MEMORANDUM OF UNDERSTANDING

This MEMORANDUM OF UNDERSTANDING ("MOU") is entered into by and among Montgomery County, Maryland (the "County"); University of Maryland, Baltimore ("UMB"); University of Maryland, College Park ("UMCP"); and University of Maryland Medical System Corporation ("UMMS"), each a "Party" and collectively the "Parties." UMB and UMCP are collectively referred to as the "Universities."

BACKGROUND

The Parties agree to a collaboration that will be called "*The University of Maryland 3 - Institute for Health Computing (UM-3-IHC)*" (the "Institute") in North Bethesda, which will leverage UMMS's provision of customized unique and diverse de-identified data sets and bring together world-class researchers exploring how artificial intelligence ("AI"), machine learning ("ML"), and clinical analytics can facilitate knowledge discovery for human health and wellbeing.

The Institute will be a transformative collaboration between the County, UMMS, and the Universities to establish North Bethesda as a national epicenter of computationally enabled biomedical research, population health, and precision medicine.

The Institute will employ state-of-the-art analytics, algorithms, and computation to address fundamental challenges in clinical medicine through a unique partnership between the County, UMMS, and the Universities. Additionally, the Parties will work together to provide collaboration opportunities to the Universities at Shady Grove ("USG").

The Institute will catalyze a clinical data science ecosystem at North Bethesda that draws FDA and NIH investigators, UMB and UMCP faculty, medical bioinformatic educational programs and students, and industry partners, allowing expansion of computational "dry" laboratories, virtual meeting rooms and classrooms.

The Institute will connect the University of Maryland ecosystem, with appropriate federal and state government agencies (NIST, NIH, FDA, USAMRIID, AHRQ, Walter Reed, the Naval Medical Research Center), and industry partners.

The Institute will align three pillars of expertise to advance population health in the State of Maryland and to serve patients and communities through innovations in computation:

➢ UMB, home to top-ranked health science professional schools including Medicine, Nursing, Pharmacy and Dentistry.

➢ UMCP, harnessing state-of-the-art expertise in public health, AI, ML, and virtual and augmented reality ("VR/AR").

➢ University of Maryland Medical System Corporation ("UMMS"), which serves a 5.5 million patient population across allied member organizations, all linked through electronic health care records ("EHR"), and with a formal linkage to primary care and population health and historic and longitudinal data across the care continuum.

NOW THEREFORE, in consideration of the mutual promises set forth in this MOU and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the County, UMMS, UMB, and UMCP agree as follows:

1.   Establishment of Institute.

a.   The Parties agree that the Institute will advance clinical analytics and improve patient care, by using real-time access to patient populations, driven and refreshed by UMMS's custom de-identified data curation connected with electronic medical record (EMR) data, pursuant to appropriate data licenses:

➢ Real world data;
➢ Population health;
➢ Pragmatic adaptive clinical trials; and
➢ Immersive computing for medicine and healthcare.

b.   Detailed information regarding the four initial major initiatives of the Institute is set forth on **Schedule A**, attached hereto and incorporated herein by reference. The Parties acknowledge that Schedule A is conceptual in nature, non-binding, and will be formalized in subsequent written agreements signed by authorized officials of the Parties.

c.   As part of establishing the Institute, UMB, UMCP, and UMMS will create appropriate governing documents that establish the Institute's entity formation and govern the Institute's internal operations, including without limitation bylaws; an operating agreement; and agreements related to the use and protection of intellectual property, confidentiality, data use, and other relevant matters.

2.   Goals. The project goals for the Institute are set forth on **Schedule B**, attached hereto and incorporated herein by reference. As with Schedule A, the Parties recognize that Schedule B is in early conceptual stages and will be formalized pursuant to subsequent written agreements signed by authorized officials of the Parties.

3.   Commitments of Parties. The Parties' commitments under this MOU are as follows:

        a.   Subject to the appropriation and availability of funds and to a future grant agreement that the Parties will negotiate, the County intends to commit $40 million to the Universities and UMMS to support the Institute over six years, starting in FY 2023 with a $15 million Supplemental Budget amendment, then $5 million per year for the following five fiscal years for operating support for the Institute.

        b.   The Universities commit to spending a roughly equivalent amount (although not on the same schedule) over the next six fiscal years. That amount may include funds already expended within the last three fiscal years by the Universities on aspects of AI, ML, and VR/AR that are directly related to the establishment of the programs at the Institute.

        c.   Subject to the appropriation and availability of funds, the County, commits to (and has already applied for) a $3 million federal earmark for the Institute. Subject to federal budget approval, the County has been designated to receive that additional $3 million in start-up funding.

             i.   Of the $15 million FY 2023 County intended commitment for the Institute, $3 million will be designated as the required match for the federal earmark, with the result that the combined County and federal start-up funding for the Institute will be $18 million.

             ii.   The earmark funds are contingent on the passage of an omnibus budget for the fiscal year in the current term of Congress. If the earmark is not passed, the County does not commit to replace those federal funds with County funds.

        d.   The County, UMMS, and the Universities commit to jointly seek additional funding from the State of Maryland to support the programs of the Institute.

        e.   The County may assist the Universities in identifying appropriate leased space for the Institute in the area immediately around the North Bethesda Metro Station for the next five to six years. The Parties expect that the Institute will relocate to the WMATA property at the North Bethesda Metro Station (the "Intended Site") at the end of the lease (assuming that the development of that site is proceeding). If the Intended Site is not ready, the Institute will pursue an extension of the existing lease or lease another space in the immediate area but will not move outside the North Bethesda Metro Station property area.

        f.   The County has already committed $10 million in infrastructure to support the development of the Intended Site to ensure that it is viable for development within the time

frame for the planned relocation of the Institute to a free-standing building on the Intended Site, or a portion of an appropriate shared building on the Intended Site. D

g. Insofar as permitted by law, the County commits to continuing its efforts to redevelop the surrounding area to support the environment in which the Institute will be located to help ensure its success. This provision does not bind the Montgomery County Council.

h. The County, through its business and economic development function, will also work with the Universities to identify private sector life sciences, hospitality, and other sector companies in Montgomery County that could benefit from the research and consulting services of the Institute.

4.   Term and Termination.

a. The term of this MOU will commence upon the signing by all Parties, and will be in effect until December 31, 2028, unless terminated earlier in accordance with this Article. Any renewals of this MOU must be exercised by the mutual written agreement of the Parties hereto in advance of December 31, 2028.

b. In the event of any breach, default, or other failure by a Party to perform any material provision of this MOU, another Party may terminate this MOU if the breach, default, or other failure is not cured within one hundred eighty (180) days of written notice thereof, subject to the dispute resolution provisions herein and the subsequent written agreements that address Institute operations, wind-down, and/or amended activities of the Parties.

c. The Parties may terminate this MOU at any time for convenience by unanimous mutual written consent addressing all appropriate required wind-down actions and responsibilities.

5. Miscellaneous.

a. *Relationship of Parties*. The Parties are not (and nothing in this MOU may be construed to constitute them as) partners, joint venturers, agents, representatives, or employees of the other. No Party has any right or authority to bind or obligate another Party in any manner or make any representation or warranty on behalf of another Party.

b. *Liability of Parties*. The Parties agree that each Party shall be responsible for its own actions and omissions, and the acts or omissions of that Party's officers, employees, agents, and contractors, in the performance of this MOU. Furthermore, the liability of the Universities shall be governed exclusively by the terms and provisions of the Tort Claims Act, Title 12 of the State Government Article, Annotated Code of Maryland, as amended from time to time. The County's liability and performance under this MOU is subject to, limited by, and contingent upon the appropriation and availability of funds, as well as the notice requirements and damages limitations stated in the Local Government Tort Claims Act, Md. Code Ann., Cts. & Jud. Proc. Sec. 5-301, et seq. (the "LGTCA"); and Md. Code Ann., Cts. & Jud. Proc. §5-5A-02, (together the "County Indemnification Statutes"), all as amended from time to time. This MOU is not intended

to create any rights or causes of action in any third parties or to increase the Applicant's liability over and above the caps provided in the Indemnification Statutes. This MOU does not bind the County in its regulatory capacity.

c. *Insurance*. Each Party shall maintain adequate insurance, in the forms (including self-insurance), types and amounts, that it deems appropriate, in its sole and absolute discretion, for its provision of services under this MOU, including as applicable, professional liability, errors and omissions insurance, commercial general liability insurance, cyber liability insurance, and worker's compensation insurance.

d. *Confidential Information*. Prior to any sharing any confidential information, including but not limited to UMMS data, the Parties will enter into separate agreements to address confidentiality and data use.

e. *Notices*. Any written notice required under this MOU shall be sent to the attention of the signatories hereto at the addresses set forth on the signature page.

f. *Governing Law*. This MOU shall be governed by the laws of the State of Maryland without reference to its conflicts of laws principles.

g. *Modifications*. The Parties agree to periodically meet and discuss the terms of this MOU to make any necessary amendments or modifications. This MOU shall only be modified by written agreements signed by the authorized representatives of each Party.

h. *Disputes*. The Parties will work to resolve disputes amicably and shall elevate disputes to their chief executives if such disputes cannot be resolved at the project level within thirty (30) days of good faith resolution efforts. Additional executive resolution and collaboration procedures shall be memorialized in the anticipated operating agreement or other governing document between the Parties.

i. *Assignment*. This MOU and any rights and obligations hereunder shall not be assigned without the prior written consent of the non-assigning Parties, which shall not be unreasonably withheld.

j. *Waiver*. No provision of this Agreement shall be waived unless done so in a writing signed by all Parties to this MOU. The waiver of any provision of this MOU shall not be deemed to be a continuing waiver or the waiver of any other provision of this MOU.

k. *Entire Agreement.* This MOU and its attachments constitute the entire understandings of the Parties with respect to the subject matter of this MOU. All prior agreements, whether oral or written, are superseded by this MOU.

l. *Counterparts*. This MOU may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including PDF or any electronic signature complying with the U.S. federal ESIGN Act of 2000, e.g., www.docusign.com),

or other transmission method. Any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

[Signatures on following page]

IN WITNESS WHEREOF, the parties enter into this Memorandum of Understanding.

MONTGOMERY COUNTY

By: _____   Date: _____
    Marc Elrich
    County Executive

Address: 101 Monroe Street, 2nd Floor
    Rockville, MD 20850

UNIVERSITY OF MARYLAND, BALTIMORE

By: _____   Date: _____
    Bruce E. Jarrell, MD, FACS
    President

Address: Office of the President
    220 Arch Street, 14th Floor
    Baltimore, Maryland 21201

UNIVERSITY OF MARYLAND, COLLEGE PARK

By: _____   Date: _____
    Darryll J. Pines, PhD
    President

Address: Office of the President
    Main Administration Building
    7901 Regents Drive
    College Park, MD 20742-5025

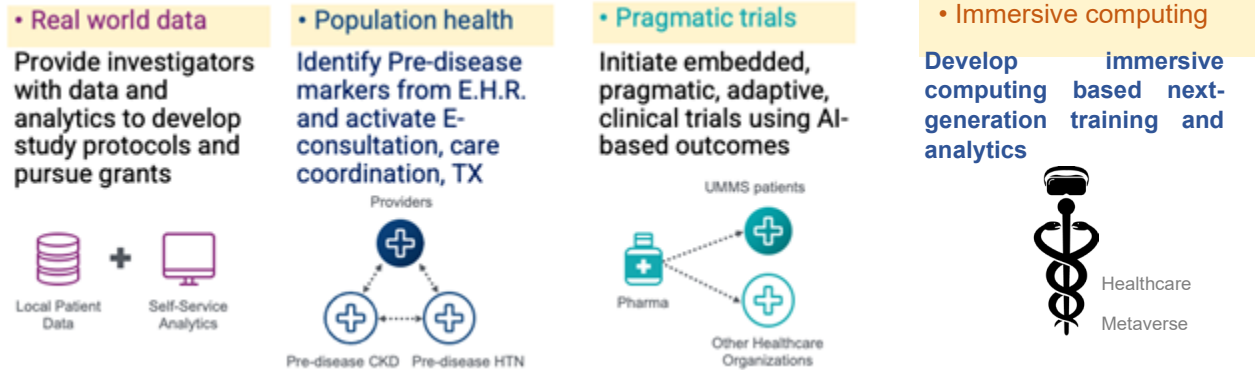**UNIVERSITY OF MARYLAND MEDICAL SYSTEM CORPORATION**

By: _____   Date: _____
    Mohan Suntha, MD, MBA
    President and CEO

Address: 250 West Pratt Street
    Baltimore, Maryland 21201

Real-time access to patient populations, driven and refreshed
by electronic medical record (EMR) data

• Real world data

Provide investigators with data and analytics to develop study protocols and pursue grants

Local Patient Data + Self-Service Analytics

• Population health

Identify Pre-disease markers from E.H.R. and activate E-consultation, care coordination, TX

Providers

Pre-disease CKD   Pre-disease HTN

• Pragmatic trials

Initiate embedded, pragmatic, adaptive, clinical trials using AI-based outcomes

UMMS patients

Pharma

Other Healthcare Organizations

• Immersive computing

Develop immersive computing based next-generation training and analytics

Healthcare

Metaverse

1. **Real-World Data**: Harmonize and analyze UMMS clinical data and UMB research data to create multi-omics and real-world clinical information data sets to advance systems biology and clinical analytics. De-identification systems with removal of >16 identifiers allow for HIPAA-compliant (as applicable) data sharing and analysis across the University of Maryland ecosystem.

    a. Examples of real-world data include the use of ML algorithms to study emerging disease and risk stratification, such as the risk factors for development of early kidney disease, early predictors of risk in pregnancy, and predictors for the development of addiction and overdose.

    b. Real-world health records are being increasingly characterized by multiple data streams of heterogeneous data, such as biomedical sensors in an ICU (temperature, blood pressure, respiratory rate), real-time brain imaging (fMRI, fNIRS, EEG, or MEG), and several other sources. Systemic approaches to developing real-time algorithms, software systems and toolkits for ingestion, filtering, visualizing, and analyzing multiple interacting data streams will revolutionize the use of big data in health care and medicine.

2. **Population Health:** UMMS has a uniquely diverse and vulnerable patient population, presenting a critically important opportunity to identify early signs of disease that are easily accessible from the electronic health care record. Programs will be developed to reach out to patients with these risk factors via electronic consultation, nurse educators and care coordinators, and specialty services to recommend early interventions and to partner with the primary care community and patients to bend the curve of "pre-disease" towards health.

a. Examples include programs that identify pre-diabetes or out of control diabetes using lab values like high glucose and hemoglobin A1C to target health education and drug treatment. Similar approaches target early kidney disease by rising creatinine, and early high blood pressure in pregnancy, known to worsen pregnancy outcomes. Identification of rapidly rising weight allows opportunities to improve healthy living, target food desserts, and introduce new highly potent weight loss treatments, like the GLP1 agonists and SGLT-2 inhibitors.

b. As physicians and scientists engage with data-driven models of disease progression, it is critical that they incorporate fairness from the ground up by bringing together scholars of medicine, data science, and AI/ML with members of the very communities suffering from the burdens of race and history. Disparities in race, gender, and socioeconomic status impact healthcare systems in ways that are hard to identify, and yet they are often reproduced in biased AI/ML predictions because their training data incorporate biases arising from population health disparities.

3. **Pragmatic Adaptive Clinical Trials:** The future of clinical research is to move the trials outside of the "white tower" of academic medical centers and into the community. Patients can be identified through the EHR after diagnosis in outpatient clinics and regional hospitals.

The EHR is "flagged" to ask if the doctor and patient want to enroll in an intervention trial of a new therapy and then a research coordinator remotely calls the patient and family for consent. The patient is randomized to treatment A, B, C, vs. placebo, and outcomes are monitored continuously by blinded artificial intelligence protocols that assess pre-specified efficacy outcomes in the electronic health care record, e.g., *Which treatment is working better to improve organ function, survival, hospitalization, etc.?*).

If one treatment is better than the other, the next patients are adaptively randomized in greater and greater proportions to the treatments that work, thus limiting the risk of a patient receiving a treatment that does not work. Once a treatment is statistically superior, the trial is automatically stopped.

- Examples include the REMAP-CAP clinical trials group which adaptively randomized patients with SARS-CoV2 in hundreds of regional hospitals and rapidly established the efficacy of hydrocortisone, anti-IL6, and heparinization, improving mortality during severe COVID-19 pneumonia.

4. **Immersive Computing for Medicine and Healthcare:** Metaverse is the next horizon in healthcare. Immersive VR/AR for medical training has the potential to fundamentally change, improve, and reduce the cost of training and maintaining skills across all aspects of healthcare—in Maryland, across the United States, and in developing countries worldwide.

The Institute will develop VR tools for medical education and training for several scenarios including: (a) clinical encounters and patient interviews, (b) planned medical surgeries and medical procedures, and (c) time-critical surgeries at a shock-trauma center.

The Institute's goal is to facilitate an immersive experience of such medical encounters and procedures, in the form of immersive playback from high-fidelity VR recordings that can be navigated in space and time. Annotations (multimedia, text, graphics) added by experts could further enhance the effectiveness of such reconstructions as compelling education, communication, and archival tools.

Currently, surgeons and other healthcare providers must simply remember how to perform operations. This is especially problematic for complex and often emergent operations like femoral artery closure, upper extremity fasciotomy, and subclavian artery procedures. Immersive VR for training has the potential to fundamentally change, improve, and reduce the cost of training and maintaining skills in these procedures, and across all aspects of healthcare.

The State of Maryland is fortunate to have what is arguably the world's finest trauma care facility, the R Adams Cowley Shock Trauma Center in Baltimore. Known simply as "Shock Trauma," the center admits more than 8,000 critically ill and injured patients each year, with a survival rate of approximately 96 percent.

Shock Trauma, working closely with computer science experts at UMCP, will develop a unique program at the Institute that would use the latest advances in immersive networked technologies—VR/AR over 5G networks—to train emergency care providers in Maryland, in the nation, and around the world. These emerging technologies could be rapidly deployed and scaled up, and prototypes of various systems are already under development.

- One example is a virtual training system in development that provides an almost lifelike experience in conducting a lower extremity fasciotomy (LEF), a limb-saving technique of cutting the sheath of tissue encasing a muscle to treat loss of circulation.

- Other telepresence training modules would address the latest advances in onsite stabilization and transportation to medical facilities, specialized diagnostic imaging techniques, emergency airway intubation, and more.

The immersive technologies being developed by Shock Trauma, UMB, and UMCP can be easily scaled up over 5G networks, offering time-critical expertise to almost any number of physicians at virtually any location that has internet access. This includes rural areas in Maryland, which could be used as a testbed for these lifesaving training modules before they are deployed on a global scale.

Years 1-2:

1. Establish initial (temporary) location and begin first endeavors utilizing existing MPower projects.

2. Consolidate de-identified electronic health care data from inpatient and outpatient practices of UMMS and University of Maryland Faculty Physicians, Inc. ("FPI") into a central data warehouse (and cloud-based systems). This is largely complete (real-world data is currently accessible and informs the demographic presentations contemplated in this MOU).

3. Design deidentification systems to allow clinical and multi-omics patient-centered real-world investigation available at the investigators' desktops.

4. Design HIPAA-protected clinical analytics systems to improve the efficiency and quality of patient care, design and initiate pragmatic and adaptive clinical trials, and support implementation science.

5. Recruit Institute Director(s), Center Director(s), and data scientists with dual appointments and physical presence at UMMS, the Institute, UMB and/or UMCP. This could include additional physical presence of the director at the Universities at Shady Grove.

   - Examples include population health focused on maternal health, disparities, cardiovascular, renal, oncology, and infectious disease, pharmacoepidemiology, climate medicine, real-world data ML, quantum-biomedical computing, emerging pathogen detection, precision medicine, patient-centered drug design, and pragmatic adaptive clinical trials.

6. Leverage existing educational programs at Universities at Shady Grove and develop "big data" and VR/AR training programs (undergraduate, masters, and graduate programs) virtually and physically integrating with the Institute. Capitalize on undergraduate and graduate student experiential learning opportunities as research integrated with the Institute.

7. Assess the existing and potential partnerships with NIH, NIST AHRQ, FDA, and other federal agencies.

Years 3-5

1. Plan and build a new, permanent home for the Institute at the Intended Site.

2. Consolidate multi-omics data sets, provisioned by UMMS, from UMB basic and translational research into a central data warehouse (or cloud-based systems) including genomics,

transcriptomics, proteomics, metabolomics, lipidomics, and phenomics for project-based and systems-based analysis.

3. Use clinical and linked population-based data analytics to drive programs in population health that identify early disease or pre-disease risk factors and deliver targeted preventive health care for individuals and target populations.

4. Expand embedded randomized adaptive pragmatic clinical trials architecture in all UMMS hospitals and UMMS/FPI clinics.

5. Develop population-based clinical analytics and data-driven interventions designed to eliminate unconscious bias and health care disparity and inequity.

6. Develop competitively funded project partnerships between UMB, UMCP and UMMS that break down silos and catalyze partnerships between basic, clinical, population health, and computational science domains.

Program Leadership

Leadership will be tasked with an overarching mission to rapidly develop the infrastructure and architecture to leverage the vast clinical and biological sciences information in UMMS and UMB, which must be coupled to a parallel major initiative to recruit data scientists and train the next generation of data scientists at UMCP. These data will not be useful without a rich ecosystem of translational data scientists, and the scientists will not succeed without access to rich data sources. These catalytic investments are expected to drive NIH, Patient-Centered Outcomes Research Institute (PCORI), State, County, and industry funding and partnerships.

Dr. Amitabh Varshney, Dean of the University of Maryland College of Computer, Mathematical, and Natural Sciences, and Dr. Mark T. Gladwin, Dean of the University of Maryland School of Medicine will oversee the recruitment of three key leaders representing UMB, UMCP, and UMMS. Dr. Warren D'Souza, PhD, MBA, FAAPM, Vice President, Enterprise Data and Analytics and Chief Innovation Officer, UMMS, will lead the UMMS efforts with additional resources dedicated immediately to accelerate the development of data integration, distribution, programming, and clinical analytics in collaboration with computational partners from UMCP to accelerate development.

Three Institute Directors will be assigned as interim or recruited as co-Institute Directors: one co-Institute Director from UMMS, Warren D'Souza; one co-Institute Director from UMB, ideally a physician-scientist and an expert in systems biology and clinical analytics (real-world evidence, pragmatic and adaptive clinical trials, multi-omics systems biology); and a second co-Institute director from UMCP, who is an expert in mixed reality, advanced computing, and AI.

The Deans and Institute Directors will recruit Center Directors and data scientists, as well as align current faculty, to "mine, analyze, and visualize" the real-world data and develop programming strategies to embed new population health initiatives and pragmatic trials structure into the

electronic health care record and regional hospital/clinic environments. This will require additional recruits in complementary areas of computational science (programming, VR/AR, advanced statistics, and AI/ML Bayesian outcomes analysis).

The Deans and Institute Directors are expected to develop robust partnerships with community representatives, NIH, FDA, DOD, and industry allies to advance the scientific, clinical, and regional development missions.