11 – Notices

Notices and communications hereunder shall be deemed made if given by overnight courier or by registered or certified envelope, post prepaid, and addressed to the party to receive such notice or communication at the address given below or such other address as may hereafter be designated by notice in writing:

If to COMPANY ACRONYM:

Company name

Company address 1

Company address 2

with a copy to:

Collaborative Scientist name

Collaborative Scientist address 1

Collaborative Scientist address 2

If to University:

Name of University Contract Contact
Contract Contact address 1
Contract Contact address 2
Contract Contact address 3

Phone: _____
 Fax: _____
 Email: _____

Notice given pursuant to this Article shall be effective as of the day of receipt of notice.

Article 12 – Governing Law

This Agreement shall be governed in all respects by the laws of the State of the University PI, without regard to conflict of law principles. In the event of a conflict between this Agreement and any attachment hereto, the terms of this Agreement will govern.

Article 13 – General Provisions

- 13.1 Non-assignability – The rights and obligations of the parties under this Agreement shall not be assignable without written permission of the other party.
- 13.2 Severability – If any provision hereof is held unenforceable or void, the remaining provisions shall be enforced in accordance with their terms.
- 13.3 Entire Agreement - This Agreement contains the entire and only agreement between the parties

respecting the subject matter hereof and supersedes or cancels all previous negotiations, agreements, commitments, and writings between the parties on the subject of this Agreement. This Agreement may not be amended in any manner except by an instrument in writing signed by the duly authorized representatives of each of the parties hereto.

[SIGNATURES APPEAR ON FOLLOWING PAGE]

IN WITNESS WHEREOF, the parties hereto have caused these presents to be executed in duplicate.

INSTITUTION OF PI

COLLABORATING COMPANY NAME

By: _____

By: _____

Name: _____

Name: _____

Title: _____

Title: _____

Date: _____

Date: _____

READ AND ACKNOWLEDGED:

Principal Investigator, while not a party to this Agreement, hereby acknowledges that Principal Investigator has read this Agreement and understands Principal Investigator's obligations hereunder.

By: _____

Name: *Name of PI* _____

Date: _____

EXAMPLE SCOPE OF WORK FOR NASH CRN COLLABORATIVE STUDY

EXHIBIT A

Scope of Work

Study title: NASH CRN collaborative study

Institution Principal Investigator: Name of NASH CRN study PI

COMPANY ACRONYM Collaborating Scientist: Name of Collaborating Scientist

Study Overview:

Insert brief description

Prior Publication References:

Insert referenced citation(s)

Protocol Reference: TO BE PROVIDED BY INSTITUTION

Description of Samples:

Institution will arrange for NIH (NIDDK) repository to send COMPANY ACRONYM *specifications of amount and type of* samples for *specified service*. There will be approximately Number samples for *specified service* from the NASH CRN study or trial of sample collection.

Testing Services to be performed by COMPANY ACRONYM:

Type of testing/service:

Insert the itemized list of specified measures or product

NASH algorithms (when available):

- *EXAMPLE*: Test that identifies subjects with NASH and liver fibrosis (stages F2/F3) to replace liver biopsy