Memorandum of Understanding (MOU)
Between VA Greater Los Angeles Healthcare System and University of California Los Angeles
With Regard to Collaboration on the Use of Animals in Research

A. Parties to this MOU are:

A.1. VA Greater Los Angeles Healthcare System (hereafter abbreviated "GLA").

A.2. The Regents of the University of California (on behalf of its Los Angeles campus, hereafter abbreviated "UCLA").

B. Purpose. The purpose of this MOU is to define the expectations of GLA and UCLA (referred to individually as "Party" and collectively as "Parties") with regard to their collaboration on the use of animals (defined as all vertebrate species) in research, teaching, and testing, in order to promote scientific collaboration, while reducing duplication of effort, ensuring regulatory compliance, and maintaining quality animal care and high standards of ethical conduct. For the purposes of this document, "collaboration" includes all joint efforts of GLA and UCLA to conduct, manage, or oversee animal research, teaching, and testing. The effective date shall be the date of the last signature by the authorized agents of the Parties to this MOU.

C. References. The most recent versions of the following documents are the foundation for the terms of this MOU. This is not an exhaustive list of all regulatory, legal, and policy documents that apply to collaborative animal research in the United States, but highlights the references of particular relevance to the expectations described herein.

C.1. The Animal Welfare Act (7 USC § 54:2131-2159) as implemented in the United States Department of Agriculture (USDA) Animal Welfare Act Regulations (9 CFR Parts 1, 2, and 3; USDA Animal Welfare Act), with special emphasis on Sections 2.31 [Institutional Animal Care and Use Committee (IACUC)], 2.32 (Personnel Qualifications), and 2.33 (Attending Veterinarian and Adequate Veterinary Care).

C.2. The Health Research Extension Act of 1985 (Public Law 99-158: 495) as implemented in the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals.

C.3. Office of Laboratory Animal Welfare (OLAW) Frequently Asked Question D.8, "When institutions collaborate, or when the performance site is not the awardee institution, which IACUC is responsible for review of the research activity?", and National Institutes of Health (NIH) Notice NOT-OD-01-017, "No Requirement for Duplicate Review".

C.4. "Guide for the Care and Use of Laboratory Animals" (*Guide*), 8th edition, with special emphasis on meeting the requirements for collaborative research found on page 15 in the "Collaborations" section.

C.5. AAALAC International (AAALAC) Rules of Accreditation.

C.6. Veterans Health Administration (VHA) Directive 1200, "Veterans Health Administration Research and Development Program".

C.7. VHA Handbook 1058.01, "Research Reporting Requirements".

C.8. VHA Handbook 1200.01, "Research and Development Committee".

C.9. VHA Handbook 1200.02, "Business Operations".

C.10. VHA Handbook 1200.07, "Use of Animals in Research".

D. General stipulations

D.1. Parties agree to comply with the References cited under Section C above, as applicable to the activity and as per each Party's requirements, with regard to the collaborative activities covered by this MOU.

D.2. Parties agree that all VA animal research and any additional collaborative animal research that is conducted on property owned or leased by VA is subject to oversight by the GLA IACUC, and other committees as applicable, to ensure compliance with VA policy.

D.3. Parties agree that all UCLA animal research and any additional collaborative animal research that is conducted on property owned or leased by UCLA, except for leased property at VA, is subject to oversight by the UCLA IACUC to ensure compliance with the policies of UCLA.

D.4. Parties agree that collaborative animal research may be subject to the oversight of both the GLA IACUC and the UCLA IACUC, in which case, each Party agrees that such research shall meet the internal requirements of both GLA and UCLA.

D.5. Parties agree that the ultimate authority to interpret any regulatory requirement rests with the agency or entity that published and administers it.

D.6. Parties agree to make good faith efforts to facilitate reciprocal physical access to personnel, records, and facilities, as well as to provide information and data, as needed for both Parties to meet their respective regulatory obligations related to their collaboration under this MOU and to respect the security and access requirements of each Party.

D.7. In case of any open records request [e.g., any request submitted under the terms of the Federal Freedom of Information Act (FOIA), 5 U.S.C. § 552, or any California open records laws] that addresses any aspect of the collaboration under this MOU, Parties commit to making good faith efforts to coordinate their responses, and permit reasonable opportunity for each to review materials before release, to the extent allowed by law and by each Party's policies.

D.8. Parties agree to make good faith efforts to grant representatives of recognized regulatory or accrediting entities (e.g., USDA, OLAW, AAALAC, and VA) access to facilities and records as needed for both Parties to meet their regulatory obligations. Parties agree to keep each other apprised of

visits by such regulatory or accrediting entities and to share with each other any reports or findings relevant to the collaborative work.

D.9. Each Party shall allow representatives, as determined appropriate by each Party, from the other Party to attend and participate in meetings, facility inspections, and program evaluations of the other Party as they relate to research studies covered by this MOU if it is permitted by the agency conducting the facility inspection or program evaluation.

D.10. The use of infectious agents, toxic chemicals, or radioisotopes in conjunction with collaborative activities under this MOU requires the prior written approval of the Biosafety Committee, the Radiation Safety Committee, and/or the Office of Environment, Health and Safety of the Party whose IACUC approved the protocol, and notification of such use must be available to the veterinary staff attending to such animals.

E. Stipulations related to the facilities

E.1. The facilities to be used for animal research involving USDA-regulated species at GLA or at UCLA, and subject to the oversight of either the GLA IACUC and/or the UCLA IACUC, must be registered with USDA (USDA AWAR, ref. C.1, above). Each animal of a USDA-regulated species must be reported to USDA only once for each year in which it participated in a research study, by a party registered with USDA. Any USDA-regulated animal that underwent more than one procedure must be reported in the column of Animal and Plant Health Inspection Service (APHIS) Form 7023 (Annual Report of Research Facility) that corresponds to the pain and distress associated with the procedure that involved the most pain and distress. GLA will report USDA-regulated animals that reside at GLA, and UCLA will report USDA-regulated animals that reside at UCLA. If any USDA-regulated animal was transferred between facilities during the reporting year, it shall be reported by the Party in which facility the animal last resided.

E.2. The facilities that are to be used for animal research at GLA or at UCLA, and are subject to the oversight of either the GLA IACUC or the UCLA IACUC, must be covered by a PHS Assurance approved by OLAW. Each Party shall maintain its own independent PHS Assurance, approved by OLAW, covering those of its facilities that are used for animal research that is subject to the oversight of the Party's IACUC.

E.3. AAALAC accreditation must be maintained for the facilities used for any animal research that is subject to the oversight of either the GLA IACUC or UCLA IACUC, at GLA or at UCLA. Each Party shall maintain accreditation by AAALAC, covering those of its facilities that are used for any animal research that is subject to the oversight of either the GLA IACUC or the UCLA IACUC.

E.4. Appropriate veterinary care and routine husbandry shall be provided to all animals involved in research under the terms of this MOU (including all animals used in the collaborative activities) by the personnel and according to the Standard Operating Procedures (SOPs) of the Party that houses the animals, regardless of which Party owns them.

E.5. If animals are scheduled to be transported to either facility and will not be returned to the original facility, responsible personnel will make housing arrangements with the veterinary staff of

the receiving facility per that facility's policies and procedures. The transported animals must be alert and should not be under the influence of any anesthetics, unless permission has been obtained from the veterinary staff of the receiving facility, and a qualified person is accompanying the animals during transport. If animals are to be housed temporarily in one facility and will be returned to the other, responsible personnel shall make arrangements with the veterinary staff for a special space assignment in advance of the animals' arrival. Animals that will be returned must be housed in the receiving facility in a room separate from other animals unless other arrangements have been made with the attending veterinarian. The attending veterinarians will consult with each other regarding vendors, health certifications, and other considerations to prevent cross contamination.

E.6. All personnel involved in collaborative use of animals covered by this MOU must have the opportunity to participate in an Occupational Health and Safety Program (OHSP) that addresses the risks related to exposure to animals or their unfixed tissues or fluids.

E.6(a) All personnel involved in collaborative use of animals covered by this MOU are eligible to participate at no charge in the OHSP offered by GLA or UCLA, and which comply with PHS Policy.

E.6(b) Parties agree that personnel may decline to receive services not required to protect the health of the animals or other personnel. Personnel who decline optional services are considered to be enrolled in the OHSP as long as each Party documents that they were given the opportunity to receive these services.

F. Stipulations related to IACUC oversight

F.1. Each IACUC shall keep the other IACUC informed of any matters that arise relevant to the collaborative activities, and shall provide in a timely fashion any information or documentation required for the other IACUC to meet its regulatory obligations.

F.2. Although each Party may agree generally to accept or approve the outcomes of the other Party's protocol reviews, program and facility reviews, investigations, or determinations about reporting, each Party retains the right to act independently and solely at its own discretion. Each Party agrees to exercise that discretion only as necessary to meet its oversight responsibilities. Each Party agrees to inform the other Party promptly of its findings and determinations, and to consider the other Party's findings and determinations in its own deliberations.

F.3. There is no regulatory requirement for dual review of protocols for collaborative activities (NIH Notice NOT-OD-01-017, ref. C.3, above). The Party overseeing the animal program at which the research is conducted shall assume primary responsibility for review of those activities. Research conducted at GLA shall be submitted to the GLA IACUC using the VA form. With the exception of research conducted using VA funds, research conducted at UCLA shall be submitted to the UCLA IACUC using the UCLA form. In the case of VA-funded research, regardless of where the study is performed, the VA form must be used and must be approved by the GLA IACUC. The sponsoring Party may, at its discretion, impose additional requirements for review of activities conducted at the other Party's facility. In cases where the UCLA IACUC reviews VA research, UCLA shall submit to GLA a copy of the approved protocol and approval notice for GLA approval. In cases where the GLA IACUC reviews UCLA research, GLA shall submit to UCLA a copy of the approved protocol and approval notice for UCLA approval. Similar records shall be submitted to the other Party following

approval of any amendment applications and continuing reviews of ongoing research activities, as well as following expiration and/or closure of any applicable studies.

F.4. Each IACUC that reviews any protocol for collaborative animal use shall confirm that all research personnel identified on the protocol are qualified to perform the procedures assigned to them on the protocol and have completed the training specified by the local IACUC.

F.5. Each IACUC must evaluate semiannually the animal use programs and facilities that are covered by its own PHS Assurance, and shall make available for review a copy of those portions of the final IACUC-approved report of its evaluation that apply to the collaboration (see "sharing of information", Section G, below). The other IACUC may review the report as part of its own semiannual evaluation, but may also perform its own independent evaluation of those components of the animal use program and facilities of the first Party that are relevant to the collaboration. Each IACUC is independently responsible for reporting the results of each semiannual evaluation to its own Institutional Official (IO).

F.6. For collaborative activities that lead to any concerns about potential regulatory noncompliance related to animal welfare, one Party shall take primary responsibility for investigating, determining whether regulatory noncompliance is involved (and, if so, what corrective actions are appropriate), and reporting to the applicable regulatory entities. Neither IACUC has any authority to investigate or address any aspect of the animal care and use program of the other Party that is not related to the collaborative activities, but each IACUC is obligated to bring concerns about the other program to the attention of the IACUC that oversees it. Any reports to external non-VA oversight entities shall clearly acknowledge the involvement of both Parties (including the relevant identifiers for USDA registration, PHS Assurances, grants, AAALAC accreditation, etc.) in the collaborative activity.

F.6(a) To facilitate coordination of oversight, each Party agrees to notify the other promptly (within two business days) if its IACUC acts to change the approval status of any protocol that it has previously approved for collaborative animal use (e.g., suspension of IACUC approval, and lifting the suspension of IACUC approval).

F.6(b) The GLA IACUC shall submit any reports about collaborative activities that are required by the VHA Office of Research and Development (ORD) or the VHA Office of Research Oversight (ORO), regardless of which Party takes primary responsibility for the investigation. Because VHA Handbook 1058.01 (ref. C.7, above) includes specific requirements with regard to the timing of correspondence with ORO about noncompliance, UCLA agrees to provide information promptly to the GLA IACUC, as follows:

F.6(b)(1) Any information suggesting potential regulatory noncompliance related to the collaborative activity shall be forwarded to the GLA IACUC within five business days of receipt.

F.6(b)(2) Any determination by the UCLA IACUC that a matter is reportable shall be communicated to the GLA IACUC immediately, so that the GLA IACUC can forward this information to the GLA Institutional Official within five business days of the determination.

F.6(b)(3) Information about any corrective action plan prepared, corrective actions completed, or sanctions imposed or lifted, shall be communicated promptly to the GLA IACUC within five business days of the actions being taken.

F.6(c) Primary responsibility for addressing each matter of potential noncompliance shall be taken by the IACUC of the Party that houses the involved animals, if all involved animals are housed by only one Party. Otherwise, primary responsibility will be assigned by mutual agreement, on a case-by-case basis.

G. Stipulations regarding the sharing of information between GLA and UCLA

G.1. Each Party agrees to make good faith efforts to provide all information, copies of documents, and access necessary for the other Party to meet its regulatory obligations related to the collaboration. Each Party has its own independent IACUC, and each IACUC agrees to provide relevant information and documents to the other IACUC as appropriate.

G.2. Redaction of information from copies of documents to be provided.

G.2(a) Parties agree that documents that are otherwise publicly available shall not be redacted.

G.2(b) GLA agrees that any UCLA document to be shared with GLA may be redacted of information not relevant to GLA, provided the unredacted version is available for GLA representatives to review at UCLA during normal business hours, within three business days of request.

G.2(c) UCLA agrees that any GLA document to be shared with UCLA may be redacted of information not relevant to UCLA, provided the unredacted version is available for UCLA representatives to review at GLA during normal business hours, within three business days of request.

G.3. Documents to be shared routinely. Each Party agrees to provide routinely and in a timely fashion to the other Party a copy (which may be redacted as described in G.2, above) of each document relevant to the collaboration, including the following:

G.3(a) The IACUC-approved version of each protocol, amendment, or renewal related to the collaborative activity.

G.3(b) Any correspondence relevant to the collaborative activity, that is sent to or received from an oversight entity [e.g., routine (annual) reports, reports of noncompliance, reports from routine or for-cause site visits, responses to site visit reports, and notifications of any changes in status (PHS Assurance, AAALAC Accreditation)], unless the correspondence is related to research misconduct, in which case each Party's policies must be followed.

G.3(c) Any correspondence relevant to the collaborative activity that is sent to or received from research personnel.

G.4. Other information to be shared routinely. Each Party agrees to notify the other Party promptly about any other matter relevant to the collaboration, including the following:

G.4(a) Receipt of any complaint, allegation, or other information suggesting concerns about animal welfare or potential regulatory noncompliance relevant to the collaboration. The other Party shall be notified within two business days of receipt of the information.

G.4(b) The outcome of any investigation by the IACUC regarding any matter that is potentially reportable and relevant to the collaboration.

G.4(c) Receipt of any FOIA request or other open records request regarding collaborative matters. The other Party shall be notified within two business days of receipt of the request.

G.4(d) Any public disclosure (including press releases) regarding collaborative matters. Each Party shall notify the other Party at least five business days before release, to provide an opportunity for the other Party to comment and request revision. Parties agree to give reasonable consideration to all requested edits received.

G.4(e) Identification of key individuals. Each Party shall identify and provide to the other Party the contact information of its personnel who are responsible for the following functions in support of the collaboration:

G.4(e)(1) animal care (including emergency contact information):

[redacted]

G.4(e)(2) IACUC operations and communications with the other Party:

[redacted]

H. Additional Terms and Conditions

H.1. Parties agree to work in good faith with each other to update this document promptly as needed to reflect changes in the circumstances or policies of either Party. Revisions of this MOU shall be made in writing and signed by the authorized agents of both Parties.

H.2. This MOU shall be automatically renewed every five years, unless either Party elects to terminate the agreement and provides written notice to the other Party six months prior to the renewal date.

H.3. If either Party fails to satisfactorily fulfill its obligations under this MOU or breaches any of the promises, terms, or conditions of this MOU, and having been given reasonable notice of and opportunity to correct any such default and not having taken satisfactory corrective action within the time specified by the non-breaching Party, the non-breaching Party shall have the right to terminate this MOU by giving written notice to the breaching Party of such termination at least 30 calendar days before the effective date of such termination. Without cause, either Party to this MOU has the right to terminate this MOU by giving written notice to the other Party of such termination at least six months before the effective date of such termination. After a termination notice is received, no additional animals shall be procured for collaborative work; the Parties shall make good faith efforts to transfer ownership and possession of all remaining animals, equipment, and data in a timely, orderly, and mutually agreeable manner; and the collaborative work shall terminate no later than when the MOU terminates.

H.4. Disputes. Any dispute shall be submitted jointly to GLA and UCLA. Both Parties agree to make all reasonable good faith efforts to resolve the dispute by mutual agreement. Both Parties agree that the VHA Chief Veterinary Medical Officer (CVMO) and UCLA's DLAM Executive Director and Attending Veterinarian may be consulted for guidance in resolving the dispute. If GLA and UCLA are unable to jointly resolve the dispute within 30 calendar days after notification, the VHA Office of the Under Secretary for Health may propose a resolution. If the dispute remains unresolved, VA policy is to encourage the use of alternative dispute resolution procedures, but nothing in this section prevents GLA or UCLA from pursuing any additional administrative remedies that may be available and, after exhaustion of such administrative remedies, pursuing judicial remedies. Pending the resolution of any dispute pursuant to this paragraph, the Parties agree to diligently pursue performance of all obligations to the extent possible.

H.5. *Force Majeure*. No Party shall be liable for any unforeseeable event beyond its reasonable control and not caused by its own fault or negligence, and which it has been unable to overcome by the exercise of due diligence, which causes the Party to be unable to perform its obligations under this MOU. If a *force majeure* event occurs, the Party unable to perform shall promptly notify the other Party. It shall use reasonable efforts to resume performance as quickly as possible and shall suspend performance only for such period of time as is necessary as a result of the *force majeure* event.

H.6. The undersigned certify that they are authorized to bind the Party they represent to the terms of this MOU and have read and agree to all terms stated herein.

For UCLA:

1/2/18

Signature
Roger M. Wakimoto, Ph.D.
Vice Chancellor for Research
Institutional Official

Date

For GLA:

12/14/17

Signature
Ann R. Brown, FACHE
Medical Center Director
Institutional Official

Date

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