INSTITUTIONAL REVIEW BOARD AUTHORIZATION AGREEMENT

This Institutional Review Board Authorization Agreement (this "**Agreement**"), by and between the **University of Southern California**, a California nonprofit public benefit corporation (the "**USC**") and USC Arcadia Hospital (the "**Research Site**") is effective as of March 15, 2024 (the "**Effective Date**").

WHEREAS, USC has established several institutional review boards (each, an "IRB") to oversee the human subjects research conducted by USC;

WHEREAS, the Research Site conducts human subjects research and desires to rely on the Designated IRB (as defined in Section 1 below);

WHEREAS, Research Site's employees will be performing services for the Research;

and

NOW, THEREFORE, for and in consideration of the agreements, covenants, representations and warranties herein contained, and intending to be legally bound, the parties agree as follows:

1. Designated IRB. The following IRB shall be the "Designated IRB" for purposes of this Agreement:

Name: **University of Southern California Social Behavioral IRB**
IRB Registration Number: **IRB00000387**
FWA Number (if applicable): **00007099**

2. Reliance on the Designated IRB. USC hereby authorizes the Research Site to rely on the Designated IRB for review and continuing oversight, as more specifically described below, of the human subjects research described in this Section 2 (the "**Research**") (select one):

___XX____ All protocols previously approved by the University of Southern California Social Behavioral IRB for the purpose of adding Research Site as an additional location.

3. FWA Designation. If the Research Site has filed an FWA with the U.S. Department of Health and Human Services, Office of Human Research Protections ("**OHRP**"), it is the sole responsibility of the Research Site to identify the Designated IRB on its FWA approved by the OHRP.

4. Protection of Human Subjects.

(a) The Designated IRB is responsible for adopting and implementing institutional policies and procedures for protecting human subjects with respect to the Research

in compliance with its FWA. The Designated IRB is authorized to review, oversee and monitor the Research Site's compliance with the policies and procedures of the Designated IRB, relevant ethical principles, and applicable state and federal laws, regulations, guidance, and rulings relating to the protection of human subjects (collectively, the "**Standards**"), with respect to the Research.

(b) The Research Site is responsible for complying with all determinations of the Designated IRB and will accept the final authority and decisions of the Designated IRB, including but not limited to directives to terminate participation in designated research activities or requirements to participate in any education training required by the Designated IRB or USC.

(c) The Research Site is responsible for ensuring that its researchers promptly report any proposed changes in the Research conducted under this Agreement and will not initiate changes in such Research without prior approval by the Designated IRB, except where necessary to eliminate apparent immediate hazards to subjects.

(d) The Research Site is also responsible for ensuring that its researchers:

(1) Comply with this Agreement and abide by all determinations of the designated IRB, including but not limited to directives to terminate participation in the Research activities;

(2) Not enroll subjects in the Research covered by this Agreement prior to its review and approval by the Designated IRB.

(3) Accept primary responsibility for safeguarding the rights and welfare of each Research subject, and that the subject's rights and welfare must take precedence over the goals and requirements of the Research;

(4) Adhere to sponsor requirements, USC's applicable policies and procedures, and applicable laws and regulations, including but not limited to: (i) The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (or other internally recognized equivalent); (ii) Title 45, Part 46 of the Code of Federal Regulations (the "**Common Rule**"); (iii) the relevant statutes, rules, regulations, and policies of the U.S. Food and Drug Administration; and (iv) all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in the Research.

(5) Complete any educational training required by USC or the Designated IRB prior to initiating research;

(6) Report promptly to the Designated IRB any proposed changes in the Research conducted under this Agreement;

(7) Report immediately to the Designated IRB any unanticipated problems involving risks to subjects or others in the Research covered under this Agreement; and

(8) Obtain, document, and maintain records of informed consent for each subject or each subject's legally authorized representative as required under 45 CFR Part 46 (or

any other intentional or national procedural standards selected on the FWA for the Designated IRB) and stipulated by the Designated IRB.

(9) Identify any special conditions concerning the Research and the obligations of the Designated IRB.

(e) Each party shall promptly notify the other if it becomes aware at any time of a breach by any person conducting the Research of any Standard.

5. Compliance with FWA Requirements. If the Research Site has filed an FWA, USC agrees that the review and continuing oversight performed by the Designated IRB will meet the human subjects protection requirements of the Research Site's FWA (the "**FWA Requirements**"); provided, however, that the Research Site shall not modify the FWA Requirements without the prior written consent of USC. The Research Site shall provide a copy of its FWA to USC, if it has an FWA.

6. Research Site Employees. Research Site will ensure that its employees that perform Research under this Agreement and will comply with the following requirements:

a. Research Site employees will follow the requirements of Research protocols, written instructions from USC or Research sponsors and applicable laws and regulations.

b. Research Site employees have never been and will not be debarred, suspended, or excluded under the Federal Food, Drug and Cosmetic Act, as amended, or disqualified under the provisions of 21 CFR §312.70;

c. Research Site will ensure that its employees protect the confidential nature of the protocols for Research and any other confidential information shared related to USC or Research sponsors;

d. Research Site warrants that its employees have agreed to assign their rights to any intellectual property developed in the performance of the Research to Research Site and Research Site agrees to assign those rights to USC.

7. Term and Termination.

(a) The term of this Agreement shall commence on the Effective Date, and shall continue for an initial term of one (1) year. Thereafter, the term shall renew automatically for successive periods of one (1) year each, for a maximum term of five (5) years, on the same terms and conditions as specified in this Agreement, unless sooner terminated in accordance with this Section 6.

(b) Either party may terminate this Agreement at any time upon thirty (30) days prior written notice in the event the other party breaches an obligation hereunder, provided such breach is not cured within said thirty (30) day period to the reasonable satisfaction of the non-breaching party.

(c) Either party may terminate this Agreement without cause upon sixty (60) days prior written notice.

8. Access to Records and Confidentiality.

(a) The Research Site shall make available to USC, and shall cause its employees and agents to make available to USC, documentation required by the Designated IRB to perform the services hereunder. USC shall protect the confidentiality of all such documentation in accordance with relevant federal and state laws and regulations.

(b) The Designated IRB shall prepare and maintain documentation relating to the Research as required by the Standards and other requirements made known in writing by the Research Site to the Designated IRB, and shall cooperate fully with the Research Site's reasonable requests to inspect and copy, at its sole cost, such documentation relating to the Research.

(c) In connection with the performance of the services set forth herein, the parties may have access to certain oral and written information concerning each other that is non-public, confidential and/or proprietary in nature. The parties acknowledge the confidential or proprietary nature of such information and agree to, at all times, hold such information in strict confidence, refrain from delivering or disclosing any part of the information to any third party, and refrain from making any copies or reproductions of any of such information, each unless previously authorized to do so in writing by the other party. The parties also agree to limit access and use of such information to those employees to whom such information is necessary in order to fulfill their respective obligations under this Agreement.

(d) Each party shall comply with the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d-1329d-8; 42 U.S.C. 1320d-2) ("**HIPAA**"), the regulations promulgated thereunder ("**HIPAA Regulations**") and applicable state law, including those applicable provisions that relate to Business Associates as defined in the HIPAA Regulations. Each party shall use its reasonable efforts to preserve the confidentiality of Protected Health Information (as defined by the HIPAA Regulations) it receives from the other party, and shall be permitted only to use and disclose such information to the extent permitted by the HIPAA Regulations.

9. USC does not, and shall not, assume any liability for the activities of Research Site or Research Site employees. Research Site shall maintain comprehensive liability and medical malpractice insurance and/or other applicable insurance, with limits sufficient to cover Research Site's obligations hereunder. Research Site shall maintain coverage for claims arising during the term of this Agreement and during the applicable statute of limitations. Upon USC's request, Research Site shall provide USC with a current certificate evidencing such coverage. Research Site shall promptly notify USC of any change in the amount or scope of coverage. Research Site will be responsible for any breach by Research Site or its employees of the terms of this Agreement, or the negligence or willful misconduct of Research Site or its employees. The provisions of this Section 7 shall survive the termination of this Agreement.

10. Non-Exclusivity. Nothing in this Agreement is intended to limit the right of USC, through the Designated IRB or any other University IRB, to provide review and continuing oversight of human subjects research conducted by or on behalf of any other person or entity.

11. Notices. Any and all notices or other communications required or permitted to be given under any of the provisions of this Agreement shall be in writing and shall be deemed to have been duly given when personally delivered or mailed by first class registered mail, return receipt requested, or via overnight delivery addressed to the parties at the addresses set forth below:

If to USC:

Institutional Review Board
University of Southern California
Credit Union Building
3720 South Flower Street, 3rd Floor
Los Angeles, CA 90089-0702

With a copy to:

University of Southern California
1510 San Pablo St.
Los Angeles, CA 90033
Attn: Associate General Counsel

If to the Research Site:

USC Arcadia Hospital
300 W. Huntington Drive
Arcadia, CA 91007

12. Assignment. This Agreement shall be binding upon and inure to the benefit of the parties and their heirs, successors, assigns and representatives. This Agreement may not be assigned, nor the duties hereunder delegated, by either party without the other party's written consent.

13. Amendment. This Agreement may be amended only by the written agreement of the parties.

14. Governing Law and Dispute Resolution. This Agreement shall be governed and construed in accordance with the laws of the State of California. All disputes arising under or in connection with this Agreement shall be submitted to JAMS or successor organization for binding arbitration by a single arbitrator. The arbitrator shall be selected by JAMS in an impartial manner determined by it. The arbitration hearing will be commenced within one hundred eighty (180) days of the filing of an arbitration demand with JAMS by any party hereto, and a decision shall be rendered by the arbitrator within thirty (30) days of the conclusion of the hearing. The arbitrator shall have complete authority to render any and all relief, legal and equitable, appropriate under this Agreement. The arbitrator shall award costs of the proceeding, including reasonable attorney's fees, to the party determined to have substantially prevailed.

15. Severability. Should any provisions of this Agreement or application thereof be held invalid or unenforceable, the remainder of this Agreement shall continue to be valid and enforceable to the fullest extent permitted by law unless its continued validity and enforcement would defeat the purpose of this Agreement. Notwithstanding the foregoing, the parties agree to

modify this Agreement if either party reasonably determines that such modification is required in order to comply with any change in applicable laws or regulations or the official interpretation thereof. If the parties are unable to agree upon a modification, either party may terminate this Agreement upon thirty (30) days advance written notice to the other.

16. Waiver. The failure by a party at any time to require performance of any provision of this Agreement shall not constitute a waiver of such provision and shall not affect the right of such party to require performance at a later time. Any waiver of the breach of any term or condition of this Agreement by either party shall not be a continuing waiver and shall not operate to bar the waiving party from claiming a breach of this Agreement for any subsequent breach hereunder.

17. Nothing in this Agreement shall be deemed to create an employer-employee or principal-agent relationship. Neither Research Site, nor Research Site employees shall have power or authority to bind USC or to assume or create any obligation or responsibility, express or implied, on behalf of or in the name of USC.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed as of the Effective Date.

University of Southern California

DocuSigned by:

By: _____
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Julie Slayton

Title: HRPP Director

Date: 3/15/2024

USC Arcadia Hospital

DocuSigned by:

By: Ikenna Mmeje
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Ikenna Mmeje

Title: President & CEO

Date: 3/15/2024