**OFFICE OF RESEARCH AND DEVELOPMENT**

**VETERANS HEALTH ADMINISTRATION**

**Drafting an MOU**

(Template Tool Provided by the Office of the CVMO)

# DATE: January 03, 2020 Guidance Document: AR2015-005

*INSTRUCTIONS FOR USING THIS TEMPLATE TOOL*

*{This is a tool for creating a Memorandum of Understanding (MOU) that complies with the Guide for the Care and Use of Laboratory Animals (the Guide, p. 15, see C.4, below) statement that “the participating institutions should have a formal written understanding” about the shared responsibilities related to collaborative research with animals. This tool has been reviewed by USDA and OLAW for consistency with their requirements, and the Specialty Team Advising Research (STAR) group of the Office General Counsel (OGC) for VA, for consistency with VA legal requirements, and incorporates compliance with all the minimum regulatory and accreditation requirements, including those of VA policy and the Guide, as well as other elements recommended to protect both Parties while facilitating effective collaboration on work involving use of animals. It is designed for collaboration between a VA facility and another domestic US institution. Please consult with the office of the CVMO for additional guidance about foreign collaborations.*

*{Instructions and explanations are presented in italics and curly brackets}.*

Suggested text is presented without italics.

*Here are the steps for using this tool:*

1. *Enter the information requested and select the options that apply to your situation.*
2. *Save your draft.*
3. *Delete all options that were not selected, and all text that is in italics and curly brackets.*
4. *Save again.*

*The result will be a framework MOU for your general situation, ready for further customization, as needed. Topics that might be addressed in additional paragraphs include, for example, provisions for emergency housing of animals belonging to one party in the animal facility of the other party, and stipulations about the procurement and use of controlled substances in each location. Add to the framework MOU any further details or specifics that both Parties wish to include.*

*Agreements regarding transfer of funds or commitment of other specific resources (e.g., assignment of space, provision of supplies) are better handled in separate documents, which may be referenced, but are not included directly, in the MOU. Please contact your applicable VA Office of General Counsel (OGC) attorney for further guidance regarding the legal review of any of those documents.*

*This template tool does not provide guidance regarding the appropriateness of any specific proposed collaborative activity, but instead addresses elements that are critical to any collaboration the Parties choose to engage in... “Collaboration” here refers to the interinstitutional relationships for which the Guide (p. 15, see C.4, below) recommends establishment of a formal written understanding.*

*Please consult with the Veterans Health Administration (VHA) Chief Veterinary Medical Officer (CVMO) for issues related to VHA Handbook 1200.07, “Use of Animals in Research”, and with the VHA Office of Research Oversight (ORO), Research Safety and Animal Welfare Team (RSAW), for issues related to VHA Handbook 1058.01, “Research Compliance Reporting Requirements.”*

*It is recommended that the draft MOU be reviewed by each party’s legal counsel before it is signed by those who are authorized to enter into the Agreement, and that the MOU be reviewed by each party at regular intervals and by any individuals who are newly appointed after the MOU takes effect, to ensure that those responsible for carrying out the terms of this document are familiar with its terms.}*

Memorandum of Understanding (MOU)

Between *{Enter the name of the VA Facility}* and *{Enter the name of the Collaborating Institution}*

With Regard to Collaboration on the Use of Animals in Research

Effective Date: The date of the last signature by the authorized agents of the Parties to this MOU.

*{Item H.7 may be moved to this point in the document if the Parties prefer for the signatures and dates to show on the first page.}*

A. Parties to this MOU are:

A.1. *{Enter the name and address of the VA Facility}* (hereafter abbreviated “VAMC” *{Replace “VAMC” with any preferred abbreviation wherever “VAMC” appears in this tool}*).

A.2. *{Enter the name and address of the Collaborating Institution}* (hereafter abbreviated “Collaborating Institution” *{Replace “Collaborating Institution” with the preferred abbreviation wherever “Collaborating Institution” appears in this tool}*).

B. Purpose. Collaborative endeavors depend fundamentally on the good faith efforts of all parties involved, to maintain a healthy, cooperative, and mutually beneficial relationship. The purpose of this MOU is to facilitate those good-faith efforts by defining the expectations of the parties with regard to their collaboration on the use of animals in research, 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 MOU, the terms “Collaboration” or “Collaborative” refer to any joint effort of the Parties to conduct, manage, or oversee research with animals. This includes any work involving contributions from both institutions, such as, but not limited to, personnel conducting the work, facilities where the work is conducted, or resources (e.g., funding, supplies, equipment, or administrative support) used to support the work. *{Add a description of any specific purposes that the Parties wish to include explicitly.}*

C. References. The most recent versions of following documents are the foundation for the terms of this MOU. This is not an exhaustive list, but highlights the regulatory references of particular relevance to collaborative efforts involving animal research.

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 (PL 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 (formerly “Association for Assessment and Accreditation of Laboratory Animal Care International”) 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 Directive 1200.01, “Research and Development Committee.”**

**C.9. VHA Directive 1200.02, “Business Operations.”**

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

**C.11. USDA “Animal Welfare Inspection Guide”.**

D. General stipulations

D.1. Parties agree to comply with the References cited under Section C regarding the Collaborative activities covered by this MOU. *{This commits the VAMC to keeping the Collaborating Institution informed about relevant VA policies, and the Collaboration Institution to cooperating with efforts to comply with VA policies, but does not commit the Collaborating Institution to being expertly versed with all of VA’s policies.}*

D.2. For the purposes of this document, Parties agree that the term “VAMC IACUC of record” refers generally to the Institutional Animal Care and Use Committee (IACUC) that is held responsible for oversight of VAMC research with animals, according to the terms of the applicable Public Health Service Animal Welfare Assurance (PHS Assurance) approved by the National Institutes of Health Office of Laboratory Animal Welfare (OLAW) and this MOU. The various arrangements under which an IACUC may take on this role are described in par. F, below.

D.3. Parties agree that all animal research that is considered “VA research” must comply with VA policy, as set forth in VHA Handbooks 1200.07 (ref. C.10, above), 1058.01 (ref. C.7, above), and 1200.02 (ref. C.9, above), and VHA Directive 1200.01 (ref. C.8, above). This includes not only research that is supported by Department of Veterans Affairs (VA) funds, but also any research conducted on VA property or by VAMC personnel on VA duty time, or otherwise as defined by VHA Directive 1200 (ref. C.6, above). Parties agree that VA research with animals may not begin at the VAMC or at the Collaborating Institution until after the VAMC IACUC of record notifies the VAMC Research and Development (R&D) Committee that the activity has been granted IACUC approval according to the terms of this MOU, and the VAMC Associate Chief of Staff for Research and Development (ACOS/R&D) notifies the Principal Investigator (PI) in writing that the work has been granted approval by the VAMC R&D Committee (VHA Directive 1200.01, ref. C.8, above, and Handbook 1200.07, ref. C.10, above).

D.4. Parties agree that all research that is considered “Collaborating Institution research” must comply with the policies of the Collaborating Institution. Parties agree that Collaborating Institution research with animals may only begin with the permission of the Collaborating Institution. *{Revise this stipulation to reflect what the Collaborating Institution’s wishes to specify in this MOU.}*

D.5. Parties agree that Collaborative research with animals may be subject to the oversight of both the VAMC IACUC of record and the Collaborating Institution’s IACUC, in which case, each Party agrees that such research will be conducted only if it meets both the requirements of the VAMC and the requirements of the Collaborating Institution.

D.6. Parties agree that the ultimate authority to interpret any regulatory requirement rests with the agency or entity that published and administers it.

D.7. Parties agree to document in writing the ownership of each animal used in Collaborative research, and to report the use of animals to USDA according to Section E, below.

D.8. 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, and to respect the security and access requirements of each Party.

D.9. 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 state open records laws) that addresses any aspect of their Collaboration, 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.10. 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 activities.

E. Stipulations related to the facilities to be used for research with animals that is covered by this MOU

E.1. The facilities to be used for research covered by this MOU and involving animals regulated by USDA, must be registered with the USDA (USDA AWAR, ref. C.1, above, and VHA Handbook 1200.07, ref. C.10, above). Each animal of a USDA-regulated species that must be reported to USDA on the Animal and Plant Health Inspection Service (APHIS) Form 7023 (Annual Report of Research Facility), must be reported only once for each year in which it participated in research, by a party registered with USDA. If more than one procedure was performed during the year, the animal must be reported in the column of Form 7023 that corresponds to the procedure that requires the highest assignment (B being the lowest, and E being the highest), regardless of who owned the animal or where it was housed when the procedure was performed (ref. C.1 and C.11, above).

***{Select one of the five options below, E.1(a)-E.1(e), regarding USDA registration and reporting the use of USDA-regulated animals.}***

*{E.1(a) [ ]}* Only the VAMC is independently registered with USDA, so Collaborative research with USDA-regulated animals covered by this MOU may only be conducted at the VAMC, and the VAMC will report all of the animals involved in that research in addition to all those used by the VAMC alone.

*{E.1(b) [ ]}* Only the Collaborating Institution is independently registered with USDA, so Collaborative research with USDA-regulated animals covered by this MOU may only be conducted at the Collaborating Institution, unless the VAMC is included as one of the Collaborating Institution’s sites in the Collaborating Institution’s registration. The Collaborating Institution will report all of the USDA-regulated animals used in the research covered by this MOU.

*{E.1(c) [ ]}* Both the VAMC and the Collaborating Institution are independently registered with USDA, and each Party will report all of the USDA-regulated animals that it housed during the reporting year. If an animal was housed by both Parties at different times during the reporting year, it will be reported by the Party that housed it when the procedure that requires the highest assignment was performed. If the procedures performed while the animal was housed by each Party require the same column assignments, it will be reported by the Party that housed it last.

*{E.1(d) [ ]}* Both the VAMC and the Collaborating Institution are independently registered with USDA and each Party will report all of the USDA-regulated animals that it owned during the reporting year. If ownership of an animal was transferred during the reporting year, it will be reported by the Party that owned it when the procedure that requires the highest assignment was performed. If the procedures performed while the animal was owned by each Party require the same column assignments, it will be reported by the Party that owned it last.

*{E.1(e) [ ]}* *{Enter a description of any other arrangement by which registration with USDA and reporting animals of USDA-regulated species are to be handled.}*

E.2. The facilities that are to be used for research with animals covered by this MOU must be covered by a PHS Assurance approved by OLAW (VHA Handbook 1200.07, ref. C.10, above).

***{Select one of the two options below, E.2(a) or E.2(b), regarding how the facilities will be covered.}***

*{E.2(a) [ ]}* Each Party will maintain its own independent PHS Assurance, approved by OLAW, covering those of its facilities that are used for research with animals that is covered by this MOU.

*{E.2(b)[ ]}* The Collaborating Institution will maintain a PHS Assurance, approved by OLAW, that covers the VAMC’s program of research with animals, including the VAMC’s facilities for research with animals, as a named component of the Collaborating Institution’s program for animal care and use. *{VA policy requires that the VA program be covered by an OLAW-approved PHS Assurance.}* The IACUC described in the PHS Assurance is the single IACUC recognized by OLAW as responsible for the oversight of all research with animals at either the VAMC or the Collaborating Institution.

E.3. Full AAALAC International accreditation must be maintained for the facilities used for any research with animals that is covered by this MOU, at the VAMC or at the Collaborating Institution (VHA Handbook 1200.07, ref. C.10, above).

***{Select one of the two options below, E.3(a) or E.3(b), regarding how the facilities will be accredited.}***

*{E.3(a) [ ]}* Each Party will maintain independent full accreditation by AAALAC International, covering all portions of its facilities that are used for any research with animals that is covered by this MOU.

*{E.3(b) [ ]}* The Collaborating Institution will maintain full accreditation by AAALAC International, covering the facilities of the VAMC as a named satellite facility of the Collaborating Institution, as well as all portions of its own facilities that are used for research with animals that is covered by this MOU.

E.4. Appropriate veterinary care and routine husbandry will be provided as follows to all animals involved in research under the terms of this MOU:

***{Select one of the five options below, E.4(a)-E.4(e), regarding how veterinary care and routine husbandry will be managed.}***

*{E.4(a) [ ]}* 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.4(b) [ ]}* by the personnel and according to the SOPs of the Party that owns the animals, regardless of which Party houses them.

*{E.4(c) [ ]}* by VAMC personnel according to VAMC SOPs, regardless of where the animals are housed or which Party owns them.

*{E.4(d) [ ]}* by Collaborating Institution personnel according to the Collaborating Institution’s SOPs, regardless of where the animals are housed or which Party owns them.

*{E.4(e) [ ]}* *{Enter a description of any other arrangement by which the responsibilities of providing veterinary care and routine husbandry are to be assigned.}*

E.5. As required by PHS Policy, all personnel involved in Collaborative activities covered by this MOU must have the opportunity to participate in an Occupational Health and Safety Program (OHSP) that includes a periodic individual risk assessment related to exposure to animals or their unfixed tissues or fluids (VHA Handbook 1200.07, ref. C.10, above).

E.5(a) All personnel involved in Collaborative activities covered by this MOU are eligible to participate at no charge in the OHSP that is offered by the VAMC, which complies with PHS Policy and is described in Appendix C of VHA Handbook 1200.07 (ref. C.10, above).

E.5(b) Parties agree that personnel involved in activities covered by this MOU may waive participation in the VAMC OHSP only if they participate instead in a PHS-compliant OHSP that is offered by the Collaborating Institution or another institution acceptable to the VA. *{VA policy requirement}*

*{Enter any stipulations of the Collaborating Institution with regard to participation of the personnel in an OHSP.}*

F. Stipulations related to IACUC oversight. All Collaborative research with animals that is covered by this MOU is subject to the oversight of the VAMC IACUC of record, which is the IACUC identified in the OLAW-approved PHS Assurance that covers the VAMC program of research with animals.

*{Note: Because of PHS Policy requirements, there are three options for the VA IACUC of record:*

* *Option 1. The VAMC is covered by its own OLAW-approved PHS Assurance and has an internal IACUC of record, which is a committee hosted and managed by the VAMC. Go to Option 1 below and delete Options 2 and 3.*
* *Option 2. The VAMC is covered by its own OLAW-approved PHS Assurance and has an external IACUC, which is a committee hosted and managed by the Collaborating Institution. Note that OLAW requires the VAMC director to appoint each of the members of this committee to the VAMC IACUC because it is the VAMC IACUC recognized by the VA’s PHS Assurance. Go to Option 2 below and delete Options 1 and 3.*
* *Option 3. The VAMC does not have its own OLAW-approved PHS Assurance, but is instead covered as a named component of the Collaborating Institution’s program in the Collaborating Institution’s OLAW-approved PHS Assurance. OLAW recognizes only one IACUC per Assurance, so the IACUC of the Collaborating Institution is the VAMC IACUC of record. OLAW does not require the VAMC director to appoint members to this IACUC because the VAMC does not have its own Assurance. Go to Option 3 below and delete Options 1 and 2.}*

*{Select one of the three options below:}*

*{Option 1 [ ]}* The Parties hold independent OLAW-approved PHS Assurances and have independent IACUCs (referred to as “internal IACUCs”). Each internal IACUC oversees all activities for which its institution bears complete or partial responsibility. Both Parties share responsibility for any Collaborative activities covered by this MOU, and agree to coordinate that shared oversight as described below:

***{all of the following stipulations, F.1 through F.6, apply if the Parties hold independent PHS Assurances and have independent internal IACUCs.}***

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

*{Option 1}*F.2. Although each Party may agree generally to rely (as described below) on the outcomes of the other Party’s actions related to Collaborative activities (including but not limited to protocol reviews, program and facility reviews, investigations, and determinations about reporting), each Party retains the right to act independently, if circumstances dictate, and solely at its own discretion. Each Party agrees to exercise that discretion only as necessary to meet its oversight responsibilities, and to allow access to the other Party to its facilities and records as needed for the other Party 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.

*{Option 1}*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). For Collaborative activities between domestic institutions that each holds an approved PHS Assurance, PHS policy also does not require dual approval. VA policy requires that research with animals may be conducted on VA property only with appropriate IACUC approval, as described in this paragraph. VA policy also requires that research with animals that is supported with VA funds must be processed in the VA Just-in-Time (JIT) system. These requirements will be addressed for work covered by this MOU as follows:

***{Select one of the two options below, F.3(a) or F.3(b), to indicate how the review and approval of protocols for Collaborative research with animals will be handled by the two IACUCs.}***

*{Option 1:F.3(a) [ ]}* Each IACUC will make its own independent determination regarding approval, based on its own complete review of each protocol or relying at its discretion on the determination of the other IACUC. For activities to be supported by VA funding, the VAMC IACUC will reviewed only protocols on the current VA Animal Component of Research Protocol (ACORP) form, as that form is required for JIT processing before release of funding. After granting approval, each IACUC will provide documentation of its review and approval, and a copy of the approved protocol, to the other IACUC. Each IACUC will review any changes in the protocol required by the other IACUC, and will require modification to secure approval of the protocol it oversees, to ensure that the two protocols are congruent and compliant with regulatory requirements. No work on the Collaborative activity may be carried out until both the VAMC IACUC and the Collaborating Institution’s IACUC have granted approval of congruent protocols for the Collaborative activity. Unless the Parties agree otherwise in writing, on a case-by-case basis, the IACUC that will review the protocol first will be:

***{Select one of the five options below, F.3(a)(1) – F.3(a)(5), regarding how it will be decided which party will review the protocol first.}***

*{Option 1:F.3(a)(1) [ ]}* the IACUC of the Party that houses the animals for the protocol, if all animals on the protocol are housed by only one Party.

*{Option 1:F.3(a)(2) [ ]}* the IACUC of the Party that owns the animals, if all animals on the protocol are owned by only one Party.

*{Option 1:F.3(a)(3) [ ]}* the VAMC IACUC, regardless of where the animals are housed or which Party owns them.

*{Option 1:F.3(a)(4) [ ]}* the Collaborating Institution’s IACUC, regardless of where the animals are housed or which Party owns them.

*{Option 1:F.3(a)(5) [ ]}* *{Enter a description of any other arrangement by which the primary responsibility for review of a protocol for Collaborative activity is to be assigned.}*

*{Option 1:F.3(b) [ ]}* The CVMO has granted approval for the VAMC to rely on the review and approval of the IACUC of the Collaborating Institution, for protocols to be conducted at the Collaborating Institution.  *{Approval of the CVMO is a VA requirement.}* The VAMC IACUC will accept the approval of that IACUC as sufficient for meeting the VA requirement for IACUC approval. The Collaborating Institution will provide documentation of its review and approval, and a copy of the final approved version of the protocol, to the VAMC IACUC. The VA does not require the protocol to be on the VA ACORP form, but the Collaborating Institution understands that if work on the protocol requires VA secondary review (see Guidance Document AR2017-001), the Collaborating Institution’s IACUC will be responsible for responding as instructed to the secondary review comments, so that VA permission for the work to proceed can be secured, and VA funding can be released.

*{Option 1}*F.4. Each IACUC that is responsible for granting approval of any protocol for Collaborative activity covered by this MOU will confirm that all research personnel identified on the protocol are qualified to perform the procedures assigned to them on the protocol. The minimum training requirements are as follows:

F.4(a) VA policy requires that each individual (regardless of institutional affiliation) who is identified as a member of the research staff on a protocol for VA research with animals must complete the training specified by VA policy (VA training requirements available on request). *{Enter any additional local requirements of the VAMC.}* The VAMC will provide on request by the Collaborating Institution, documentation of the status of each individual for the training required by VA.

F.4(b) Collaborating Institution policy requires *{Enter any additional training requirements of the Collaborating Institution.}* The Collaborating Institution will provide on request by the VAMC, documentation of the status of each individual for the training required by the Collaborating Institution.

*{Option 1}*F.5. Each IACUC must evaluate semiannually the animal use programs and facilities that are covered by its own PHS Assurance, and will inform the other IACUC promptly of any important concerns noted, and corrective actions planned and taken, that are relevant to the Collaborative activities. Both Parties agree to review such information that is received, and to honor reasonable requests submitted by the other IACUC for additional details and updates (see “sharing of information”, Section G, below). Each IACUC is independently responsible for reporting the results of its own semiannual evaluations to its own Institutional Official (IO).

*{Option 1}*F.6. In cases of potential regulatory noncompliance related to the animals involved in Collaborative activities covered by this MOU, one Party will 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 any aspect of the other program to the attention of the IACUC that oversees it. Any reports to external oversight entities will clearly acknowledge the involvement of both Parties in the Collaborative activity (including the relevant identifiers for USDA registration, PHS Assurances, grants, AAALAC accreditation, etc.).

*{Option 1}*F.6(a) To facilitate coordination of oversight, each Party agrees to notify the other promptly (within two (2) business days) if its IACUC acts to change the approval status of any protocol that it has previously approved for Collaborative activity (e.g., suspension of IACUC approval, lifting the suspension of IACUC approval). Any Collaborative activity covered by this MOU must stop if any approval that was granted is suspended, and may not resume until the suspension is lifted. In cases in which the VAMC relies on the approval granted by the Collaborating Institution’s IACUC, the Parties agree that the Collaborating Institution will honor requests from the VAMC to suspend approval for a project covered by this MOU, and the VAMC will only request suspension if it would otherwise have suspended its own approval.

*{Option 1}*F.6(b) The VAMC IACUC will submit any reports about Collaborative activities that are required by the VHA Office of Research and Development (ORD) or the VHA 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 non-compliance, the Collaborating Institution agrees to provide information promptly to the VA IACUC, as follows:

*{Option 1}*F.6(b)(1) Any information suggesting potential regulatory noncompliance related to the Collaborative activity covered by this MOU will be provided to the VAMC IACUC within five (5) business days of receipt, regardless of the status of any investigation, as required by VHA Handbook 1058.01.

*{Option 1}*F.6(b)(2) Responses to reasonable requests submitted by the VAMC IACUC for updates on the Collaborating Institution’s investigation and additional details of information already collected (see “sharing of information”, Section G, below) will be provided in a timely fashion so that the VAMC can be prepared to respond to inquiries from the public

*{Option 1}*F.6(b)(3) Any determination by the Collaborating Institution’s IACUC that a matter is reportable will be communicated to the VA IACUC immediately, so that the VA IACUC can forward this information to the VA Medical Center Director within five (5) business days of the determination, as required by VHA Handbook 1058.01.

*{Option 1}*F.6(b)(4) Information about any corrective action plan prepared, corrective actions completed, or sanctions imposed or lifted, will be communicated promptly to the VAMC IACUC (within five (5) business days of such actions being taken).

*{Option 1:F.6(c). Enter here any corresponding requirements of the Collaborating Institution with regard to the timeline for receiving information about potentially reportable matters from the VAMC.}*

*{Option 1}*F.6(d). Unless the Parties agree otherwise in writing for a particular matter, primary responsibility for addressing any matter of potential noncompliance regarding Collaborative activities will be taken by:

***{Select one of the six options below, F.6(c)(1)- F.(c)(6), to indicate how primary responsibility for addressing each potential regulatory noncompliance related to animal welfare is to be assigned.}***

*{Option 1:F.6(c)(1) [ ]}* the IACUC of the Party to whose attention any matter of potential noncompliance was initially brought

*{Option 1:F.6(c)(2) [ ]}* the IACUC of the Party in whose facilities the involved animals were all housed at the time of the potential noncompliance

*{Option 1:F.6(c)(3) [ ]}* the IACUC of the Partythat owned the involved animals at the time of the potential noncompliance

*{Option 1:F.6(c)(4) [ ]}* the VAMC IACUC, regardless of where the animals are housed or which Party owns them.

*{F.6(c)(5) [ ]}* the Collaborating Institution IACUC, regardless of where the animals are housed or which Party owns them.

*{F.6(c)(6) [ ]} {Enter a description of any other arrangement by which primary responsibility for addressing potential noncompliance is to be assigned.}*

***{Go to Paragraph G}***

*{Option 2 [ ]}* The Parties hold independent OLAW-approved PHS Assurances and the members of the Collaborating Institution’s IACUC also serve as the members of the VAMC IACUC (referred to as an “external VAMC IACUC”).

*{Option 2}*F.1. Each individual appointed by the Chief Executive Officer of the Collaborating Institution to serve as a member of the Collaborating Institution’s IACUC will also be appointed officially, in writing, by the VAMC Director (who is the CEO of the VAMC) to serve as a member of the external VAMC IACUC (VHA Handbook 1200.07, ref. C.10, above).

*{Option 2}*F.2. The Collaborating Institution will include as full voting members of its IACUC, the VAMC Attending Veterinarian and a VAMC representative appointed by the VAMC Director, as VA requires these to be members of the external VAMC IACUC. These members are expected to help inform the IACUC of VA-specific requirements as needed. If the Non-Affiliated Member of the IACUC for the Collaborating Institution is affiliated with the VAMC, the Parties agree to ensure that the IACUC includes another member who qualifies to serve as the Non-Affiliated Member for the VAMC IACUC.*{Option 2}*F.3. The external VAMC IACUC will comply with VA policy (as established in VHA Handbook 1200.07, ref. C.10, above) for all matters related to VAMC research with animals. This includes, but is not limited to, the following:

*{Option 2}*F.3(a). When the external VAMC IACUC reviews protocols that require VA secondary review (see Guidance Document AR2017-001), it will require the protocols to contain all of the information required by the VA ACORP form. The external VAMC IACUC may accept protocols submitted on the VA ACORP form, or if the forms of the Collaborating Institution are used instead, the external VAMC IACUC will require all information that is required on the ACORP but not requested on the standard form of the Collaborating Institution to be provided as an appendix or to be otherwise included for review and approval as part of the protocol. Any omissions or inadequacies in a protocol (including its appendices) that is submitted for JIT processing will be identified in the secondary review, and instructions will be provided for addressing these. The external VAMC IACUC will be responsible for responding as instructed to the secondary review comments, so that VA permission to proceed with the work can be secured, and VA funding can be released.

*{Option 2}*F.3(b) Confirming that each individual (regardless of institutional affiliation) who is identified as a member of the research staff on a protocol for VAMC research with animals completes the training specified by VA policy (VA training requirements available upon request). The VAMC will provide on request, documentation of the completion of the training required by VA

*{Option 2}*F.3(c) Ensuring that at least two (2) Designated Members participate whenever protocol review by the external VAMC IACUC is conducted by Designated Member Review.

*{Option 2}*F.4. The Collaborating Institution agrees to inform the VAMC of any action of the external VAMC IACUC pertinent to the VAMC program of research with animals. This includes, for example, prompt verbal notification when a potentially reportable matter has come to the attention of the external VAMC IACUC and is pending investigation. The VAMC Attending Veterinarian and VAMC representative on the external VAMC IACUC serve as liaisons and are authorized to communicate freely with the VAMC regarding any action of the external VAMC IACUC.

*{Option 2}*F.5. The VAMC will be responsible for submitting any reports about Collaborative activities that are required by the VHA ORD or ORO.

***{Go to Paragraph G}***

*{Option 3 [ ]}* The VAMC’s program of research with animals is covered as a named component of the program of the Collaborating Institution in the OLAW-approved PHS Assurance held by the Collaborating Institution, so the Collaborating Institution’s IACUC serves as the VAMC IACUC of record.

*{Option 3}*F.1. The Collaborating Institution will include a VAMC representative as a full voting member of the Collaborating Institution’s IACUC, which serves as the VAMC IACUC of record. *{A VA requirement}* This VAMC representative serves as a liaison between the Collaborating Institution’s IACUC and the VAMC, keeping the VAMC informed of IACUC actions, and keeping the IACUC informed of VA requirements. The VAMC representative will be selected by the VAMC Research and Development Service and representatives of the Collaborating Institution to be mutually acceptable to both Parties.

*{Option 3}*F.2. The Collaborating Institution’s IACUC serving as the VAMC IACUC of record will comply with VA policy (as established in VHA Handbook 1200.07, ref. C.10, above) for VA research with animals. This includes, but is not limited to, the following:

*{Option 3}*F.2(a) When the Collaborating Institution’s IACUC serving as the VAMC IACUC of record reviews protocols that require VA secondary review (see Guidance Document AR2017-001), it will require the protocols to contain all of the information required by the VA ACORP form. The IACUC may accept protocols submitted on the VA ACORP form, or if the forms of the Collaborating Institution are used instead, the IACUC will require all information that is required on the ACORP but not requested on the standard form of the Collaborating Institution to be provided as an appendix or to be otherwise included for review and approval as part of the protocol. Any omissions or inadequacies in a protocol (including its appendices) that is submitted for JIT processing will be identified in the secondary review, and instructions will be provided for addressing these. The IACUC will be responsible for responding as instructed to the secondary review comments, so that VA permission to proceed with the work can be secured, and VA funding can be released.

*{Option 3}*F.2(b) Confirming that each individual (regardless of institutional affiliation) who is identified as a member of the research staff for a protocol for VAMC research with animals completes the training specified by VA policy (VA training requirements available upon request). The VAMC will provide on request, documentation of the completion of the training required by VA

*{Option 3}*F.2(c) Ensuring that at least two (2) Designated Members participate whenever review of a protocol for VAMC research with animals is conducted by Designated Member Review.

*{Option 3}*F.3. The Collaborating Institution agrees to inform the VAMC of any IACUC action pertinent to VAMC research with animals. This includes, for example, prompt verbal notification when a potentially reportable matter has come to the attention of the Collaborating Institution’s IACUC, even if IACUC investigation is still pending. The VAMC representative on the Collaborating Institution’s IACUC serves as liaison and is authorized to communicate freely with the VAMC regarding any action of the IACUC serving as the VAMC IACUC of record.

*{Option 3}*F.4. The VAMC will be responsible for submitting any reports about Collaborative activities that are required by the VHA ORD or ORO.

G. Stipulations regarding the sharing of information between the VAMC and the Collaborating Institution

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.

***{Select one of the two options below, G.1(a) or G.1(b), regarding delivery of the information and documents.}***

*{G.1(a) [ ]}* Each Party has its own independent IACUC, and each IACUC agrees to provide the information and documents to the other IACUC.

*{G.1(b) [ ]}* VAMC research with animals is overseen by an external VAMC IACUC *{Option 2 for paragraph F, above}*, or by the Collaborating Institution’s IACUC serving as the VAMC IACUC of record *{Option 3 for paragraph F, above}*, so the IACUC agrees to provide the information and documents to the VAMC ACOS/R&D and/or the VAMC R&D Committee.

G.2. Redaction of information from copies of documents to be provided (VHA Handbook 1200.07, ref. C.10, above).

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

G.2(b) The VAMC agrees that any Collaborating Institution document to be shared with VA may be redacted of information not relevant to matters covered by this MOU, provided the unredacted version is available for VA representatives to review at the Collaborating Institution during normal business hours, within three (3) business days of request.

G.2(c) The Collaborating Institution agrees that any VAMC document to be shared with the Collaborating Institution may be redacted of information not relevant to matters covered by this MOU, provided the unredacted version is available for Collaborating Institution representatives to review at the VAMC during normal business hours, within three (3) business days of request.

G.3. Documents to be shared– Each Party agrees to provide promptly on request all documents needed by the other Party to meet its regulatory obligations, and to limit its own requests to those documents that are reasonably needed. Each Party agrees to provide to the other Party, routinely and in a timely fashion, without waiting for request, a copy (which may be redacted as described in G.2, above) of each of the following documents relevant to the Collaborative activities covered by this MOU (VHA Handbook 1200.07, ref. C.10, above):

G.3(a) The full current version of each protocol, amendment, or renewal that was approved by the IACUC of record for the Collaborative activity, and documentation of the approval by the IACUC of record.  *{This is a PHS requirement.}*

G.3(b) Documentation that a PHS Assurance approved by OLAW is currently in place, and the date on which that approval will expire.

G.3(c) Documentation of current AAALAC International Accreditation status (e.g., continuing full, deferred, probationary) and the date of the most recent update of that status.

G.3(d) Correspondence with any oversight entity, that is relevant to the Collaborative activities with animals – e.g., reports of noncompliance, reports from an oversight entity about routine or “for cause” site visits, institutional responses to site visit reports.

***{Select item G.3(e), below, for sharing of IACUC documents if the VAMC does not have an internal IACUC of record.}***

*{[ ]}* G.3(e) The VAMC has an external IACUC *{Option 2 for paragraph F, above}*, or the Collaborating Institution’s IACUC serves as the VAMC IACUC of record *{Option 3 for paragraph F, above}*, so the IACUC agrees to provide to the VAMC ACOS/R&D and/or the VAMC R&D Committee the final version of each report of a semiannual evaluation, signed to indicate approval by a majority of the total voting membership of the VAMC IACUC of record. This final version of the report will be reviewed with the VAMC Director by representatives of the VAMC IACUC of record, as described in guidance document AR2016-001 (available at <https://www.research.va.gov/programs/animal_research/guidance.cfm>). This review must be conducted promptly after the report is approved by the IACUC, so that a copy showing the VAMC Director’s signature can be sent to the office of the CVMO within sixty (60) calendar days of when it was approved by the IACUC. *{This is a VA requirement.}*

G.4. Other information to be shared routinely – Each Party agrees to notify the other Party promptly about all other matters relevant to the Collaborative activities covered by this MOU (VHA Handbook 1200.07, ref. C.10, above), 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 will be notified within two (2) business days of receipt of the information, even if IACUC investigation of the matter is still pending, so that both Parties can be prepared to address any inquiries received.

G.4(b) The outcome of any investigation by the IACUC regarding any matter that is potentially reportable and relevant to the Collaboration; the VAMC will receive notification of such outcomes immediately, so that VA requirements for reporting to the VAMC Director and then to the VHA ORO can be met. *{Add here any requirement of the Collaborating Institution regarding the timeline it requires.}*

G.4(c) Receipt of any FOIA request or other open records request regarding Collaborative activities; the other Party will be notified within two (2) business days of receipt of the request.

G.4(d) Any public disclosure (including press releases) regarding Collaborative activities; each Party will notify the other Party at least five (5) 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) Transportation of animals between the facilities of the two Parties; in addition to information needed for the other Party to prepare appropriately for sending or receipt of animals (species, numbers, mode of transportation, schedule, etc.), each Party will identify each of the key members of its personnel who are responsible for the approval of the transfer, the transport process, or the receipt of the animals, and provide their contact information to the other Party.

G.4(f) Identification of key individuals – Each Party will identify and ensure that the other Party has the current contact information for its personnel who are responsible for the following functions in support of the Collaboration *{The language below, for providing the names and contact information in the MOU is just for convenience. If the Parties prefer, the MOU may specify only that the information for these functions will be provided.}*:

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

For VAMC: *{Enter the name and contact information for the individual who will serve as the VAMC point of contact regarding the care of the animals addressed by this MOU.}*

For Collaborating Institution: *{Enter the name and contact information for the individual who will serve as the Collaborating Institution’s point of contact regarding the care of the animals addressed by this MOU.}*

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

For VAMC: *{Enter the name and contact information for the individual who will serve as the VA point of contact regarding IACUC operations and communications with the other Collaborating Institution.}*

For Collaborating Institution: *{Enter the name and contact information for the individual who will serve as the Collaborating Institution’s point of contact regarding IACUC operations and communications with the VAMC.}*

H. Additional Terms and Conditions

H.1 This MOU neither authorizes nor memorializes any exchange or commitment of funds between the Parties. Should the Parties’ relationship and reciprocal responsibilities mature to the point where funds must be exchanged or committed, appropriate procurement/contracting/reimbursable agreements and documents will be implemented and executed by the Parties’ authorized representatives. Each Party is responsible for its own costs and expenses, and the VA’s participation is subject to the availability of appropriated funds.

H.2. Parties agree to work in good faith to amend this document as needed to reflect changes in the circumstances or policies of either Party. Amendments must be bilaterally executed in writing and signed by authorized representatives of both Parties. No oral or unilateral amendments will be effective. The current version of the MOU will be reviewed by each Party at least annually, to ensure that its provisions continue to be appropriate and to identify and address any changes that are needed. *{Enter maximum interval between reviews, as preferred by both Parties.}*

H.3. This MOU will remain in effect indefinitely *{H.2, above, specifies that the MOU is to be reviewed annually, so “indefinitely” here merely reduces the risk of a lapse. Any shorter interval that the Parties prefer may be specified here instead.}*, unless either Party elects to terminate the agreement and provides written notice to the other Party six (6) months prior to the termination date.

H.4. If either Party fails to satisfactorily fulfill its obligations, promises, terms, or conditions of this MOU, and having been given reasonable notice of and opportunity to take corrective actions and not having taken satisfactory corrective action within the time specified by the other Party, the other Party will have the right to terminate this MOU by giving written notice of such termination at least fourteen (14) 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 (6) months before the effective date of such termination. After a termination notice is received, no additional animals will be procured for Collaborative activities; the Parties will 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 activities will terminate no later than when the MOU terminates. *{Enter further specific provisions about termination as desired by both Parties.}*

H.5. Disputes – Disputes will be documented in writing that clearly states the disputed issue and the reason for the dispute. Any dispute will be submitted jointly to VAMC and Collaborating Institution in accordance with G.4.f(2). Both Parties agree to make all reasonable good faith efforts to resolve the dispute by mutual agreement. Both Parties agree that the VHA CVMO and senior administrators of the Collaborating Institution may be consulted for guidance in resolving the dispute. If agreement cannot be reached at this level, the disagreement will be raised to the next highest level. 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.6. Liability - Neither Party indemnifies the other Party for any action. Collaborating Institution will be responsible for any loss or damage caused by its and its employees, officers, and directors' acts or omissions in the performance of this MOU. VA is a federal entity of the United States. The liability, if any, of the United States for damage to or loss of property, or personal injury or death will be governed exclusively by the provisions of the Federal Tort Claims Act. *{Enter any provisions required by the Collaborating Institution with regard to addressing negligence on the part of the Collaborating Institution’s personnel.}*

H.7. Each of the undersigned certifies that s/he is authorized to enter into this MOU on behalf of the Party s/he represents and has read and agrees to all terms stated herein.

For the Collaborating Institution

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Signature Date

Name:

Title:

For the VAMC

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Signature Date

Name:

Title: Medical Center Director