

**Directions:** This Agreement outlines the roles and responsibilities of an institution and a central IRB when arrangements are made to rely on a central (external) IRB for oversight of human research. Please use this template as a guide to document your Institution's specific requirements, including where applicable, FWA requirements. This reliance agreement also serves as an IRB Authorization Agreement (IAA) as required for research conducted under your Institution's FWA. Schulman IRB can execute this agreement as a global agreement with your Institution or as a study-specific agreement during the start-up phase of a specific study. The term "Institution" used throughout this document may be replaced with the actual institution name, if desired. For more information, please contact Schulman IRB at 513-761-4100 to speak to a member of our Institutions team or e-mail [institutions@sairb.com](mailto:institutions@sairb.com).

[This page is not a part of the contract document.]

## External IRB Authorization & Reliance Agreement

**Name of Organization Providing IRB Review:** Schulman Associates Institutional Review Board, Inc  
("Schulman IRB")

- FWA Number: FWA00023875
- IRB Registration #: IRB00000971
- Address: 4445 Lake Forest Drive, Suite 300, Cincinnati, Ohio 45242
- Responsible Individual's Name, Title, and Contact Information: Michele Russell-Einhorn Institutional Official, 513-761-4100, Submissions@sairb.com

**Name of Institution Relying on the Designated IRB ("Institution"):** University of Southern California

- FWA Number: FWA00005906
- Address: Health Sciences Campus, University of Southern California, Los Angeles, CA 90033
- Responsible Individual's Name, Title, and Contact Information:  
Sandra K Jean, MS  
HSIRB Director, Institutional Official Designee  
Phone: 323-276-2231  
Email: sjean@usc.edu

### **I. Scope of the Agreement:**

List all of the Institution's sites that may submit to Schulman IRB covered by this agreement. Include all sites involved in research and those sites that may not share your institutional name. The Officials signing below agree that the Institution shall rely on Schulman IRB for review and continuing oversight of human subject research conducted at *(may include separate attachment for lengthy lists)*:

- Keck Medicine of USC

This agreement is limited to studies conducted under the Cystic Fibrosis Therapeutics Development Network (TDN).

*(Choose one)*

☐ The Institution attests that all human research is conducted under the Institution's FWA.

OR

☒ The Institution only requires federally funded research to be conducted under the Institution's FWA.

OR

☐ The Institution does not have an FWA.

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 Schulman IRB 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.



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### **II. Responsibilities of Schulman IRB:**

- a. The review performed by Schulman IRB will meet the human subject protection requirements of the Common Rule (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. Schulman IRB will follow written procedures for reporting its findings and actions to the Principal Investigator (PI), Sponsor, and appropriate officials at the Institution. Schulman IRB will provide access to IRB related approval documents pertaining to research study materials reviewed by Schulman IRB for the Institution. Applicable IRB meeting minutes will be available upon request.
- b. Schulman IRB services shall include, but not be limited to: review and approval or disapproval of new protocols; review and approval, disapproval or modification of consent forms; continuing review; review and approval or disapproval of the Investigator(s) to conduct the research and changes in research; collection and review of reports of unanticipated problems and serious or continuing noncompliance; and maintenance of required IRB records pursuant to applicable federal regulations. Schulman IRB shall conduct continuing review of new research studies appropriate to the degree of risk in such studies, not less than annually.
- c. Schulman IRB shall promptly notify the currently-approved Principal Investigator (PI) of the study under review—as well as the institutional offices and individuals identified by the relying organization or institution—of all IRB decisions and shall make available to the PI all applicable study related documents.
- d. Schulman IRB shall notify the Institution's Responsible Official promptly, 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 Schulman IRB's operating procedures that might affect the Institution's reliance on Schulman IRB reviews; (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 Schulman IRB determines that serious or continuing non-compliance has occurred, and any steps that Schulman IRB 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 Schulman IRB Human Research Protection Program.

*Optional: HIPAA if Institution is a covered entity and requests Schulman IRB to act as a Privacy Board*

Upon request, Schulman IRB 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 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



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information is used and disclosed in a HIPAA-compliant manner. It is understood and agreed that, by providing these services, Schulman IRB is not a "business associate" of the Institution as defined by HIPAA.

*Optional: Conflicts of Interest. If not included, Schulman IRB will review investigator COI independently*

The Institution may perform its own investigator conflict of interest analysis under its relevant policies and provide Schulman IRB Institution's plan, or a summary of the plan, for managing the conflict of interest. Schulman IRB will review institutional 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 Schulman IRB determines an institutional conflict is not managed appropriately, Schulman IRB will promptly inform the PI and the Institution's Responsible Official. Schulman IRB will review all study-specific investigator COI according to Schulman IRB Standard Operating Procedures. Once the Institution's plan is accepted by Schulman IRB, the Institution shall ensure implementation of the plan and report any noncompliance with the same.

### **III. Responsibilities of the Institution**

- a. The Institution is responsible for requiring investigator compliance with the protocol, IRB determinations, applicable federal and state regulations, sponsor requirements, and, if applicable, with the terms of its OHRP-approved FWA.
- b. It is the responsibility of the Institution to identify and interpret the requirements of applicable state or local laws, regulations, institutional policies, and to communicate such requirements to Schulman IRB.
- c. The Institution agrees to provide all information required by Schulman IRB in order to conduct its reviews. The Institution may not approve any research study that has been disapproved by Schulman IRB. The Institution may, however, disapprove any study that is approved by Schulman IRB. The Institution agrees to abide by the decisions of Schulman IRB, including the use of the Schulman IRB-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.
- d. 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 requested by Schulman IRB.
- e. The Institution shall require an institutional process exists 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 Schulman IRB in accordance with the timeframes specified by Schulman IRB.



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- f. The Institution shall cooperate with any Schulman IRB 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, Schulman IRB shall have the authority to determine whether serious or continuing noncompliance or unanticipated problems involving risks to subjects or others have occurred.
- g. The Institution shall notify Schulman IRB's Responsible Official promptly (1) if there is ever a suspension or restriction of the Institution's authorization or ability to conduct studies; (2) of any Institutional policy decisions or regulatory matters that might affect Schulman IRB's ability to review the Institution's research; (3) of unanticipated problems involving injury or risks to subjects or others in a study reviewed by Schulman IRB; (4) if the Institution believes that serious or continuing non-compliance has occurred in a study reviewed by Schulman IRB, and any steps the Institution has deemed necessary for remediation of non-compliance; (5) of suspension or termination of Institutional approval; (6) of any communication with the FDA, OHRP or any funding agency relating to the Institution's studies being reviewed by Schulman IRB or (7) changes in the accreditation status of the Institution's Human Research Protection Program, if any.

*Optional: Federally Funded Studies, if applicable*

The Institution will maintain a current, approved Federalwide Assurance (FWA) with OHRP for the duration of this Agreement. The Institution will notify Schulman IRB 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 and agrees to treat such information as confidential (hereinafter referred to as "Confidential Information"). 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 Schulman IRB 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.

*Optional: Protected Health Information, if applicable*

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



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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 (hereinafter referred to as "**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 twenty-four (24) hours 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 parties' rights and subjects' privacy. It is expressly understood and agreed that, by providing review services as described herein, Schulman IRB is not a "Covered Entity" and is not a "Business Associate" of the Institution as defined by HIPAA.

### **b. Record Keeping**

Schulman IRB 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**

Schulman IRB 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 applicable to this agreement and will provide the other party with copies of all documents relating to any such audit or review in accordance within the timeframes specified by Schulman IRB.

### **d. Inspection**

Schulman IRB or its authorized representatives shall be permitted upon request 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, 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 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 Schulman IRB'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.

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

If Schulman IRB 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. Schulman IRB will share the report with the Institution and PI before it is sent to the Sponsor/oversight authority, and will copy the other parties' institutional official(s) and/or designees. 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.

*Optional: Clinical Trial Agreements and Compensation for Research Related Injury, if applicable*

Schulman IRB 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. Schulman IRB 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 Schulman IRB.

## V. General Terms and Conditions

### a. Term and Termination

The term of this Agreement shall commence upon execution of this Agreement by both parties, and shall continue until the conclusion of the study or until such time as either party gives sixty (60) days written notice of termination. Notwithstanding the foregoing, in the event that either party is in default in the performance of any of its obligations under this Agreement, and the default has not been remedied within 60 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 Schulman IRB 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 Schulman IRB should cease providing IRB Services under this Agreement for any reason, upon the Institution's reasonable request, Schulman IRB shall provide to the Institution copies of all documentation related to the provision of IRB Services by Schulman IRB under this Agreement.

### b. Assignment:



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This Agreement may not be assigned or transferred by either party without the prior written consent of the other party.

### ***Re: Notices:***

All notices relating to this Agreement shall be delivered personally, by facsimile, 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 Institution: Sandra K Jean, HSIRB Director  
General Hospital Suite 4700  
1200 North State Street  
Los Angeles, CA 90033

If to Schulman IRB: Eli Alford, Chief Operating Officer  
4445 Lake Forest Drive, Suite 300  
Cincinnati, OH 45242

### ***Re: IRB Review Fee:***

Schulman IRB will charge for services in accordance with its current, published fee schedule. Schulman IRB will provide advance notice of changes to its fee structure prior to implementation. For new studies, Schulman IRB shall bill the Institution, 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. The Compensation provisions of this Agreement will survive termination of this Agreement.

### ***Re: 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.

### ***Re: Insurance***

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



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other research personnel for bodily injury, death and professional liability. The Institution will provide evidence of its insurance or self-insurance to Schulman IRB, upon request.

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

This section shall survive the termination of this Agreement.

### ***Re: Amendment/Modification***

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

### ***Re: Governing Law***

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

*[The rest of this page intentionally left blank]*

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IN WITNESS WHEREOF, each party accepts the terms herein as evidenced by their authorized signatures below.

University of Southern California

Schulman Associates Institutional Review Board, Inc.

  
(Authorized Signature)

  
(Authorized Signature)

Name: Sandra K Jean, MS

Name:

**Adam Roth**  
**Director of Operations**

Title: HSIRB Director, Institutional Official Designee

Title:

Date: August 8, 2017

Date:

8/10/17