AGR-24632

COLLABORATION AGREEMENT

This agreement (the "Agreement") is made and entered into as of the date of the last signature hereto (the "Effective Date") by and between University of Foggia, having a principal address at _____ ("COLLABORATOR") and Icahn School of Medicine at Mount Sinai, a New York not-for-profit education corporation having an office at One Gustave L. Levy Place, New York, NY 10029 ("MOUNT SINAI"). Each party hereto is at times referred to herein as "Party" or jointly as the "Parties".

NOW, THEREFORE, in consideration of the mutual promises and undertakings set forth herein and intending to be legally bound, the Parties agree as follows:

1.0 STATEMENT OF WORK

1.01 The Parties agree to use reasonable efforts to collaborate on a research project entitled "Immune response in SARS-CoV2 vaccinated or infected kidney transplant recipients" and to perform the research activities described in attached Exhibit A (the "Research Project") using certain materials to be exchanged between the Parties as described in Exhibit B (the "Materials"). Exhibit B may be updated by written amendment executed by both Parties to include new Materials.

1.02 The Research Project will be supervised by Dr. Paolo Cravedi from MOUNT SINAI and Dr. Gianluigi Zaza from COLLABORATOR (the "Principal Investigators").

2.0 TERM

2.01 The term of this Agreement shall begin on the Effective Date and, subject to Section 7 below, shall expire on the termination of the Research Project.

3.0 COLLABORATION COSTS AND EXPENSES

3.01 Each Party shall bear its own cost in connection with the activities contemplated under this Agreement. At all times during the term of this Agreement, the Parties must provide prompt written notice to identify any source of funding used to support the research contemplated under this Agreement that may contain provisions inconsistent with the terms of this Agreement.

4.0 LIABILITY

4.01 Neither Party shall be responsible or liable for any injuries or losses caused by the implementation, transfer or use by the other Party of the Materials or results of the Research Project or research data generated under this Agreement.

4.02 Unless prohibited by law, each Party agrees to assume all liability with respect to any expense, claim, loss, damage, or costs caused by its own use of the Materials, data or results from the Research Project except to the extent such expense, claim, loss, damage, or costs are caused by the gross negligence or willful misconduct of the other Party.

5.0 DISCLAIMER OF WARRANTY

5.01 ANY INFORMATION, DATA, OR MATERIALS FURNISHED PURSUANT TO THIS AGREEMENT ARE ON AN "AS IS" BASIS. THE PARTIES MAKE NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, AS TO ANY MATTER, INCLUDING BUT NOT LIMITED TO WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE, MERCHANTABILITY, PATENTABILITY, OR THAT USE OF THE MATERIALS OR RESULTS OBTAINED THEREFROM WILL BE FREE FROM INFRINGEMENT OF PATENTS, COPYRIGHTS, TRADEMARKS OR OTHER RIGHTS OF THIRD PARTIES.

6.0 INTELLECTUAL PROPERTY RIGHTS

6.01 It is expressly agreed that neither Party shall transfer by operation of this Agreement to the other Party any patent right, copyright, or other proprietary right that either Party owns as of the Effective Date of this Agreement, or developed outside the Research Project, except as specifically set forth herein.

6.02 "Invention" as used herein means inventions and/or discoveries, whether patentable, copyrightable or otherwise, conceived (as defined by U.S. patent laws) and reduced to practice in performance of the Research Project during the Term under this Agreement. Inventorship in Inventions shall be determined in accordance with U.S. patent law and ownership shall follow inventorship. Therefore, MOUNT SINAI shall own all rights, title and interest in and to Inventions conceived solely by MOUNT SINAI, its faculty, staff, employees, agents or students; COLLABORATOR shall own all rights, title and interest in and to Inventions conceived solely by COLLABORATOR's faculty, staff, employees, agents or students under this Agreement; MOUNT SINAI and COLLABORATOR shall jointly own Inventions jointly conceived by both Parties hereunder. Each Party will promptly disclose to the other Party any Invention which disclosure shall be the Confidential Information of the Party making such disclosure. In the event of joint Inventions, the Parties agree to discuss and negotiate in good faith an arrangement regarding the patenting and commercialization of joint inventions.

6.03 Each Party shall solely own results of the Research Project solely generated by such Party. Results jointly generated shall be jointly owned. Each Party shall

have the right to use the other Party's results of the Research Project, including, without limitation, any Inventions owned by the other Party, for its own internal non-commercial research, academic, teaching, and patient care purposes. For clarity, industry sponsored research is non-commercial research provided that no rights or option to rights in the Research Project results of the other Party are extended to the sponsor of such research.

7.0 TERMINATION

7.01 Either Party may terminate this Agreement prior to the expiration of the designated term by giving thirty (30) days' prior written notice to the other.

7.02 Upon expiration or early termination of this Agreement, the Parties shall return or destroy (at the disclosing Party's option) all of disclosing Party's Material and Confidential Information. In the case of destruction the Party destroying such Materials and/or Confidential Information shall confirm such destruction in writing to the other Party within thirty (30) days of expiration or termination of this Agreement; provided however that each Party may retain in its respective confidential files one copy of written Confidential Information of the other Party solely for monitoring its ongoing obligations.

8.0 USE OF NAMES

8.01 Neither Party shall use the other's logo, name or the name of any of the other Party's trustees, officers, directors, faculty members, students, employees, faculty, consultants, or representatives, or any adaptation of any of the foregoing, including in any advertising, promotion, or to suggest endorsement, without such other Party's prior written consent, which may be granted or denied in such Party's discretion. In the case of MOUNT SINAI, such consent may only be granted with prior, written approval by Mount Sinai Innovation Partners.

9.0 GOVERNING LAW; JURISDICTION

9.01 This Agreement will be construed and governed in accordance with the laws of the State of New York, without giving effect to any conflicts-of-laws principles to the contrary. The Parties hereby submit to exclusive jurisdiction and venue in any state or federal courts located in the city of New York, state of New York, with respect to any and all disputes concerning or otherwise arising under this Agreement.

10.0 INDEPENDENT CONTRACTOR

10.01 Nothing contained in this Agreement is to be construed to constitute MOUNT SINAI and COLLABORATOR as partners or joint venturers of each other, or to constitute the employees, agents or representatives of either Party as the employees, agents or representatives of the other Party, it being intended that the relationship between the MOUNT SINAI and the COLLABORATOR shall at all times be that of independent contractors. Neither Party hereto shall have any express or implied right or authority to assume or create any obligations on behalf of, or in the name of, the other Party; or to bind the other Party to any contract, agreement or undertaking with any third party.

11.0 PUBLICATION

11.01 It is the intent of the Parties to pursue joint publications on study results generated in performance of the Research Project ("Results") whenever applicable. Criteria for authorship of any publication arising from the Research Project will be determined in accordance with accepted academic standards, taking into consideration the relative contributions of the Parties.

11.02 Both Parties agree not to disclose the Results to any third party or submit for publication, prior to disclosure of such Results and data in writing to the other Party. Both Parties agree to allow for appropriate review by the other Party of the proposed publication thirty (30) days in advance of submission for publication. At the expiration of such thirty (30) day period, the Parties may proceed with submission for publication provided, however, that upon notice by one Party to the other Party before the expiration of such thirty (30) day period that the notifying Party reasonably believes a patent application claiming an invention should be filed prior to such publication, such publication shall be delayed for an additional sixty (60) days or until any patent application(s) have been filed, whichever shall first occur. In no event shall the submission of such publication of results be delayed for more than a total of ninety (90) days from the date first submitted for review. Notwithstanding the foregoing, in the event there has been no joint publication submitted within twelve (12) months of completion of the Research Project, each Party reserves the right to publish independently, subject to the notice requirements provided for in this Section 11.02, with respect to its own work on the Research Project. No right of manuscript approval is implied by this Section.

12.0 CONFIDENTIAL INFORMATION

12.01 The Parties acknowledge that it may be desirable for a Party to disclose information it owns or controls that is confidential to it (a Party's "Confidential Information") in order for the Parties to perform the Research Project and collaborate as set forth herein. To preserve the information's confidentiality, the

disclosing Party agrees either to: 1) mark such information as "confidential" upon disclosure to the other Party, or if such information is disclosed in intangible form, 2) to indicate upon disclosure the information's confidential nature, and provide the receiving Party within (30) days of the intangible disclosure with a written memorandum summarizing such disclosure and reiterating its confidential status; provided however that failure to so mark, indicate, or summarize such Confidential Information shall not compromise or alter its confidential status if a reasonable person would recognize, based upon its content and/or context of its disclosure, that such disclosure was intended as confidential. Confidential Information may be used by a receiving Party solely for the Research Project and may not be used for any commercial or other purpose, without the prior express written permission of the disclosing Party. For clarity the receiving Party shall not use any of disclosing Party's Confidential Information for regulatory or patent filing purposes, or for initiation or pursuit of any proceeding to challenge the patentability, validity, or enforceability of any patent application or issued patent (or any portion thereof) that is owned or controlled by disclosing Party (including e.g. via pre-issuance submissions, post grant review, or inter partes review). Any such excluded use is hereby deemed a material breach of this Agreement and in such event, notwithstanding anything to the contrary herein, in addition to any other relief granted to the non-breaching Party, the breaching Party shall pay to the non-breaching Party all costs such non-breaching Party incurs in such proceeding including in defense of such patent application or patent. Any such payment shall be made within thirty (30) days of written demand.

12.02 The receiving Party shall not disclose or cause to be disclosed any Confidential Information of the disclosing Party, without the disclosing Party's prior written consent.

12.03 Notwithstanding the foregoing, the obligation of non-disclosure shall not apply to any information that the receiving Party can demonstrate by written and/or electronic records:

a. is in the public domain at the time of disclosure;
b. becomes part of the public domain after disclosure through no fault of the receiving Party;
c. is in receiving's Party possession prior to disclosure by the disclosing Party;
d. is disclosed to the receiving Party by a third party (who has the legal right to do so and does so without imposing any obligation of confidentiality with respect thereto) after the time of providing Party's disclosure; or
e. is independently developed by the receiving Party without reference to the disclosing Party's confidential information as shown by written or electronic records created contemporaneously with such independent development.

In addition, the receiving Party may disclose Confidential Information provided by the disclosing Party to the extent and solely for the purpose that it is required to do so by law, court order or other legal authority with jurisdiction, provided that the receiving Party promptly informs the disclosing Party in writing of such

requirement (to the extent legally permissible) and complies, at the disclosing Party's written request and expense, with the disclosing Party's legal efforts to prevent or limit the scope of such required disclosure. In the event such legally compelled disclosure is made as permitted hereunder, receiving Party shall continue in all other ways to maintain the confidentiality obligations and use restrictions herein with respect to such information.

12.04 A receiving Party's obligation of non-disclosure of the other Party's Confidential Information shall survive the expiration or earlier termination of this Agreement for a period of five (5) years.

13.0 MATERIALS

13.01 All Materials, including any progeny and unmodified derivatives and parts thereof, shall remain the property of the Party providing such Materials (the "Provider") and will be used by the receiving Party (the "Recipient") solely for the Research Project. The Materials and any residual Materials left after performing the Research Project under this Agreement will be returned to the Provider or destroyed by the Recipient, as requested by Provider, at the end of the Term of this Agreement or upon early termination of this Agreement, whichever occurs first.

13.02 Neither the Materials nor any progeny, unmodified derivatives or modifications of the Materials shall be distributed to any third party without prior written consent of the Provider of such Materials. Nothing in this Agreement shall preclude each Provider from transferring its solely owned Materials to other third parties for commercial or research purposes.

13.03 The Materials shall be used with prudence and appropriate caution in any experimental work. THE PARTIES MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.

13.04 Each Party agrees to use the Materials in compliance with all applicable statutes and regulations, including but not limited to 45 CFR part 46 and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) as amended, and all similar applicable state laws and regulations (collectively, "HIPAA"). The Materials are not for use in human subjects, including, without limitation, for diagnostic purposes.

a. The Provider represents that the collection of Material and its sharing with Recipient for research purposes was approved or exempted by the relevant Institutional Review Board and authorized by donors under informed consent in

accordance with federal, state and local laws and regulations which address protection of human subjects in research, including 45 CFR part 46.

b. The Recipient represents that its intended use of Material for research purpose has been approved or exempted by the relevant Institutional Review Board.

c. Materials derived from human donors may not be transferred with any individual donor-identifying information. Recipient shall make no attempt to re-identify any such Material or information. Notwithstanding the foregoing, if Recipient believes it has received identifiable patient information hereunder, it will hold such information in strict confidence indefinitely, immediately inform Provider and comply with Provider's instruction at Provider's expense, with respect to return or destruction of the same.

d. The Provider agrees and shall assure that Materials and any associated data transferred hereunder will be Anonymized. "Anonymized" means (a) information which does not relate to an identified or identifiable natural person or (b) information rendered anonymous in such a manner that no natural person is or may be identified or identifiable by any person, third-party, or entity.

13.05 No option, license, or conveyance of rights, express or implied, is granted by one Party to the other Party in connection with any Materials provided under this Agreement, except the right to use the Materials strictly in accordance with the terms of this Agreement.

14.0 MISCELLANEOUS

14.01 This Agreement constitutes the entire agreement between the Parties with respect to its subject matter and supersedes and terminates all prior agreements covenants, promises, agreements, warranties, representations, conditions, and understanding between the Parties with respect to such subject matter. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as set forth herein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by the respective authorized officers of the Parties.

14.02 This Agreement is not assignable, and any attempt to do so shall be null and void.

14.03 This Agreement may be executed in counterparts and exchanged by electronic delivery in .pdf format. Each counterpart so exchanged shall be deemed to be an original for all purposes, and all of which counterparts, taken together, shall constitute one and the same instrument. The Parties hereby agree that the electronic signatures, as defined in the Electronic Signatures in Global and National Commerce Act of 2000 ("ESIGN"), used in execution of this Agreement are legally binding and, as such, equivalent to traditional handwritten signatures under ESIGN and other

applicable laws. The Parties further agree that the electronic signatures used in execution of this Agreement shall constitute an original for all purposes.

14.04 The following shall survive termination of this Agreement: Articles 4, 5, 6, 8, 9, 10, 11, 12 and 13 and Sections 7.02 and 14.04.

SIGNATURES TO FOLLOW

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their respective duly authorized representatives.

ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI

By:_____

Name:
Title:
Date:

COLLABORATOR:

By:_____

Name:
Title:
Date:

READ AND UNDERSTOOD BY PRINCIPAL INVESTIGATORS:

By: _____
Name:
Title:
Date:

By: _____
Name:
Title:
Date:

Exhibit A – Research Project

ABSTRACT

Solid organ transplant recipients have increased morbidity and mortality in response to infection with SARS-CoV-2, the virus responsible for COVID19. While the general population has greatly benefited from the rapid development of several vaccines that are protective against the development of severe infection, the transplant recipient population has sub-optimal responses to similar vaccination regimens. Herein, we provide preliminary data on the cellular and serological responses to SARS-CoV-2 mRNA vaccination in both liver and kidney transplant recipients. Liver transplant recipients are significantly more likely to respond to a two-dose regimen with both viral specific T cells and seroconversion when compared with kidney transplant recipients. Interestingly, although both seroconversion efficiency and T cell activation are affected by the levels of immunosuppression, the organ transplanted (liver versus kidney) has an independent effect on the humoral and cellular responses. However, an in depth, mechanistic evaluation of these adaptive immune responses is lacking. We hypothesize that there are intrinsic differences in immune function, irrespective of the degree of immunosuppression, between liver and kidney transplant recipients. This proposal builds on an already productive collaboration between the laboratories of Paolo Cravedi (Mount Sinai) and Gianluigi Zaza (University of Foggia). The overall goal of this work is to use cryopreserved samples and obtain additional samples to mechanistically understand the features that characterize effective immune response to SARS-CoV-2 vaccination in kidney transplant recipients.

To address this goal, we propose the following specific Aims: Aim 1: Assess the differences in T cell phenotype and function between solid organ transplant (SOT) recipients that are SARS-CoV-2 vaccine responders versus non-responders; Aim 2: Determine differences in chromatin accessibility and gene expression in vaccine responders versus non-responders; Aim 3: Build a comprehensive biobank that can be used to identify mechanisms responsible for the response to SARS-CoV-2 vaccination. This project builds upon the productive collaboration between the Cravedi and Zaza laboratories and leverages their expertise. Success of this high-risk proposal has the potential to comprehensively delineate the immune responses in both kidney and liver transplant recipients upon SARS-CoV-2 vaccination, a point of critical importance to define biomarkers of response and envision strategies to improve response (high reward).

Exhibit B – Materials

Provider	Materials
COLLABORATOR	human cells
MOUNT SINAI	