

MEMORANDUM OF UNDERSTANDING REGARDING THE CARE AND USE OF
LABORATORY ANIMAL SUBJECTS BETWEEN LOYOLA UNIVERSITY
CHICAGO - STRITCH SCHOOL OF MEDICINE AT LOYOLA UNIVERSITY
MEDICAL CENTER AND THE EDWARD HINES JR VETERANS AFFAIRS
HOSPITAL

I. Purpose

Loyola University Chicago - Stritch School of Medicine (LUC/SSOM) and the Department of Veterans Affairs Edward Hines Jr. Hospital (HVA) make this agreement pertaining to laboratory animal care and use at LUC/SSOM facilities where such animals are purchased and/or supported with HVA funds and to laboratory animal care and use at HVA facilities where such animals are purchased and/or supported with LUC/SSOM-sponsored/administered funds. This agreement also covers animals that will be housed or used only temporarily at the HVA or LUC/SSOM. This agreement is effective until February 28, 2014 and will be re-evaluated by both sites annually.

II. Definitions

For the purpose of this agreement, “**LUC/SSOM-sponsored research**” is defined as research conducted by LUC/SSOM personnel (faculty, HVA personnel with LUC/SSOM appointments, staff, post-doctoral fellows, or students) and supported by a contract, grant or gift awarded to LUC/SSOM and administered by LUC/SSOM, including money from extramural sponsors, money awarded to a LUC/SSOM-managed research program, and any other internal LUC/SSOM award appropriated for research support. Excluded from the definition of LUC/SSOM sponsored research are research studies supported by a contract, grant or gift awarded to HVA personnel with LUC/SSOM appointments by the Department of Veterans Affairs or its Nonprofit Research Corporations, and administered by HVA or Chicago Association for Research and Education in Science (CARES), the non-profit research corporation of HVA.

For the purpose of this agreement, “**HVA-sponsored research**” is defined as research conducted by HVA personnel and supported either by a contract, grant or gift awarded by or to the Department of Veterans Affairs and administered by HVA, including money from extramural sponsors, VA Merit Awards, VA Career Development Awards and other internal awards appropriated for research support. Not included in the definition of “HVA-sponsored research” is research conducted by HVA personnel, but whose research support is awarded to and administered by organizations other than HVA. Also excluded from the definition of “HVA-sponsored research” are HVA personnel with LUC/SSOM appointments who are conducting research supported by a contract, grant or gift awarded by or to LUC/SSOM and administered by LUC/SSOM.

For the purpose of this agreement, “**HVA Nonprofit-sponsored research**” is defined as research conducted by HVA personnel and supported either by a contract, grant or gift awarded by or to a HVA Nonprofit Research Corporation (presently CARES) and administered by the HVA Nonprofit Research Corporation, including money from extramural sponsors and internal awards appropriated for research support. Not included in the definition of “HVA Nonprofit-sponsored

research” is research conducted by HVA personnel, but whose research support is awarded to and administered by organizations other than CARES. Also excluded from the definition of “HVA Nonprofit-sponsored research” are HVA personnel with LUC/SSOM appointments who are conducting research supported by a contract, grant or gift awarded by or to LUC/SSOM and administered by LUC/SSOM.

For the purpose of this agreement, the “**LUC/SSOM form**” is defined as the LUC/SSOM Animal Component of Research Protocol (LUC/SSOM ACORP). The “HVA form” is defined as the HVA Animal Component of Research Protocol (HVA ACORP).

III. Responsibilities

Each institution (LUC/SSOM and HVA), along with its respective Institutional Animal Care and Use Committee (IACUC), is obligated to ensure continued compliance with all applicable laws and regulations governing the use of animals in research including the Animal Welfare Act and all applicable local and federal statutes and other regulations relating to research animals. Each institution will also maintain full accreditation with the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC, International) and maintain a current Animal Welfare Assurance with the Office of Laboratory Animal Welfare (OLAW).

In addition, each institution is required to maintain adequate programs to ensure compliance with the laws and regulations pertinent to research but not specific to animal research, such as an occupational health and safety program, a radiation safety program, and a biohazard program.

By signing the present agreement, both institutions agree that the institution that manages the funding source will assume compliance oversight and the ultimate responsibility for the care and use of animals housed for research activities at either the HVA or the LUC/SSOM. In the case of USDA covered species, animals and records maintained at the HVA that are supported by LUC/SSOM-sponsored funds will be subject to USDA inspections, and LUC/SSOM will be the responsible site in terms of USDA actions.

IV. Veterinary Care

Both institutions shall provide adequate veterinary care at their respective institutions in accordance with the Animal Welfare Act [Title 9, CFR Part 2, Subpart C, Section 2.33] and the most recent edition of the *Guide for the Care and Use of Laboratory Animals*.

In addition to providing adequate veterinary care, responsible veterinarians and/or designees will conduct periodic (at least once monthly) evaluations of records and activities related to the health and welfare of all animals supported by funding managed at their site and housed at either the HVA or LUC/SSOM. Included in this review are ACORPs, animal procedures, animal records and census, husbandry and PI records, and other documents required by the IACUC and regulatory agencies.

V. Protocol Review

The appropriate forms that all investigators will be required to complete as part of the IACUC approval process will be dictated by the submission format outlined in Table I.

Table 1. IACUC Protocol Submission and Review Requirements

	LUC/SSOM-SPONSORED RESEARCH	HVA-SPONSORED RESEARCH	HVA Nonprofit-SPONSORED RESEARCH
Animals housed or used solely at LUC/SSOM	<ul style="list-style-type: none"> • LUC/SSOM form • Reviewed by LUC/SSOM IACUC only 	<ul style="list-style-type: none"> • HVA form • Reviewed by LUC/SSOM IACUC and HVA IACUC 	<ul style="list-style-type: none"> • LUC/SSOM form • Reviewed by LUC/SSOM IACUC only
Animals housed or used solely at HVA	<ul style="list-style-type: none"> • HVA form • Reviewed by HVA IACUC and LUC/SSOM IACUC 	<ul style="list-style-type: none"> • HVA form • Reviewed by HVA IACUC only 	<ul style="list-style-type: none"> • HVA form • Reviewed by HVA IACUC only
Animals housed or used at both LUC/SSOM and HVA	<ul style="list-style-type: none"> • HVA form • Reviewed by HVA IACUC and LUC/SSOM IACUC 	<ul style="list-style-type: none"> • HVA form • Reviewed by HVA IACUC and LUC/SSOM IACUC 	<ul style="list-style-type: none"> • HVA form • Reviewed by HVA IACUC and LUC/SSOM IACUC

By this outline the LUC/SSOM IACUC agrees to accept as valid the HVA form as indicated and the HVA IACUC agrees to accept as valid the LUC/SSOM form as indicated.

If a protocol must be reviewed by both IACUCs, personnel may not initiate the research until both IACUCs approve the protocol. If there are differences not easily resolved between the two IACUCs, the chairpersons or designated representatives of the two IACUCs will meet with the investigator to attempt to resolve the issues. However, the final outcome of the resolution must be approved by both IACUCs.

If a protocol requires transportation between institutions for same day treatment, procedures, etc., the protocol will be provided to both IACUCs for review. The institution with the facility to be utilized for the procedure/treatment must approve the transportation.

Prior to initiating changes, investigators who plan to make changes to an approved protocol must obtain written approval from the IACUC that originally reviewed that protocol form. In cases where both IACUCs reviewed the protocol form, written approvals must be obtained from both IACUCs prior to implementing such changes.

Each institution agrees to communicate and accept the decision of the other institution's IACUC with regard to ACORP protocols reviewed by that IACUC. Disapproval of ACORP protocols by HVA's IACUC may not be overturned by LUC/SSOM. Similarly, disapproval of protocols by LUC/SSOM's IACUC may not be overturned by HVA. Each IACUC will report disapproved

protocol titles to the other institution.

VI. Record Keeping and Reports

Each institution agrees to provide the other with copies of approved minutes of their IACUC meetings promptly upon their adoption. Upon request, each institution shall also provide the other with reports, documents and correspondence relevant to animal care and use.

For LUC/SSOM-sponsored research conducted at HVA, the HVA IACUC will provide the LUC/SSOM IACUC a copy of each approved ACORP and a copy of the investigator approval letter. The HVA IACUC will also provide the LUC/SSOM IACUC copies of all approved modifications, annual certifications and adverse event reports.

For HVA-sponsored research conducted at LUC/SSOM, the LUC/SSOM IACUC will provide the HVA IACUC a copy of each approved ACORP and a copy of the investigator approval letter. The LUC/SSOM IACUC will also provide the HVA IACUC copies of all approved modifications, annual certifications and adverse event reports.

Each institution agrees to assist the other in preparing and providing reports (including reports of animal counts) for the USDA, OLAW, AAALAC and VA Central Office and providing other documents or correspondence relevant to animal care and use. Animal numbers will be reported to AAALAC and OLAW annually by the institution housing and maintaining the animals. In the case of USDA-covered species, counts for animals maintained at the HVA that are supported by LUC/SSOM-sponsored funds will be included in the report by LUC/SSOM.

Each institution will conduct its own semiannual evaluations. Each institution agrees to send the other institution a copy of the semiannual inspection report as soon as it is approved by the institution's IACUC.

In addition to receiving results of the semiannual evaluations, the IACUC Administrator/Coordinator and/or designee employed by the institution that manages the funding source will conduct periodic (no less than monthly) evaluations of records/reports related to the care and welfare of animals supported at both sites the HVA and LUC/SSOM. Included in this review are grants, ACORPs, animal records, incident reports, IACUC agenda and meeting minutes, semi-annual inspection and program review reports, and other documents required by the IACUC and regulatory agencies.

VII. IACUC Representation

Each institution agrees to include in its membership voting members of the other institution's IACUC. These liaison representatives will serve as voting members of that IACUC and will be expected to attend monthly meetings and serve as liaison for policies and procedures, informational updates, and other issues as appropriate. Any voting IACUC member may be designated by the respective Chair to serve as a liaison representative to the other institution's committee.

Two LUC/SSOM IACUC liaison members, in addition to the CMF veterinarian, will serve as voting members of the HVA IACUC. ACORPs for animals housed at the HVA and supported by funds managed by LUC/SSOM will be assigned for review to one HVA IACUC member and one LUC/SSOM IACUC liaison member, and reviewed at the HVA IACUC meeting. The LUC/SSOM IACUC liaison member will subsequently present to the LUC/SSOM IACUC the HVA IACUC ACORP's review process, deliberations and outcome at the next scheduled LUC/SSOM IACUC meeting. The LUC/SSOM IACUC will then discuss and vote on the ACORP submission. The LUC/SSOM IACUC reserves the right for a full LUC/SSOM committee review of ACORPs using USDA covered species and studies under USDA Pain Category E. Similar reciprocal review will take place for VA-funded research that houses animals at LUC/SSOM (see Table 1).

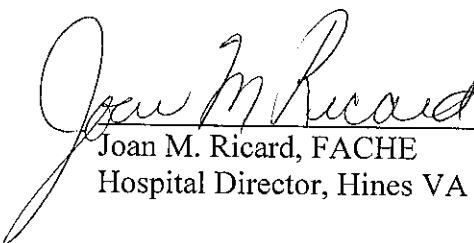
VIII. Non-Compliance

Each IACUC will be responsible for promptly investigating incidents of non-compliance at their own institution which involve LUC/SSOM-, HVA-, or LUC/SSOM/HVA nonprofit-sponsored research relevant to this memorandum. The approving IACUC will submit a written report describing the non-compliance violation and the recourse to correct the violation to the responsible Institutional Official and/or Federal agency. In the case of USDA-covered species, the report will be submitted by LUC/SSOM with input from the HVA-IACUC as appropriate. Information on all verified issues of noncompliance, relevant to this memorandum, must be shared in writing by both IACUCs so that an effective review of related policies and procedures can be completed as required for effective ongoing institutional self-monitoring.

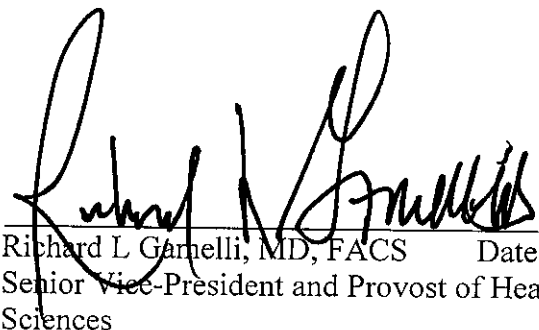
IX. Alteration of Agreement

This Agreement may be modified or altered only by a written document signed by the designated Institutional Officials at both institutions. Either institution may terminate this Agreement on thirty days written notice. Citations from regulatory/federal agencies may result in review, and possible termination of the agreement.

Effective Date: March 01, 2013



Joan M. Ricard, FACHE Date
Hospital Director, Hines VA Hospital



Richard L. Gamelli, MD, FACS Date
Senior Vice-President and Provost of Health
Sciences