


Data Transfer and Use Agreement (“Agreement”)	
Provider: HMH Hospitals Corporation d/b/a Center for Discovery and Innovation Provider Principal Investigator/ Scientist: <u>PI NAME</u> Center for Discovery & Innovation Hackensack Meridian Health 111 Ideation Way Nutley, NJ 07110 e-mail:	Recipient: <div style="background-color: #e0ffff; height: 20px; width: 100%;"></div> Recipient Principal Investigator/ Scientist: Name: Email:
	Project Title:
<p>THIS AGREEMENT (hereinafter "Agreement") is by and between Hackensack Meridian Health on behalf of HMH Hospitals Corporation d/b/a/ Center for Discovery and Innovation (hereinafter “HMH” or “Provider”); and (hereinafter “Recipient”), principally located at 111 Ideation Way Nutley, NJ 07110</p> <p style="text-align: center;">RECITALS:</p> <p>WHEREAS, HMH and Recipient have entered into this Agreement under which Recipient may use and/or disclose certain information, in connection with the research set forth in the Proposal by _____ entitled study on convalescent plasma therapy for COVID-19 patients in pilot trial (“Project” or “Research”) which is attached hereto as Attachment 1;</p> <p>WHEREAS, the Parties intend to maintain the information in accordance with applicable federal and state statutes and regulations and with applicable policies of HMH and the Recipient; and</p> <p>WHEREAS, HMH and Recipient agree that this Agreement sets forth the terms and conditions pursuant to which the information will be handled between Recipient and HMH and with third parties during the term of the Agreement and after the termination of the Project.</p> <p>NOW THEREFORE, in consideration of the foregoing, the mutual representations, covenants and agreements set forth below, and for other good and valuable consideration, the Parties, intending to be legally bound, hereby agree as follows:</p>	
Terms and Conditions	

A. Definitions

- 1) "Data" means information, which originated at HMH and/or its affiliates, and which originally contained Protected Health Information, as such is defined by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA")(45 C.F.R. § 160.103), but now is unidentifiable because it has been de-identified or stripped of any and all of the 18 personal identifiers which constitute the elements of Protected Health Information in accordance with 45 CFR 164.514.
- 2) "Research" means those procedures set forth in the Proposal by entitled

B. Uses and Disclosures

1. Recipient may use and disclose Data in accordance with the federal regulations governing the conduct of research studies involving human subjects, 45 CFR 46.101 et seq, any applicable confidentiality or privacy laws, and with the approvals of the Research conferred by the Institutional Review Boards of HMH and of the Recipient.
2. Recipient may only use and disclose the Data in connection with its implementation of the Research and solely by Recipient Scientist and Recipient's faculty, employees, fellows, students, and agents ("Recipient Personnel") and Collaborator Personnel (as defined in Attachment 2) that have a need to use or provide a service in respect of, the Data in connection with the Research and whose obligations of use are consistent with the terms of this Agreement.
3. Compliance with Agreement: At all times during the Research when using and disclosing the Data, Recipient shall comply with the terms of this Agreement and with all other relevant institutional policies and applicable federal or state laws when using and disclosing the Data including the completion of any IRB or ethics review or approval that may be required.
4. No Re-Identification/Contact: Recipient shall not attempt to re-identify the Data or otherwise attempt to contact the individual(s) who may be connected to the Data. Recipient shall ensure that any of its employees or agents who receive the Data shall not attempt to re-identify the Data or contact the individual(s). Should Recipient inadvertently receive identifiable information or otherwise identify a subject, Recipient shall promptly notify Provider and follow Provider's reasonable written instructions, which may include return or destruction of the identifiable information.
5. Prohibition on "Sale" and "Marketing:" Recipient shall not directly or indirectly accept remuneration, financial or otherwise, except Recipient may accept such remuneration from HMH which is a reasonable cost-based fee to prepare and/or transmit the data providing the same is negotiated by the Parties as a budget for this Research.
6. Disclosures outside United States: Recipient shall NOT disclose Data to any third-party outside the borders and jurisdiction of the United States of America, without the prior written consent of HMH, which consent may not be unreasonably withheld.

C. Confidentiality

1. For the purposes of this Agreement, "Confidential Information" includes any and all non-public and/or proprietary information of a party ("Disclosing Party"), or jointly developed by the parties under this Agreement ("Jointly Developed Information"), including but not limited to inventions, devices, know-how and data, protocols, research tools, biological materials, formulations, educational, research and development plans, designs, algorithms, business plans, information about business (including clinical and research) activities and other business relationships, and all other intellectual property, and all enhancements and improvements thereto, whether patentable or unpatentable, and whether or not reduced

to practice, and all United States patents or patent applications, copyrights, trademarks, or trade secrets and the research data generated pursuant to Research, that either party, either individually or together with the other party, asserts are, or would typically be considered to be, confidential and proprietary, except for information that:

- (i) has been published or otherwise publicly available at the time of disclosure to the receiving party ("Receiving Party"); or
- (ii) was in the possession of or was readily available to the Receiving Party from another source prior to the disclosure as evidenced by written records; or
- (iii) become publicly known, by publication or otherwise, not due to any unauthorized act by the Receiving Party; or
- (iv) the Receiving Party can demonstrate it developed independently, or it acquired without reference to or reliance upon such Confidential Information; or
- (v) are required to be disclosed by law.

2. Data represents a significant investment on the part of the Provider. Receiving Party agrees to employ all reasonable efforts to keep the Confidential Information of Disclosing Party and Jointly Developed Information secret and confidential, such efforts to be no less than the degree of care employed by Receiving Party to preserve and safeguard its own confidential information. The Confidential Information of the Provider and Jointly Developed Information shall not be disclosed, revealed, or given to anyone by Recipient, except employees of Recipient who have a need to know about the Confidential Information in connection with performing activities under this Agreement, and such employees shall be advised by the Recipient of the confidential nature of the Confidential Information and that the Confidential Information shall be treated accordingly. This obligation shall survive termination of this Agreement and shall continue for a period of three (3) years after Receiving Party's receipt of Confidential Information.
3. Notwithstanding anything in the preceding section (2) to the contrary, the parties agree to work together to make the results of their collaborative Research publicly available consistent with the applicable terms of any third-party agreements related to such Research. In addition to complying with any publication requirements of such third party agreements, before a party submits a paper or abstract for publication (related to the collaborative Research), it shall provide the other party with a copy of the proposed publication, and the other party shall have thirty (30) days to review the proposed publication to ensure that its Confidential Information is protected. A party may request the removal of its Confidential Information provided that such removal does not include the Study Data and Results or impact the integrity of the Publication. The other party may request in writing that the proposed publication be delayed for up to thirty (30) additional days as necessary for the purposes of filing a patent application. Recipient agrees to recognize the contribution of the Provider as the source of the Data in all written, visual, or oral public disclosures concerning Recipient's research using the Data, as appropriate in accordance with scholarly standards and the specific format that is indicated in Attachment 1 pertaining to Project Specific Information.
4. Notwithstanding anything in the preceding section (2) to the contrary, the parties acknowledge that the Provider(s) may need to disclose Confidential Information or Jointly Developed Information in order to satisfy any regulatory reporting requirements. Such disclosures to the applicable regulatory agency shall not be considered to violate this Agreement, provided that the provider(s) of the information will follow its standard practices in requesting confidential treatment by the regulatory agency of such information.
5. Upon termination of this Agreement or when the Research is completed, Recipient shall promptly return to HMM its Confidential Information, including all copies thereof. At HMM's option, the Confidential Information that is otherwise required to be returned to Recipient shall be destroyed and such destruction shall be certified in writing to HMM by an authorized representative of Recipient. Notwithstanding the foregoing, Recipient may retain one copy of the Confidential Information in its confidential legal files for the purpose of establishing the extent of the disclosure and their obligations.

D. Security Safeguards

1. Recipient shall have in place reasonable and appropriate administrative, technical, and physical security to

preserve the confidentiality, integrity and availability of all HMH Confidential Information and Data and prevent use or disclosure of such other than as provided for by this Agreement according to commercially acceptable standards and no less rigorously than it protects its own Confidential Information and Data. Such measures shall include, but not be limited to: (a) updated anti-virus software and security patches installed on all appropriate computing equipment; (b) firewall software installed on computing environments connected to the Internet; (c) appropriate access controls to restrict access to authorized individuals; (d) use of encryption when electronically transmitting Data; and (e) such other reasonable security controls, systems, and measures as the Provider may require. The Recipient shall inform the Provider of, and provide details reasonably requested by the Provider related to, any unauthorized use or disclosure of Confidential Information or Data, or any security incident or successful breach related to the Data, as soon as reasonably possible after the Recipient learns of such use or disclosure. In the event of improper use and disclosure, the Recipient and any employee or agent shall, in consultation with HMH, mitigate, to the extent practicable, any harmful effect that is known of such improper use or disclosure. Recipient shall and Recipient shall cause its Recipient subcontractors to cooperate fully with HMH in investigating any potential or actual breaches, including assistance, if requested, in conducting any harm threshold risk analyses. Recipient shall and Recipient shall cause its Recipient subcontractors to reimburse HMH, as applicable, for all costs, expenses and damages (including reasonable attorneys' fees) directly arising out of any notification process that may be required under federal or State Law with respect to any actual or suspected breach caused by Recipient or its subcontractors.

2. Recipient shall ensure that any authorized agents to whom it provides the Data agree to the same restrictions and conditions that apply to the Recipient with respect to the Data, including but not limited to using the Data only as necessary to conduct the Research.
3. Recipient shall promptly report to [Provider Contact] or the respective designee, any incident that has or may result in the unauthorized use or disclosure of Data in violation of this Agreement, but in no case more than two (2) business days from discovery of such incident.

Commented [SA1]: 7-19 to be completed by Study team.

E. Inventions: Each party shall retain title to any intellectual property rights in inventions and works of authorship made by its employees prior to or outside the scope of this Agreement. Unless provided otherwise in an agreement between the parties or with a third party related to a specific research project, the following intellectual property terms shall apply to research and other activities conducted pursuant to this Agreement. New inventions, discoveries, compositions or derivatives thereof, new uses, software, and any and all other intellectual property conceived or reduced to practice in the conduct of this Agreement (hereinafter referred to as "New Inventions"), solely by HMH shall be the sole property of HMH in accordance with HMH's policy. New Inventions conceived or reduced to practice in the conduct of this Agreement solely by Recipient shall be the sole property of Recipient in accordance with Recipient's policy. New Inventions conceived or reduced to practice jointly by the parties to this Agreement shall belong jointly to the parties ("Joint Inventions"). Inventorship shall be determined by U.S. patent law, and ownership shall follow inventorship. The Parties shall promptly report in writing any such New Inventions to each other upon discovery.

F. No Warranty: Data provided pursuant to this Agreement is understood to be experimental in nature and is accepted by Recipient "as-is". PROVIDERS MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EXPRESSED OR IMPLIED, INCLUDING WITHOUT LIMITATION WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE WITH REGARD TO ITS DATA, MODIFICATIONS, OR THAT THE DATA WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHT.

G. State Law: The Parties agree that if any provision or requirement concerning privacy or security of data under New Jersey law is more stringent or provides individuals with more rights regarding the Data than does this Agreement, such state law shall be followed.

H. Termination

1. Noncompliance: If HMH notifies Recipient regarding an activity or practice that constitutes a material breach or violation of an obligation under this Agreement, and Recipient does not take reasonable steps to or otherwise does not successfully cure the breach or end the violation, as applicable, within a reasonable

time as determined by HMM, HMM may terminate this Agreement and Recipient's authority to access, use and/or maintain the Data, and report the breach or violation.

2. Return of Data: Upon termination of this Agreement, and following HMM's instructions, Recipient shall either return to HMM or destroy all Data that Recipient or any of its employees and/or agents maintain in any form. Recipient and its employees and agents shall not retain any copies of the Data.

I. Amendment: The Parties acknowledge that state and federal laws relating to electronic data security and privacy are rapidly evolving and that amendment of this Agreement may be necessary to address such developments. Upon either Party's request, the Parties agree to, in good faith, promptly enter into negotiations concerning the terms of an amendment to this Agreement.

J. Independent Contractor: Nothing contained herein shall be deemed or construed by the Parties hereto or by any third-party as creating the relationship of employer and employee, principal and agent, partners, joint ventures, or any similar relationship. HMM and Recipient expressly acknowledge and agree that Recipient is an independent contractor, and not an agent of HMM, under federal agency law or otherwise.

K. Binding Effect: This Agreement shall inure to the benefit of and be binding upon each Party hereto and their respective successors and assigns.

L. Notices: All notices to be made under this Agreement shall be given in writing and shall be deemed to have been duly given and effective if personally delivered or sent by confirmed facsimile transmission, e-mail, certified or registered mail, return receipt requested, to the other Party at the address set forth in at the beginning of this Agreement.

If to HMM, copy to:

Center for Discovery & Innovation
Hackensack Meridian Health
111 Ideation Way
Nutley, NJ 07110

If to Recipient:

Commented [SA2]: 7-19 To be completed by the Study team

M. Modification: This Agreement may be amended, superseded, terminated or extended, and the terms hereof may be waived, only by a writing signed by the Parties.

N. Severability: If any provision of this Agreement is held by a court of competent jurisdiction to be invalid or unenforceable, such provision shall be deemed severed from this Agreement, and the remainder of the provisions will remain in full force and effect.

IN WITNESS WHEREOF, the Parties hereto have duly executed this Agreement effective as of the date of the signatures below (the "Effective Date"):

<p>By an Authorized Official of Provider:</p> <p>_____ Date</p> <p>Name:</p> <p>Title: <u>Contact Information for Formal</u></p> <p>Notices: Name:</p> <p>Address:</p> <p>Email:</p>	<p>By an Authorized Official of Recipient:</p> <p>_____ Date</p> <p>Name:</p> <p>Title: <u>Contracts Team Lead Contact</u></p> <p>Information for Formal Notices: Name:</p> <p>Address:</p> <p>Email:</p> <p>Phone:</p>
<p>By Principal Investigator:</p> <p>I have read the Agreement and acknowledge and understand all the terms and obligations</p> <p>_____ Date</p> <p>Name:</p> <p>Email:</p>	

Commented [SA3]: 7-19 requires the contact information for Touro's signatory

Commented [SA4]: 7-19 requires the contact information of the Touro PI

FOR INTERNATIONAL AGREEMENTS

Name: Bob Garrett Signature: _____
Title: President/CEO HMM Date: _____

Attachment 1
Data Transfer and Use Agreement
Project Specific Information

1. Description of Data:

See Next Page - "List of variables to be collected"

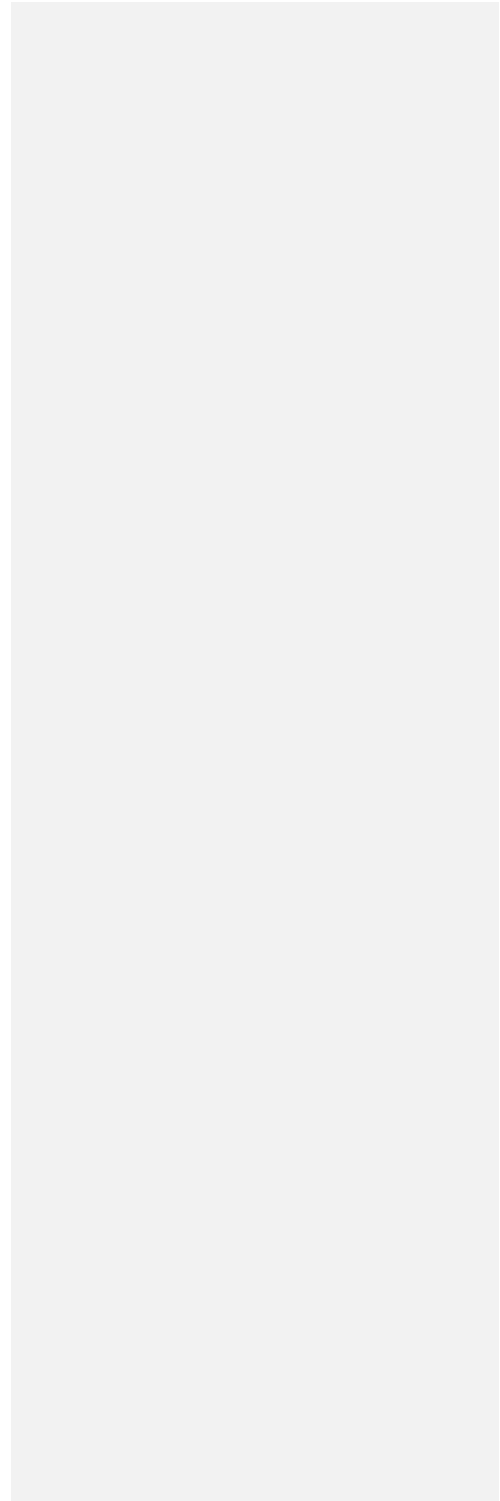
2. Description of Project:

3. Provider Support and Data Transmission:

Provider shall transmit the Data to Recipient: (select one)
 electronically or by mail to:

Name:	
Address:	
Email:	
Phone:	

List of variables to be collected



Upon execution of this Agreement, Provider shall send any specific instructions necessary to complete the transfer of the Data to the contact person listed above, if not already included below in this section of Attachment 1.

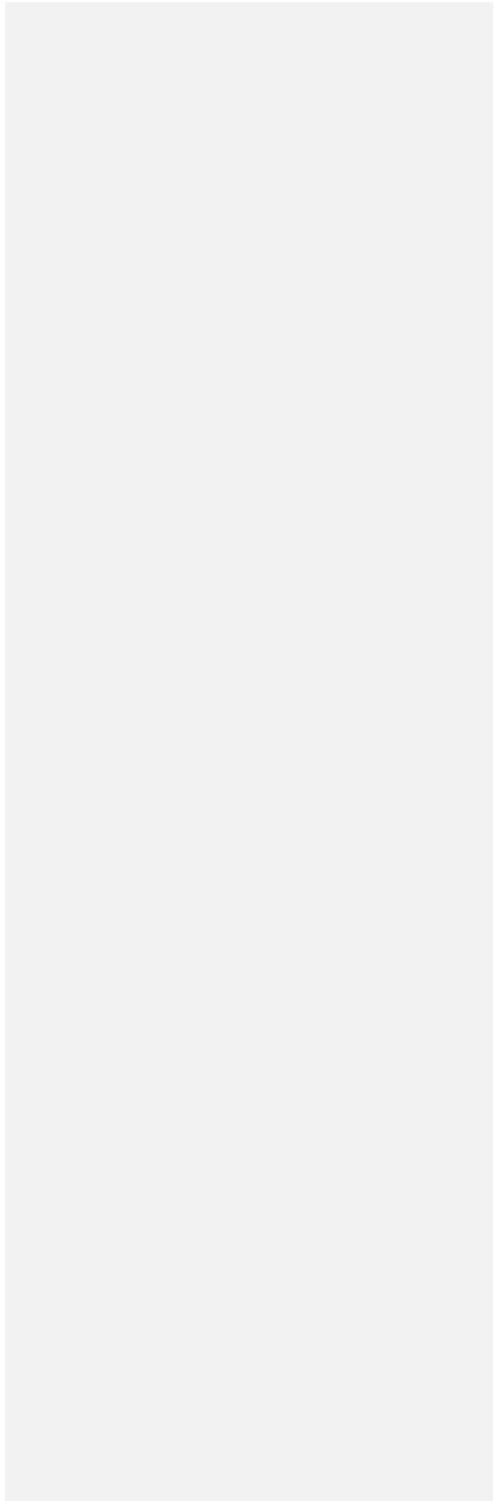
4. Reimbursement of Costs:

None

As governed by a separate written agreement between the parties Reimbursement Agreement Reference # (if required):

As set forth herein:

5. Disposition Requirements upon the termination or expiration of the Agreement:



Attachment 2
Data Transfer and Use Agreement
Identification of Permitted Collaborators (if any)

For all purposes of this Agreement, the definition of “Collaborator Personnel” checked below will pertain:

“Collaborator Personnel” means: None. No collaborators are permitted on the Project.

-OR-

“Collaborator Personnel” means as set forth below and agreed upon between the Parties:

“Collaborator Personnel” means: faculty, employees, fellows, or students of an academic institution, which institution (i) has agreed to collaborate in the Project, (ii) has faculty, employees, fellows, or students who have a need to use or provide a service in respect of the Data in connection with its collaboration in the Project, and (iii); “has executed an agreement that is substantially similar to this Agreement”