University of California, Davis

**IRB Authorization Agreement**

**UC Davis as the Reviewing IRB of Record for**

**[insert Relying Institution]**

1. **Agreement** – This is an agreement between the Board of Regents of the University of California, on behalf of its Davis Campus (UC Davis) and [insert name of Relying Institution] (known as “Relying Institution” in this agreement). This agreement concerns reliance by Relying Institution on the review and approval of human research by the UC Davis Institutional Review Board (IRB).
2. **Project(s) Covered by this Agreement** – This agreement applies to [insert study name or all human subjects research] conducted at Relying Institution that is also being conducted at UC Davis.
3. **Compliance with Agency Guidance** – This Agreement meets the federal requirements for designation of another institution’s IRB as the reviewing IRB.
4. **Scope of this Agreement** – The parties acknowledge that Relying Institution is responsible for the development and operation of its own human subjects protections program. Through this Agreement, UC Davis is solely agreeing to provide the services of its IRB to Relying Institution for IRB review of research covered by this agreement. UC Davis does not otherwise assume responsibility for other aspects of Relying Institution’s human subjects protection programs or human subjects research operations including the qualifications of any investigators and key study personnel. Upon request, UC Davis will make determinations related to waivers of authorization under, 45 CFR §164.512(i). UC Davis will review HIPAA authorization language when required under 45 CFR §164 and the authorization is included in the informed consent form for the research.
5. **Effective Dates of this Agreement** – This agreement is effective upon execution and remains in effect until the research closes, the agreement is terminated, or the Relying Institution notifies UC Davis that it is no longer participating in the research.
6. **Definitions**–
   1. Human Subjects Research **–** The definition of human subject research is that set forth in 45 CFR §46.102 and 21 CFR §50.3, §312.3 and §812.3. In addition, California law requires IRB review and approval for research that relies on individually identifiable information from death data files held by local registrars, county recorders and the State Registrar. (California Health & Safety Code §102231(a)(5))
   2. Exempt Human Subject Research **–** The definition of exempt human subject research is set forth in 45 CFR §46.101(b) (Pre-2018 Common Rule) and 45 CFR §46.104 (2018 Common Rule) and 21 CFR §56.104.
   3. Expedited Human Subject Research **–** The definition of expedited human subject research is set forth in 45 CFR §46.110 and 21 CFR §56.110.
   4. Institutional Official **–** The Institutional Official is the Signatory Official on the Federalwide Assurance (FWA) filed with the Office for Human Research Protections (OHRP) to assure compliance with regulations governing protection of human subjects.
7. **Reliance on UC Davis IRB review** – The Institutional Officials signing below agree that Relying Institution will rely on the determinations made by the UC Davis IRB. The specific projects submitted under this agreement have not been submitted to another IRB for review or approval. In addition, once submitted to UC Davis’ IRB for review and approval, the project may not be submitted to a non-UC Davis IRB for alternate consideration. This practice is known as “IRB shopping” and is expressly prohibited.

1. **Compliance with Federal and State Law** –A determination of exemption or review and approval of human subject research under this agreement shall be conducted in accordance with all relevant federal and state statutes and regulations governing the protection of human subjects.
2. **Informed Consent** – Research subject to this agreement shall employ a consent process, as applicable, including a consent form, consent waiver, or alteration of consent that meets all federal and state requirements and is approved by the UC Davis IRB.
3. **Duties and Responsibilities of UC Davis** –
   1. **Review and Oversight** – The UC Davis IRB shall conduct initial and continuing reviews, and a shall review amendments to approved protocols and reports of unanticipated problems and serious and/or continuing noncompliance. The UC Davis IRB shall have the authority to suspend or terminate the research. UC Davis shall notify Relying Institution of all determinations. The UC Davis IRB shall notify the Relying Institution of any determinations of unanticipated problems, serious or continuing noncompliance prior to notifying applicable regulatory authorities.
   2. **Post Approval Monitoring** **–** The UC Davis IRB shall have the option, upon notice to Relying Institution's IRB, to conduct post approval monitoring, including announced and unannounced visits and/or audits of the research team at the Relying Institution to ensure research is conducted in accordance with the IRB approved protocol and Good Clinical Practices and sufficient infrastructure exists to protect the rights and welfare of research subjects. Relying Institution shall be provided a copy of any results from such visit or audit.
   3. **Record Keeping** –UC Davis IRB will keep records of studies that are subject to this Agreement as required in Federal Regulation 21 CFR §56.115 and 45 CFR §46.115. The records will include at a minimum the date the application is submitted, review determinations, dates of approval, location of research activity, and oversight actions.
4. **Duties and Responsibilities of Relying Institution**–
   1. **Determination** – Relying Institution reserves the right and retains the ultimate responsibility to determine the research to be conducted at its facilities.
   2. **Protection of Human Subjects** – Relying Institution retains the ultimate responsibility for the protection of human subjects in all research in which it engages, including (1) implementing, within its local research context, appropriate oversight mechanisms to ensure compliance with the determinations of the UC Davis IRB; and (2) requiring all investigators and key study personnel to be current and in good standing under its own human subjects training program prior to participation in the research.
   3. **Local Research Context Issues** – Relying Institution is responsible for providing to the UC Davis IRB any necessary information about local research conducted at Relying Institution.
   4. **Conflicts of Interest** – Relying Institution will ensure that any conflict of interest determinations and management plans applicable to the research covered by this agreement are reported to the UC Davis IRB.
   5. **Compliance and Oversight** –Relying Institution shall advise the UC Davis IRB of any incidents of noncompliance or unanticipated problems of which it becomes aware including, but not limited to, violations of human research protection regulations. Relying Institution shall provide written standard operating procedures, or the equivalent thereof, describing its institutional policies and procedures related to post approval monitoring and conflict of interest, as applicable. If no such documentation or policies exist, the Institution shall provide additional information to the IRB expressly for purposes of this Agreement on a case by case basis.
   6. **Post Approval Monitoring** – The UC Davis IRB shall have the option to conduct post approval monitoring, including announced and unannounced visits and/or audits of the Relying Institution to ensure research is conducted in accordance with the UC Davis IRB approved protocol and Good Clinical Practices and sufficient infrastructure exists to protect the rights and welfare of research subjects.
   7. **Approvals by Other Oversight Bodies** – Relying Institution will ensure that local institutional committee reviews and approvals are in place before the research commences at Relying Institution. This includes, but is not limited to, institutional biosafety review, radiation safety review, review and management of conflict of interest, and others as required. This agreement does not imply or require that UC Davis will conduct these additional reviews on behalf of Relying Institution.
   8. **Contact Person** – Relying Institution will provide the name and contact person of an individual who will serve as the primary contact person for the Relying Institution. This person will be the recipient of correspondence and notifications from UC Davis on behalf of the Relying Institution.
5. **Duties and Responsibilities of Both UC Davis and Relying Institution** –
   1. **Cooperation** – UC Davis and Relying Institution shall cooperate in good faith concerning the operation of this agreement. Relevant documentation to support review, compliance and oversight will be made available upon request and to appropriate regulatory agencies as needed.
   2. **Indemnification** – Both parties shall defend, indemnify and hold the other party, its officers, employees, and agents harmless from and against any and all liability, loss, expense (including reasonable attorneys’ fees) or claims for injury or damages arising out of the performance of this Agreement, but only in proportion to and to the extent such liability, loss, expense, attorneys’ fees, or claims for injury or damages are caused by or result from negligent or intentional acts of omissions of the other party, its offices, agents or employees.
   3. **Federally Funded Research** –
      1. **Federalwide Assurance** – For research that is federally funded, each party will maintain an approved FWA, provide a copy of the FWA to the other party if requested, and abide by the conditions of the respective assurance and this Agreement. In the event a party’s FWA is amended, such party will notify the other party and supply a copy of the amended FWA to the other party upon request.
      2. **Suspension or Revocation of FWA** – The parties agree to give prompt notice in writing to the other party in the event of institution of proceedings for suspension or revocation of its FWA, and to notify the other party in the event of any suspension or revocation of its FWA within seventy-two (72) hours of its occurrence. Each party at its own discretion, may terminate this agreement immediately in the event the other party is given official notice of the institution of proceedings to suspend or revoke its FWA. The party whose FWA is being terminated must, within five (5) business days of the termination of this Agreement, notify the OHRP in writing of the termination of the Agreement.
6. **Agreement on File** – This Agreement must be kept on file at both UC Davis and Relying Institution, and must be provided to OHRP, the Food and Drug Administration, or other regulatory agencies upon request.
7. **Execution** –The undersigned Institutional Officials have read and agreed to all the terms above. This agreement shall remain in effect for the duration of the project and shall be reviewed at project completion for improvements and modifications. This agreement may be terminated for any reason by written notice to the other party provided at least thirty (30) days’ notice is given.

RELYING INSTITUTION

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Institutional Official Signature Date

[Name]

[Title]

[Institution]

[Address]

[Phone/Fax]

[E-mail]

Federalwide Assurance Number: FWA \_\_\_\_\_\_\_\_\_\_\_

UC DAVIS

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For the Institutional Official Date

John Tupin, JD

Director, IRB Administration

2921 Stockton Blvd. Ste. 1400

Sacramento, CA 95877

Federalwide Assurance Number: FWA00004557

IRB# 00000425, 00000426, 00003023, 00005274