

TRI – PARTY RESEARCH 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 The Medical College of Wisconsin, Inc. a Wisconsin non-stock corporation, non-profit, educational, research and healthcare institution having a principal address at 8701 Watertown Plank Road, Milwaukee, Wisconsin, 53226 (“WISCONSIN”), Joan & Sanford I. Weill Medical College of Cornell University, a non-profit, educational, research institution having its principal place of business at 1300 York Ave, Box 89, New York, NY (“WEILL CORNELL”) and the City of Racine, a Wisconsin municipal corporation, have a principal address at 730 Washington Avenue, Room 103, Racine, Wisconsin, 53403 (“RACINE”). Each party hereto is at times referred to herein as “Party” or jointly as the “Parties”.

WHEREAS, the Parties intend to validate a novel rapid diagnostic approach to tracking the presence of SARS-CoV-2 and diagnose COVID-19 from saliva samples.

WHEREAS, the parties intend set forth the terms and conditions under which samples will be collected and analyzed thereby resulting in the exchange of de-identified data which will be recorded in REDCap.

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

The Parties agree to use reasonable efforts to collaborate on a research project entitled “Rapid On-Site Community-Wide Screening for Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2; COVID-19) in First Responders, Essential Municipal Employees and Residents of Racine, WI” and to perform the research activities described in attached Exhibit A (the “Research Project”).

The Research Project will be supervised by Dr. Christopher Mason from WEILL CORNELL and Dr. Alison Kriegel on behalf of both WISCONSIN and RACINE (the “Principal Investigators”).

2.0 TERM

2.01 The term of this Agreement shall begin on the Effective Date and shall expire on the first (1st) anniversary of the Effective Date, subject to Article 7 below (the “Term”).

2.02 Any extension to the Term must be in a writing executed by all Parties upon mutually agreeable terms.

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 Results (as defined below) of the Research Project or Data (as defined below) 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 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 RESULTS 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 DATA 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 no Party shall transfer by operation of this Agreement to the other Party any patent right, copyright, or other proprietary right that any 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. Each Party will promptly disclose to the other Party any Invention which disclosure shall be considered Confidential Information. Ownership in Inventions, created during the term of this Agreement, shall follow inventorship. 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 Subject to the terms and conditions set forth herein, each Party hereby grants to the other a non-exclusive, royalty-free, non-transferable license to use Inventions generated during the term of this Agreement for internal non-commercial research purposes.

6.03 WEILL CORNELL shall solely own Results and Data of the Research Project. Each Party shall have the right to use the Results and Data 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 to the Research Project Results and Data are extended to the sponsor of such research.

7.0 TERMINATION

7.01 Any Party may terminate this Agreement prior to the expiration of the designated term by giving thirty (30) days' prior written notice to the other. 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 sixty (60) 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.

7.02 Upon expiration or early termination of this Agreement by either Party, the receiving Party shall return or destroy (at the disclosing Party's option) all Data, Results or Confidential Information (as defined below) to the disclosing Party (except for each Parties own Confidential Information). In the case of destruction, the receiving Party shall confirm such destruction in writing to the disclosing 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 (1) copy of written Confidential Information of the other Party solely for monitoring its ongoing obligations, subject to Article 12.

8.0 USE OF NAMES

8.01 No 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.

9.0 GOVERNING LAW; JURISDICTION

9.01 Reserved.

10.0 MISCELLANEOUS

10.01 Nothing contained in this Agreement is to be construed to constitute WEILL CORNELL, RACINE and WISCONSIN 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 each Party shall at all times be that of independent contractors. No 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. Publications resulting from research or training activities under this Agreement must contain the following acknowledgement: *This research project was conducted in collaboration with Weill Cornell Medical College of Cornell University.*

11.02 The 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. The 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.

- 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 DATA

13.01 "Data" shall mean the de-identified data to be exchanged between the Parties as described in Exhibit A. Each Party may use/disclose the Data, subject to all applicable laws/regulations, as necessary to conduct the Research Project. The Data shall be used with prudence and appropriate caution in any experimental work.

13.02 Each Party agrees to use the Data 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"). As well as any requirements under the approved, "IRB PRO 37994, Rapid LAMP Assay for SARSCoV-2 (COVID-19) Screening", protocol. The Data are not for use in human subjects, including, without limitation, for diagnostic purposes.

a. Each Party represents that the collection of Data and its sharing 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. Each Party represents that its intended use of Data for research purpose has been approved or exempted by the relevant Institutional Review Board.

c. The Parties will (i) not use or disclose the Data for any purpose other than permitted by this Agreement pertaining to the Research Project or as required by law; (ii) use appropriate administrative, physical and technical safeguards to prevent use or disclosure of the Data other than as provided for by this Agreement; (iii) report to the disclosing Party any use or disclosure of the Data not provided for by this Agreement of which the receiving Party becomes aware within five (5) days of becoming aware of such use or disclosure; (iv) ensure that any agent, including a subcontractor, to whom it provides the Data, agrees to the same restrictions and conditions that apply through this Agreement to the Parties with respect to the Data; (v) not identify the information contained in the Data; and (vi) not contact (or attempt to do so), either directly or through another person, the individuals who are the subject of the PHI contained in the Data.

13.05 No option, license, or conveyance of rights, express or implied, is granted by the Parties in connection with any Data provided under this Agreement, except the right to use the Data 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 Notices, invoices, communications, and payments delivered hereunder shall be sent as follows:

THE MEDICAL COLLEGE OF WISCONSIN: The Medical College of Wisconsin, Inc., Office of Grants and Contracts, 8701 Watertown Plank Road, Milwaukee, Wisconsin, 53226

With a copy to: Office of Grants & Contracts at: grantsandcontracts@mcw.edu

WEILL CORNELL: Joan and Sanford I. Weill Medical College of Cornell University, Department of Physiology & Biophysics, 1300 York Avenue Room E-509, New York, NY 10065

With a copy to: Office of Sponsored Research Administration at grantsandcontracts@med.cornell.edu

CITY OF RACINE: City of Racine, Office of the City Clerk, 730 Washington Avenue, Room 103, Racine, Wisconsin, 53403

With a copy to: Office of the City Attorney, 730 Washington Avenue, Room 201, Racine, Wisconsin, 53403.

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

- 14.03 This Agreement is not assignable, and any attempt to do so shall be null and void.
- 14.04 This Agreement may be executed in counterparts, and by either Party on separate counterpart, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.
- 14.05 Workers Compensation and Employers Insurance.

WISCONSIN shall carry Workers Compensation and Employers Liability insurance required by Wisconsin State Statute. WISCONSIN must carry coverage for Statutory Workers Compensation, and an Employers Liability limit of:

(1) \$100,000 Each Accident

- (2) \$500,000 Disease Policy Limit
- (3) \$100,000 Disease - Each Employee

The insurance required hereunder is primary coverage and any insurance or self-insurance maintained by the City of Racine, its elected and appointed officials, officers, employees, or authorized representatives or volunteers, and each of them, will not contribute to a loss. All insurance shall be in full force prior to commencing work and remain in force until the entire job is completed. Upon request, WISCONSIN shall file with the City of Racine a certificate of insurance (Accord Form 25-S or equivalent) signed by the insurer's representative evidencing the coverage required by this Agreement.

- 14.06 The following shall survive termination of this Agreement: Articles 4, 5, 6, 8, 9, 10, 11, 12 and 13 and Sections 7.02,14.04, and 14.05.

SIGNATURES TO FOLLOW

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

JOAN & SANFORD I. WEILL MEDICAL
COLLEGE OF CORNELL UNIVERSITY

By: _____

Name: Aleta Gunsul
Title: Director, Office of Sponsored Research
Administration
Date:

INC.:

The MEDICAL COLLEGE of WISCONSIN,

By: _____

Name: April A. Haverty, MPE, JD
Title: Director, Office of Grants & Contracts
Date:

THE CITY OF RACINE, WISCONSIN:

By: _____

Name: Cory Mason, Mayor
Date:

ATTEST:

By: _____

Name: Tara Coolidge, City Clerk
Date:

Provisions have been made to pay the liability that will accrue hereunder.

By: _____

David Brown, City of Racine Finance Director

Date:

APPROVED AS TO FORM:

By: _____

Scott R. Letteney, City Attorney

Date:

READ AND UNDERSTOOD BY PRINCIPAL INVESTIGATORS:

By: _____

Name: Dr. Christopher Mason

Title: Associate Professor of Physiology and Biophysics

Date:

By: _____

Name: Alison Kriegel, PhD

Title: Associate Professor

Date:

Exhibit A Scope of Work

Research to be performed by WEILL CORNELL:

For the duration of this Agreement, Weill Cornell shall provide sufficient materials for the taking of samples and for screening or other testing outlined in the “IRB PRO 37994, Rapid LAMP Assay for SARSCoV-2 (COVID-19) Screening” protocol, including screening for up to 10,000 saliva samples collected from first responders and essential municipal employees, and the community-based screening of residents of Racine, Wisconsin.

Sequencing and analysis of de-identified samples performed by Dr. Mason’s lab at Weill Cornell. This shall include: whole genome viral DNA, whole genome human DNA, human transcriptome and bioinformatic and statistical analysis.

De-identified data associated with this project will be accessible to Dr. Kriegel at MCW and Dr. Mason’s team at Weill Cornell Medicine, where it will be stored on password protected servers.

Research to be performed by WISCONSIN:

Dr. Kriegel will be available in person to receive/collect consent forms, answer any questions a potential subject may have about the project, and to return a signed copy of the consent form to subjects who choose to enroll. After enrollment subjects will be asked to complete and submit a brief questionnaire including basic contact information and health history. A questionnaire will be used to collect contact information and basic demographic data after consent is obtained at the time of enrollment. Consent Dr. Kriegel will maintain an Excel spreadsheet key linking the subjects’ names to their assigned SI# and contact telephone number (to allow subjects to be contacted to submit an additional sample for confirmatory FDA-approved diagnostic testing). This data will be stored on MCW’s secure server accessible only through a password protected computer. Dr. Kriegel will enter the SI# and de-identified data collected from the questionnaire into REDCap and then secure store the questionnaires. Dr. Kriegel will also record de-identified assay/test results obtained from the diagnostic laboratory in REDCap.

Research to be performed by RACINE:

Racine will assign employees, specifically members of the City of Racine Fire Department, as is practicable, consistent with the daily business needs of Racine and the availability of Racine employees for such assignment, to assist in the collection and processing of saliva, nasal and nasopharyngeal samples that will be tested for the presence of SARS-CoV-2. These individuals will perform LAMP assays on collected saliva samples and record the assay date/time and the

assay result by SI# + unique sample number on the tub using REDCap on a password-protected computer. Dr. Kriegel will train and oversee the activities of such Racine employees as are assigned to perform such duties. Notwithstanding anything else contained herein, all assigned Racine employees remain under the command of the City of Racine Fire Chief at all times while performing duties pursuant to this Agreement. Dr. Stephen Andrews will order diagnostic tests for this study and return these diagnostic test results to Dr. Kriegel to be recorded (de-identified) with other de-identified data in REDCap.

As the study opens up to members of the public, scheduled time windows for enrolling subjects would be announced on the City of Racine Website.