External IRB Authorization & Reliance Agreement

This External IRB Authorization & Reliance Agreement ("Agreement") is entered into as of the last date of signature below (the "Effective Date").

Name of Institution Relying on the Designated IRB ("Institution"): Los Angeles County – University of Southern California Medical Center (LAC+USC Medical Center)

☒The Institution has an FWA
OR
☐The Institution does not have an FWA.

- The Institution's OHRP Federalwide Assurance (FWA) #, if one exists: FWA00005905
- Address: 1640 Marengo Street, 7th Floor, Los Angeles, CA 90033-9269
- Responsible Official's Name, Title, and Contact Information: Maja Mataric, PhD., Interim Vice President of Research, Institution Official, University of Southern California, Credit Union Building, 3720 South Flower Street, Los Angeles, CA 90089-4019

Name of Organization Providing IRB Review: Advarra, Inc. ("Advarra")

- FWA Number: FWA00023875
- IRB Registration #: IRB00000971
- Address: 6940 Columbia Gateway Drive, Suite 110 Columbia, Maryland 20146
- Responsible Official's Name, Title, and Contact Information: Michele Russell-Einhorn, Institutional Official, 410-884--2900, Michele.Russell-Einhorn@Advarra.com

I. Scope of the Agreement:

The parties to this Agreement agree that the Institution shall rely on Advarra for review and continuing oversight of human subject research for all studies submitted to Advarra. The following Institution sites shall be deemed sites covered that may submit to Advarra under this Agreement:

- *LAC+USC Outpatient Clinics*
- *LAC+USC 5P21 Clinics*
- *Roybal Comprehensive Health Center*
- *H. Claude Hudson Comprehensive Health Center*
- *El Monte Comprehensive Health Center*

This Agreement does not preclude the Institution from participating in any other IRB authorization agreements that it may have or may enter into with other IRB(s) for human subject research other than the studies for which review is ceded to Advarra under this Agreement. This document must be kept on file by all parties and provided to the FDA, OHRP, and/or other applicable regulatory agencies upon request. This Agreement may be executed in any number of counterparts, either in original, portable document file (PDF) or faxed form.

II. Responsibilities of Advarra:

a. The review performed by Advarra will meet the human subject protection requirements of the HHS Regulations for the Protection of Human Subjects in Research (45 CFR Part 46) when conducted under the Institution's FWA, and applicable FDA regulations (21 CFR Parts 50, 56, 312, 812) when governed by the FDA, and other federal agency regulations as applicable. Advarra will follow written procedures for reporting its findings and actions to the study principal investigator ("Principal Investigator" or "PI"), study sponsor (a "Sponsor"), and appropriate officials at the Institution. Advarra will provide access to IRB related approval documents pertaining to research study materials reviewed by Advarra for the Institution. Applicable IRB meeting minutes will be available upon request.

b. Advarra's IRB services include, but are not limited to, review and approval or disapproval, or modifications to:
   - New protocols
   - Informed consent forms
   - Continuing review
   - Principal Investigators
   - Changes to previously approved research

c. Advarra shall review and take appropriate actions regarding reports of unanticipated problems involving risks to subjects or others and serious or continuing noncompliance.

d. Advarra shall conduct continuing review of research studies appropriate to the degree of risk in such studies, not less than annually unless otherwise authorized by regulation.

e. Advarra shall promptly notify the currently-approved Principal Investigator (PI) of the study as well as individuals identified by the Institution of all IRB decisions.

f. Advarra shall promptly notify the Institution's Responsible Official, or their designee, regarding studies subject to this Agreement: (1) if there is ever a suspension or restriction of the IRB's authorization to review studies; (2) of any changes in Advarra's operating procedures that might affect the Institution's reliance on Advarra; (3) of complaints from human subjects enrolled in studies at the Institution; (4) of unanticipated problems involving injury or risks to subjects or others arising from research activities; (5) if Advarra determines that serious or continuing non-compliance has occurred, and any steps that Advarra deems necessary for remediation of non-compliance; (6) of suspension or termination of IRB approval; (7) of any communication with the FDA, OHRP or funding agency of matters relevant to human subject protections and relating to the Institution's studies conducted under this Agreement; or (8) of changes in the accreditation status of the Advarra Human Research Protection Program.

g. *HIPAA determinations if the Institution is a covered entity*

In Advarra's authority as an IRB, Advarra may review HIPAA Authorizations and grant full or partial waivers of Authorizations pursuant to 45 CFR Parts 160 and 164. Advarra will perform those determinations required by the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations (collectively, "HIPAA") with respect to the use and disclosure of Protected Health Information ("PHI") for research under Advarra's IRB review subject to this Agreement, including Authorizations and waivers of Authorization for the use and disclosure of PHI. If it becomes necessary for the parties to use and disclose PHI in ways not covered by the existing Authorization, then the parties will work together to determine if any additional steps are necessary to ensure that the required information is used and disclosed in a HIPAA-compliant manner. It is understood and agreed that, by providing these services, Advarra is not a "business associate" of the Institution as defined by HIPAA.

h. *Conflicts of Interest.*

The Institution may perform its own investigator conflict of interest ("COI") analysis under its relevant policies and provide Advarra the Institution's plan, or a summary of the plan, for managing the conflict of interest. Advarra will review the conflict of interest management plans, or a summary of the plan, to the extent that they involve human subject protection considerations, and, if provided, ensure consideration of inclusion of such mandated language in informed consent forms; and assess the adequacy of the data and safety monitoring plan. If Advarra determines an institutional conflict is not managed appropriately, Advarra will promptly inform the PI and the Institution's Responsible Official, or designee. Advarra will review all study-specific investigator COI according to Advarra Standard Operating Procedures. Once the Institution's plan is accepted by Advarra, the Institution shall ensure implementation of the plan and report any noncompliance with the same.

III. Responsibilities of the Institution

The Institution agrees to the following:

a. The Institution shall require investigator compliance with IRB determinations and requirements, applicable federal regulations, state and local laws, and, institutional requirements relating to the research. Further, the Institution shall identify the requirements of applicable state or local laws, regulations, institutional policies, and communicate such requirements to Advarra. This policy does not affect any state or local laws or regulations (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe) that may otherwise be applicable and that provide additional protections for human subjects.

b. The Institution shall require the applicable Principal Investigator to provide all information reasonably required by Advarra to conduct its reviews. The Institution may not approve any research study that has been disapproved by Advarra. The Institution may, however, disapprove any study that is approved by Advarra. The Institution agrees to abide by the decisions of Advarra, including the use of the Advarra-approved informed consent document, and shall use its best efforts to ensure that the human subject research performed by the Institution shall be conducted in accordance with those decisions.

c. The Institution shall require that investigators and other study personnel at the Institution are qualified and have appropriate resources to conduct the research, including but not limited to education and training in human research protection regulations. The Institution shall provide documentation of training and education as reasonably requested by Advarra.

d. The Institution shall maintain an institutional process by which complaints about the study can be made by local study participants or others. Complaints that meet criteria as potential unanticipated problems involving risks to subjects or others, or which may be evidence of serious or continuing noncompliance shall be reported to Advarra in accordance with the timeframes specified by Advarra.

e. The Institution shall cooperate with any Advarra investigation regarding noncompliance or unanticipated problem(s) involving risks to subjects or others related to the studies conducted under this Agreement at the Institution. Nothing in this Agreement shall prevent either party from conducting its own investigation; however, Advarra shall have the authority to determine whether serious or continuing noncompliance or unanticipated problems involving risks to subjects or others have occurred.

f. The Institution shall notify Advarra's Responsible Official promptly in the event of the following:
   - Any suspension or restriction of the Institution's authorization or ability to conduct studies
   - Any Institutional policy decisions or regulatory matters that might affect Advarra's ability to review the Institution's research;
   - Any unanticipated problems involving injury or risks to subjects or others in a study reviewed by Advarra;
   - Any serious or continuing non-compliance the Institution believes has occurred in a study reviewed by Advarra and any steps the Institution has deemed necessary for remediation of non-compliance;
   - Any suspension or termination of Institutional approval;
   - Any communication with the FDA, OHRP or any funding agency relating to the Institution's studies being reviewed by Advarra; and
   - Any changes in the accreditation status of the Institution's Human Research Protection Program.

g. The Institution will maintain a current, approved Federalwide Assurance (FWA) with OHRP for the duration of this Agreement. The Institution will notify Advarra promptly in writing if the status of the FWA is no longer in good standing with OHRP, including a terminated or expired status for any reason.

IV. Joint Responsibilities

a. Confidentiality

Each party is authorized to exchange information pursuant to this Agreement ("Confidential Information") and agrees to treat such information as confidential. No party shall disclose Confidential Information disclosed to that party pursuant to this Agreement to any individual or entity other than the disclosing party without prior written approval of the disclosing party. Notwithstanding the foregoing, nothing in this Agreement shall be construed to

restrict a party from disclosing Confidential Information as required by law, subpoena, court order, or other governmental order or request. Additionally, nothing in this Agreement shall restrict a party from disclosing that Advarra reviews research for the Institution. The Institution shall cause the Principal Investigator and all other research personnel to comply with the terms and conditions of this section in the same manner as such terms and conditions apply to the Institution. This section shall survive the termination of this Agreement.

Protected Health Information

The parties shall hold in confidence the identity of the participants in any studies and shall comply with applicable laws regarding the confidentiality of individually-identifiable subject information and the requirements of any Authorization executed by subjects for a given study. Each party shall comply with all applicable laws and regulations and such other laws and regulations that apply to each party relating to the use and disclosure and privacy and security of individually identifiable health information of human subjects ("**Subject Health Information**"). Each party shall use and disclose Subject Health Information only as authorized by the subject or legally-authorized representative. Each party shall notify the other party orally and in writing within three business days of its discovery of any Subject Health Information in its possession which is improperly used or disclosed in violation of HIPAA or the applicable subject Authorization. The parties shall cooperate with each other in taking such steps as are deemed appropriate to enjoin misuse, regain possession of the data, and otherwise protect each party's rights and all subjects' privacy. It is expressly understood and agreed that, by providing review services as described herein, Advarra is not a "Covered Entity" and is not a "Business Associate" of the Institution as defined by HIPAA.

b. Record Keeping.

Advarra and the Institution agree to maintain records in compliance with all applicable federal, state and local regulations regarding record retention and agree to make records available when required by law.

c. Federal Regulatory Agency Review.

Advarra and the Institution agree to promptly notify the other party when a federal regulatory agency has or will conduct an audit or review of a study subject to this Agreement and will provide the other party with copies of all documents relating to any such audit or review in accordance within appropriate timeframes.

d. Inspection.

Advarra or its authorized representatives shall be permitted upon advance written request at a mutually agreeable time to: (1) examine and inspect the Institution's facilities used for the performance of its research, including storage and use of any investigational products; (2) observe the conduct of the research performed at the Institution; (3) inspect and copy all documents relating to its studies covered by this Agreement, including study records and informed consent document, investigational product logs, required licenses, certificates and accreditations; (4) interview all necessary personnel involved in the research conduct of its studies covered by this Agreement and (5) audit or witness the process of informed consent occurring at the Institution in connection with a study to be reviewed hereunder.

Likewise the Institution shall be permitted upon request to (1) obtain copies of all applicable IRB correspondence pertaining to activities hereunder; (2) review Advarra's policies, procedures, roster and other information pertinent to board functions; and (3) inspect and copy all documents relating to its studies, including but not limited to protocols and informed consent documents, investigational drug brochures, reports, unanticipated problems, reports of noncompliance, required licenses, certificates and accreditations.

e. Reporting to Sponsor, Federal Agencies, or other oversight entities.

If Advarra determines that it must report the findings of an investigation to the Sponsor, OHRP, the FDA and/or other oversight entities, it will notify the Institution in advance. Advarra will share the report with the Institution and PI before it is sent to the Sponsor/oversight authority and will copy Institution's Responsible Officialand/or designees on correspondence to the Sponsor/oversight authority. Nothing in this Agreement shall be construed to prevent the Institution from promptly reporting any matter to OHRP, the FDA, or from taking additional remediation steps.

f. Clinical Trial Agreements and Compensation for Research Related Injury.

Advarra shall, unless a waiver of informed consent is issued, approve an informed consent form for use at the Institution. The Institution shall ensure that the Clinical Trial Agreement ("CTA"), and the approved consent form do not conflict with each other with regard to provisions regarding the availability of compensation for research-related injury. Advarra reserves the right to request the applicable portion of the CTA to ensure non-conflicting language is present in the consent form. In the event of a conflict between the CTA and the consent form, the research will not be fully approved until the conflict is resolved in a way acceptable to both the Institution and Advarra.

V. General Terms and Conditions

a. Term and Termination

The term of this Agreement shall commence upon the Effective Date by both parties and shall continue until the conclusion of the studies or until such time as either party gives sixty (60) days written notice of termination. Notwithstanding the foregoing, if either party is in default in the performance of any of its obligations under this Agreement, and the default has not been remedied within thirty (30) days after the date of notice in writing of such default, the party not in default may terminate this Agreement immediately upon written notice.

Upon termination of this Agreement for any reason, and if the Institution desires oversight of the affected studies by another IRB, the parties shall cooperate in good faith with one another to ensure a smooth transition to another qualified IRB. The Institution shall provide evidence to Advarra showing that oversight of the affected research studies will be undertaken without interruption by another qualified IRB. In the event notice of termination is given by either party, or if Advarra should cease providing IRB services under this Agreement for any reason, upon the Institution's reasonable request, Advarra shall provide to the Institution copies of all documentation related to the provision of IRB services by Advarra under this Agreement.

b. Assignment.

Neither party will assign any of its rights or obligations under this Agreement, to other than its affiliate, without the prior written consent of the other party. This Agreement will be binding on and shall inure to the benefit of the parties and their respective legal representatives, successors and permitted assigns, including any successor which acquires all or substantially all the business of a party; provided, however, that in no event will any assignment of rights or delegation of duties relieve a party of its obligations hereunder.

c. Amendment and Modification.

This Agreement shall not be subject to any change or modification unless such modification is in writing, signed by both parties and specifically states that it is an amendment to this Agreement.

d. Notices.

All notices relating to this Agreement shall be delivered personally, by e-mail, by registered or certified first class mail, or by overnight courier service to the contact addresses set forth below. Notice shall be effective upon receipt if personally delivered, delivered by e-mail or delivered by facsimile; upon the third business day following the date of mailing by registered or certified first class mail; or on the first business day following the date of delivery to the overnight courier. All notices hereunder shall be directed as follows:

If to the Institution:	RoseAnn Fleming, Interim IRB Director Address: 1640 Marengo Street, 7th Floor, Los Angeles, CA 90033 E-mail: irb@usc.edu
With a copy to:	University of Southern California 1510 San Pablo St. Los Angeles, CA 90033 Attn: Associate General Counsel
If to Advarra:	Contracts & Proposals Group 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046 cpg@advarra.com ATTN: Scott Uebele, CFO

e. IRB Review Fees.

In consideration of Advarra's performance of the services hereunder, the Institution will pay Advarra the applicable fees (the "Fees") set forth in Advarra's fee schedule in effect at the time the Services are rendered ("Fee Schedule"). Advarra's Fee Schedule in effect as of the Effective Date is attached hereto as Exhibit A. Advarra will provide Institution with a minimum of thirty (30) days' notice of its intent to update the Fee Schedule. The Institution will pay Advarra for Fees due within thirty (30) days of Institution's receipt of an invoice from Advarra for such Fees. For new studies, Advarra shall bill the Institution, Principal Investigators or Sponsors, or their agents, for services rendered as directed upon the applicable submission form(s). Notwithstanding the subsequent Amendment/Modification section herein, the Parties agree that modifications or amendments to the Fee Schedule shall not require written amendment to this Agreement.

f. Relationship of the Parties.

Each party's relationship with the other is and shall be that of an independent contractor, and no partnership, joint venture, co-venture, employer/employee, principal/agent, master/servant, business associate or other similar relationship is created, or intended to be created, hereby. Neither party is nor shall be the agent or employee of the other, and neither party has authority to act on behalf of the other in any matter except to the extent expressly agreed upon in writing.

g. Indemnification and Insurance.

Each party shall indemnify, defend and hold harmless the other party and its and its affiliates' directors, officers, employees, and agents (each, including the applicable party, an "Indemnitee") from and against any and all costs, damages, liabilities, or expenses (including reasonable attorneys' fees and court costs) or other losses incurred by the Indemnitee, or brought by a third party against an Indemnitee, arising from the indemnifying party's negligence, intentional misconduct, breach of this Agreement, or failure to comply with applicable laws, rules, and regulations. The Indemnitee shall give the indemnifying party prompt notice of any claim for which indemnification is sought

hereunder. The indemnifying party shall have the opportunity to undertake the defense of and to settle by compromise or otherwise any claim for which indemnification is available under this Section with legal counsel approved by the Indemnitee (which approval shall not be unreasonably withheld or delayed). If the indemnifying party so assumes the defense of any claim, the Indemnitee may participate in such defense with legal counsel of the Indemnitee's selection and at the expense of Indemnitee. If the indemnifying party, prior to the expiration of twenty (20) days after receipt of notice of a claim for indemnification under this Section, has not assumed the defense thereof, the Indemnitee may thereupon undertake the defense thereof on behalf of, and at the risk and expense of, the indemnifying party, with all reasonable costs and expenses of such defense to be paid by the indemnifying party. No compromise or settlement of any such claims shall be made without the prior consent in writing of the Indemnitee (which consent shall not be unreasonably withheld or delayed).

NOTWITHSTANDING ANYTHING TO THE CONTRARY CONTAINED HEREIN, TO THE MAXIMUM EXTENT PERMITTED BY LAW, IN NO EVENT WILL EITHER PARTY BE RESPONSIBLE FOR ANY INCIDENTAL, CONSEQUENTIAL, INDIRECT, SPECIAL, PUNITIVE, OR EXEMPLARY DAMAGES OF ANY KIND, INCLUDING DAMAGES FOR LOST GOODWILL, LOST PROFITS, LOST BUSINESS OR OTHER INDIRECT ECONOMIC DAMAGES, WHETHER SUCH DAMAGES ARISE FROM CLAIMS BASED UPON CONTRACT, NEGLIGENCE, TORT (INCLUDING STRICT LIABILITY) OR OTHER LEGAL THEORY, RESULTING FROM A BREACH OF ANY WARRANTY OR ANY OTHER TERM OF THIS AGREEMENT, AND REGARDLESS OF WHETHER A PARTY WAS ADVISED OR HAD REASON TO KNOW OF THE POSSIBILITY OF SUCH DAMAGES IN ADVANCE. Without limiting the foregoing, a party's liability to the other and the sum of a party's remedies against the other will not exceed, in the aggregate, the Fees that have been paid by the Institution to Advarra under this Agreement.

The Institution agrees that it shall maintain at its expense, or cause to be maintained, during the performance of this Agreement, insurance covering the Institution, Principal Investigators and all other research personnel for bodily injury, death and professional liability. The Institution will provide evidence of its insurance or self-insurance to Advarra, upon request.

Advarra will provide at its expense, and maintain throughout the term of this Agreement, general liability coverage and officer and director liability coverage. Upon request, Advarra agrees to provide the Institution with Certificates of Insurance demonstrating this coverage.

This section shall survive any termination of this Agreement.

h. Open Payments Program.

The parties acknowledge that the U.S. program known as "Open Payments" (which is also referred to as the "Physician Payments Sunshine Act") established by Section 1128G of the U.S. Social Security Act (42 U.S.C. 1320a-7h) and implemented by regulations at 42 C.F.R. Parts 402 and 403 requires "applicable manufacturers" to report direct and indirect payments and other transfers of value made to or at the request of, or designated on behalf of, "covered recipients," including payments or transfers of value through a third party where the applicable manufacturer requires, instructs, directs, or otherwise causes the third party to provide the payment or transfer of value, in whole or in part, to a covered recipient. All Fees paid to Advarra under this Agreement are paid directly to Advarra as described in Section V. the Institution, whether or not it is an "applicable manufacturer" under the Open Payments program, cannot and will not require, instruct, direct, or otherwise cause Advarra to provide such payments for services, in whole or in part, to licensed physician members of the IRB. Therefore, payments from the Institution for services will not be considered payments or other transfers of value to licensed physicians who are employees or independent contractors of Advarra. Advarra represents and warrants that all review services will be conducted in such a manner as to satisfy 21 C.F.R. § 56.107(a) and other applicable laws.

i. Governing Law

This Agreement shall be governed by the substantive law of the jurisdiction of the State of Delaware, without reference to that jurisdiction's conflicts-of-law rules.

j. Dispute Resolution.

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.

k. Use of Name or Trademark.

Except as required by law or permitted by this Agreement, neither party shall use the name, logo, trademark, or symbol of the other party or its affiliates in any advertising or promotional material without the prior written consent of the other party.

l. Survival.

The obligations of the parties under this Agreement which by their nature should continue beyond the termination or expiration of this Agreement or which provide meaning or context to any other provision, will remain in effect after termination or expiration.

[The rest of this page intentionally left blank; signature page follows]

IN WITNESS WHEREOF, each party accepts the terms herein and deems this Agreement effective as of the Effective Date.

University of Southern California	Advarra, Inc.
(Authorized Signature)	(Authorized Signature)
Name: Maja Mataric	Name: Scott Uebele
Title: Interim Vice President of Research	Title: President
Date: 2/23/2021	Date: 25-Feb-2021

DocuSigned by:
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Exhibit A

Fee Schedule