HUMAN MATERIAL TRANSFER AGREEMENT

This Human Material Transfer Agreement ("MTA") is between University of Foggia – Department of Medical and Surgical Sciences having a principal address at Via Gramsci no. 89/91 - 71122 Foggia - Italy and operational headquarters in Via L. Pinto n. 1 - 71122 Foggia - Italy ("PROVIDER"), 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 ("RECIPIENT"), for the transfer of human material, with or without accompanying data, for research purposes as further defined below. PROVIDER and RECIPIENT may each be referred to as Party or collectively as Parties. This MTA will become effective on the date of the last signature below and shall expire on the termination of the Research Project.

PROVIDER Investigator: Gianluigi Zaza, MD, PhD

RECIPIENT Investigator: Paolo Cravedi, MD, PhD

RECIPIENT and PROVIDER agree as follows:

1. PROVIDER will transfer to RECIPIENT the following: with the following data

- Human tissue samples, including, but not limited to; human serum/plasma, PBMC cells, biopsy tissue, saliva, stool, and urine from patients with kidney disease and donor/recipients of kidney transplant.
- De-identified data including, but not limited to, source subject's: Age, Relevant Medical History (medications, diseases, transplant date, etc.), sample date, etc.

2. Descriptive title of RECIPIENT's research with Human Material is: Multi-tissue repository for patients with kidney disease.

3. PROVIDER will provide RECIPIENT with personally identifiable information or the code to personally identifiable information with Human Material:

☐ Yes ☒ No

If Box "Yes" is checked above, then RECIPIENT's use of Human Material is subject to:

a. The Privacy Act of 1974, as amended, at 5 U.S.C. §552a ("Privacy Act") requirements;

b. Applicable human subjects regulations and guidance, which may include 45 C.F.R. Part 46, 21 C.F.R. Parts 50 and 56, and FDA Good Clinical Practice Guidelines (ICH E6 Good Clinical Practice: Consolidated Guidance, 62 FR 25692 (1997)); and c. RECIPIENT's agreement to: (i) maintain any transferred personally identifiable information in a secure manner that restricts access by any individual not involved in the Research Project (e.g., for paper records – locked file cabinets or continual physical presence in a room that locks, or for electronic records – encryption and password protection); (ii) remove or destroy the information that identifies the individual who is the subject at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the Research Project; and (iii) make no further use or disclosure of the information unless approved by the PROVIDER, except as required by law.

4. RECIPIENT will only use Human Material for the academic research, including industry sponsored research.

5. RECIPIENT represents that it has obtained Institutional Review Board approval, as appropriate, to use Human Material.

6. THE RECIPIENT AGREES THAT THIS HUMAN MATERIAL MAY NOT BE USED IN HUMANS OR FOR ANY DIAGNOSTIC, PROGNOSTIC, OR TREATMENT PURPOSES.

7. RECIPIENT will allow the use of Human Materials only by RECIPIENT Investigator and RECIPIENT Investigator's research team that are under the direct supervision of RECIPIENT Investigator and only after they have been informed of and agreed to the provisions and restrictions stated herein. Any transfer of Human Material to other than RECIPIENT Investigator's research team requires the advanced written approval of PROVIDER.

8. All Confidential Information that is transferred between PROVIDER and RECIPIENT is subject to the following: All information to be deemed confidential under this MTA shall be clearly marked "CONFIDENTIAL" by the providing Party and maintained in confidence by the receiving Party for a period of three (3) years from the receiving Party's receipt of the Confidential Information. Any Confidential Information that is orally disclosed must be reduced to writing and marked "CONFIDENTIAL" by the providing Party and such notice must be provided to the receiving Party within thirty (30) days of the oral disclosure. For the purposes of this MTA, Confidential Information includes any scientific or business data relating to the Human Material that a Party asserts are confidential and proprietary, except for data that:

a. have been published or otherwise publicly available at the time of disclosure to the receiving Party; were in the possession of or were readily available to the receiving Party without being subject to a confidentiality obligation from another source prior to the disclosure;

b. have become publicly known, by publication or otherwise, not due to any unauthorized act of the receiving Party;

c. the receiving Party can demonstrate it developed independently, or acquired without reference to, or reliance upon, such Confidential Information; or

d. are required to be disclosed by law, regulation, or court order.

9. RECIPIENT will not contact or make any effort to identify individuals who are or may be the sources of Human Material, without specific written approval from PROVIDER.

10. RECIPIENT will comply with all laws, rules and regulations applicable to the handling and use of the Human Material.

11. Either Party may terminate this MTA with sixty (60) days written notice to the other Party.

12. When the Research Project is completed or this MTA is terminated, whichever comes first, any unused Human Material will either be destroyed in compliance with all applicable statutes and regulations or will be returned to the PROVIDER as requested by the PROVIDER.

13. In all oral presentations or written publications concerning the use of Human Materials, RECIPIENT will acknowledge PROVIDER's contribution of Human Material unless requested otherwise by PROVIDER.

14. Any Human Material delivered pursuant to this MTA is understood to be experimental in nature and may have hazardous properties. PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS 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 HUMAN MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.

15. No indemnification for any loss, claim, damage, or liability is intended or provided by either Party under this MTA. Each Party shall be liable for any loss, claim, damage, or liability that said Party incurs as a result of said Party's activities under this MTA.

16. . The Parties have executed this MTA by their respective duly authorized officers on the day and year hereinafter written. Any communication or notice to be given shall be forwarded in writing to the respective addresses listed below.

17. 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.

FOR PROVIDER:

prof. Gaetano Serviddio – Head of the Department of Medical and Surgical Sciences – University of Foggia

_____ _____

(Signature of Authorized Official) Date

PROVIDER INVESTIGATOR

Gianluigi Zaza, MD, Associate Professor

(Printed Name and Title)

_____ _____

Mailing Address for Notices: giustina.depalo@unifg.it; gianluigi.zaza@unifg.it

FOR RECIPIENT:

_____ _____

(Signature of Authorized Official) Date

RECIPIENT INVESTIGATOR: I have read and understood the terms and conditions of this MTA and I agree to abide by them in the receipt and use of the Human Material.

Paolo Cravedi, MD, Associate Professor

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(Signature) Date