

DOD-CONTRACTED MEDICAL TRAINING INVOLVING USE OF LIVE ANIMALS COMMERICAL VENDOR REVIEW & APPROVAL PROCESS

This information paper provides guidance for prospective vendors, and secondarily for DoD contracting personnel, on Component specific submission, review, and approval processes for government contracting of medical training involving use of live animals, including requirements for obtaining “approved vendor” status. Any questions should be directed to the respective DoD Component Animal Use Oversight office.

Prior to submission of a solicitation proposal, all prospective vendors desiring to bid on a government contract for medical training of DoD personnel, if involving use of live animals, *must first* be granted approval and included on the most current list of approved vendors, *for each individual Component they plan to support*. All DoD and Component specific requirements must be met in order to obtain initial “approved vendor” status. Upon obtaining initial approval, in order to maintain this status, per DoD Instruction 3216.01, compliance inspections are required to be completed annually thereafter.

1. U.S. ARMY (Conventional Forces)

A. References

- (1) Animal Welfare Act, Title 7, U.S. Code, Sections 2131-2158, as amended, and Animal Welfare Act Regulations, Title 9, Code of Federal Regulations, Animals and Animal Products, chapter 1, subchapter A, Animal Welfare, Parts 1-4, as amended.
- (2) DoD Instruction 3216.01, Use of Animals in DoD Programs, 13 Sep 2010
- (3) DoD Instruction 1322.24, Medical Readiness Training, 6 Oct 2011
- (4) Army Regulation 40-33, The Care and Use of Laboratory Animals in DoD Programs, 16 Feb 2005 (*currently undergoing major revision*)
- (5) DoD Component Animal Use Management Plan for the U.S. Army, 18 Apr 2012
- (6) AR 350-1, Army Training and Leader Development, 18 Dec 2009/RAR 4 Aug 2011
- (7) HQDA EXORD 096-09, Mandatory Pre-Deployment Trauma Training (PDTT) For Specified Medical Personnel, 18 Dec 2006, with modifications
- (8) HQDA ALARACT 173-2013, Army Medical Readiness Training Involving Use of Live Animals, 13 Jul 2013
- (9) AMEDDC&S Policy Memo 13-016, Receipt and Review of Commercial Vendor Programs of Instruction (POI), 6 Jun 2013

B. Instructions for Vendors – Submission, Review, and Approval Process

(1) Program of Instruction (POI) Review: See reference (9) above. Contact the Army Medical Department Center & School (AMEDDC&S), G3/5/7 Operations, Fort Sam Houston, TX, via e-mail, at usarmy.jbsa.medcom-ameddcs.list.ops@mail.mil, to request POI submission requirements. The POI, along with any required support documents, should be submitted per AMEDDC&S guidance and NOT sent directly to the above e-mail address. Upon receipt, requests will be logged and forwarded to the Academy of Health Sciences (AHS), Office of the Dean, for review by the appropriate subject-matter-expert (SME). Once POI review has been completed, and all concerns appropriately addressed, written approval will be provided by the AMEDCC&S. Date of final POI approval will then be entered into the DoD vendor tracking database for administrative and contracting purposes.

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(2) Animal-Use Protocol Administrative Review: Concurrent with POI submission to AMEDDC&S, or upon receipt of written POI approval, contact the Program Manager, U.S. Army Medical Research and Materiel Command Animal Care and Use Review Office (USAMRMC ACURO), (301) 619-6694, to initiate the animal-use protocol administrative review process. The proposed animal-use protocol, along with required support documents, should be submitted to ACURO, via e-mail (usarmy.detrick.medcom-usamrmc.other.acuro@mail.mil). Upon completion of administrative review, ACURO will provide a list of required and recommended changes, along with items needing additional clarification. Once clarification has been provided, and all required changes made, ACURO will issue approval of the animal-use protocol. Date of final protocol approval will then be entered into the DoD vendor tracking database for administrative and contracting purposes. Following approval, ACURO will get in touch to coordinate scheduling of a compliance inspection.

(3) Compliance Inspection: All documents listed in Enclosure 1 must be submitted to ACURO for administrative review. To initiate the process, contact the Program Manager, USAMRMC ACURO, (301) 619-6694, and coordinate at least *fifteen (15) days prior to the scheduled date of compliance inspection*. Upon completion of inspection, ACURO will provide a detailed report describing results and, if determined favorable, will issue program/site approval. Date of final approval will then be entered into the DoD vendor tracking database for administrative and contracting purposes.

(4) Only after all of the above approvals have been obtained will the vendor then be added to the Army's Approved-Vendor-List (AVL). Once added to the list, vendors are eligible to bid on Army solicitations for contract medical readiness training involving the use of animals. To remain on the list, compliance inspections must be conducted annually, beginning with the date of their initial approval.

2. U.S. MARINE CORPS (Conventional Forces)

A. References

- (1) Animal Welfare Act, Title 7, U.S. Code, Sections 2131-2158, as amended, and Animal Welfare Act Regulations, Title 9, Code of Federal Regulations, Animals and Animal Products, chapter 1, subchapter A, Animal Welfare, Parts 1-4, as amended.
- (2) DoD Instruction 3216.01, "Use of Animals in DoD Programs", 13 Sep 2010
- (3) DoD Instruction 1322.24, "Medical Readiness Training", 6 Oct 2011
- (4) SECNAVINST 3900.38C, "The Care and Use of Laboratory Animals in DoD Programs", 16 Feb 2005 (*currently undergoing major revision*)
- (5) DoD Component Animal Use Management Plan for the U.S. Navy, 18 Mar 2011
- (6) Marine Corps Combat Development Command (MCCDC) Policy Memorandum, "Combat Trauma Training With Live Tissue Policy Guidance", 1 Jul 2011

B. Instructions for Vendors – Submission, Review, and Approval Process

(1) Contact the U.S. Marine Corps (USMC) Training and Education Command (TECOM) for USMC specific submission requirements. Point of contact is the Medical Programs Training Officer, tecom.mtesd.ops@usmc.mil, (703) 784-3051. *Ensure all e-mail correspondence contains "MEDPROGTRNGO" in the subject header.* Submit all required documents, as directed, to initiate the review process.

(2) The TECOM point of contact will initiate Program of Instruction (POI) review for subsequent endorsement by the Commanding General, TECOM, and will *concurrently* submit the animal-use protocol, along

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with required program support documents, to the Director of Veterinary Affairs, Department of the Navy, Bureau of Medicine and Surgery (BUMED), for administrative review (see Enclosure 1 for list of required documents).

(3) Upon completion of administrative review, TECOM will provide a list of required and recommended changes, along with items needing additional clarification. Once clarification has been provided, and all required changes made, the POI, the animal-use protocol, and the vendor's Animal Care and Use Program, may then be endorsed for final approval by The Medical Officer of the Marine Corps (TMO). Written approval will be provided by TMO.

(4) Once written approval is provided by TMO, prospective vendors should contact the Director of Veterinary Affairs, BUMED, (301) 619-9241 / animal.research@med.navy.mil, to coordinate and schedule a compliance inspection. Based on results of the inspection, the vendor may be added to the USMC's Approved-Vendor-List (AVL). Once added to the list, vendors are then eligible to bid on USMC solicitations for contract medical readiness training involving the use of animals. To remain on the list, compliance inspections must be conducted annually, beginning with the date of their initial approval.

(5) Upon addition to the USMC's AVL, the Director of Veterinary Affairs, BUMED, will input notice of approval into the DoD tracking database of "approved vendors", including date of POI approval, date of animal-use protocol approval, and date of completion of compliance inspection.

3. U.S AIR FORCE (Conventional Forces)

a. References

- (1) Animal Welfare Act, Title 7, U.S. Code, Sections 2131-2158, as amended, and Animal Welfare Act Regulations, Title 9, Code of Federal Regulations, Animals and Animal Products, chapter 1, subchapter A, Animal Welfare, Parts 1-4, as amended.
- (2) DoD Instruction 3216.01, "Use of Animals in DoD Programs", 13 Sep 2010
- (3) DoD Instruction 1322.24, "Medical Readiness Training", 6 Oct 2011
- (4) AFMAN 40-401(I), "The Care and Use of Laboratory Animals in DoD Programs", 16 Feb 2005
(*currently undergoing major revision*)
- (5) DoD Component Animal Use Management Plan for the U.S. Air Force, 4 Aug 2011

B. Instructions for Vendors – Submission, Review, and Approval Process

(1) Contact the Chief, U.S. Air Force (USAF) Animal Use Programs, Office of the Surgeon General, (703) 681-8160, for USAF specific submission requirements. Submit required documents, as directed, to initiate the review and approval process (see Enclosure 1 for list of required documents).

(2) The Chief, USAF Animal Use Programs will submit the Program of Instruction (POI) for review and approval by the Surgical Services Consultant, Air Force Medical Operations Agency (AFMOA). Following receipt of POI approval, the Chief, USAF Animal Use Programs will then administratively review the animal-use protocol and animal care and use program documents.

(3) Upon completion of administrative review, the Chief, USAF Animal Use Programs will provide a list of required and recommended changes, along with items needing additional clarification. Once clarification has been provided, and all required changes made, the Chief, USAF Animal Use Programs will issue written notification of animal care and use program and animal-use protocol approval.

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(4) Upon receipt of approval, prospective vendors should contact the Chief, USAF Animal Use Programs, to coordinate and schedule a compliance inspection. Based on results of the inspection, the vendor may then be added to the USAF's Approved-Vendor-List (AVL). Once added to the list, vendors are then eligible to bid on USAF solicitations for contract medical readiness training involving the use of animals. To remain on the list, compliance inspections must be conducted annually, beginning with the date of initial approval.

(5) Upon addition to the USAF's AVL, the Chief, USAF Animal Use Programs, will input notice of approval into the DoD tracking database of "approved vendors", including date of POI approval, date of animal-use protocol approval, and date of completion of compliance inspection.

4. U.S. SPECIAL OPERATIONS COMMAND (USSOCOM)(Special Operations Forces, "SOF")

A. References

- (1) Animal Welfare Act, Title 7, U.S. Code, Sections 2131-2158, as amended, and Animal Welfare Act Regulations, Title 9, Code of Federal Regulations, Animals and Animal Products, chapter 1, subchapter A, Animal Welfare, Parts 1-4, as amended.
- (2) DoD Instruction 3216.01, "Use of Animals in DoD Programs", 13 Sep 2010
- (3) DoD Instruction 1322.24, "Medical Readiness Training", 6 Oct 2011
- (4) Army Regulation 40-33, "The Care and Use of Laboratory Animals in DoD Programs", 16 Feb 2005 (*currently undergoing major revision*)
- (5) DoD Component Animal Use Management Plan for the USSOCOM, 11 Apr 2011
- (6) USSOCOM Directive 350-29cc, "Special Operations Forces (SOF) Baseline Interoperable Medical Training Standards", 7 Sep 2012

B. Instructions for Vendors – Submission, Review, and Approval Process

(1) *Prior to seeking USSOCOM approval*, vendors must *first* have current animal-use protocol approval, and documentation of favorable results of site inspection within the past 12 months, from at least one of the Military Services (U.S. Army, U.S. Marine Corps, or U.S. Air Force). See Enclosure 2.

(2) After receiving final approval from at least one of the Military Services as noted above, vendors must then meet additional USSOCOM specific requirements. Contact the Command Veterinarian, USSOCOM SOCS-SG-VET, 7701 Tampa Point Boulevard, MacDill AFB, FL 33621-5323, email: SOCOMVET@socom.mil, for specific requirements and POI submission instructions. See Enclosure 3.

(3) USSOCOM will provide written notification of vendor approval once all administrative requirements are met. Vendors are then eligible to bid on USSOCOM contract solicitations for medical training involving the use of animals. **NOTE:** USSOCOM approval is Service Component specific.

(4) After being added to USSOCOM's AVL, the Command Veterinarian will input notice of approval into the DoD tracking database of "approved vendors", including date of POI approval.

5. ADMINISTRATIVE RECIPROCITY

Per DoD Instruction 3216.01, all Component Animal Use Oversight offices (U.S. Army, U.S. Navy, U.S. Air Force, and USSOCOM) have established administrative reciprocity and therefore *may* accept animal-use protocol approvals and results of site inspections, initial, annual, or otherwise, when provided by one another. Approvals

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obtained from one office will be provided, as applicable, to other offices, to facilitate the review and approval process and preclude redundancy of effort. Each respective Component office, however, reserves the right to conduct Component-specific administrative reviews, site inspections, or request additional information at any time as deemed necessary. It should additionally be noted that once “approved vendor” status has been granted by one Component, such status does not automatically confer to other Components. In order to compete for a Component-specific contract, vendors **must first** be included on the AVL for that particular Component. All DoD and Component-specific requirements must be met in order to obtain “approved vendor” status. To remain on the list, compliance inspections must be conducted annually, beginning with the date of initial approval. Similar reciprocity has not been established for POI review and approval.

6. ADDITIONAL ADMINISTRATIVE REQUIREMENTS

A. Animal Use-Protocol. Animal-use protocol approvals are valid for three (3) years from date of initial approval by the vendor’s IACUC. At that time protocols are considered expired and any previously approved activities involving the use of animals must cease immediately. Such activities should not occur beyond the specific date of protocol expiration, regardless of any existing government contracts. To preclude potential interruption or cancellation of planned training events, an updated protocol, to include new literature searches, should be submitted to the respective Component Animal Use Oversight office at least 60-90 days prior to the protocol expiration date. Vendors unable to meet this requirement will be removed from all Component AVL’s on the date of protocol expiration. **NOTE:** All amendments or modifications to the IACUC-approved protocol **must** be reviewed and approved by the vendor’s IACUC, and subsequently by the respective Component Animal Use Oversight office, prior to any such changes being implemented. Any changes implemented without obtaining prior approval will be considered non-compliance and may result in immediate suspension of training activities involving animals.

B. Compliance Inspections. Per DoD Instruction 3216.01, results of compliance inspections are valid for a period of one (1) year from the date of initial completion. Thereafter, to remain on the AVL, inspections must be completed annually, beginning with the date of initial approval. It is advisable for inspections to be coordinated and scheduled with the respective Component Animal Use Oversight office at least 60-90 days prior to the annual date of expiration. Advanced coordination will help facilitate the review and approval process and preclude potential interruption or cancellation of planned training events. Vendors unable to meet this requirement will be removed from all Component AVL’s on the date of inspection expiration.

C. Program of Instruction. POI approvals are Component and course specific and are considered valid as follows: U.S. Army and USAF – for a period of three (3) years from the date of initial approval, or until the expiration date of the corresponding animal-use protocol, whichever comes first; USMC – for a period of two (2) years from the date of initial approval, or until the expiration date of the corresponding animal-use protocol, whichever comes first; USSOCOM – for a period of one (1) year, or until the expiration date of the corresponding animal-use protocol, whichever comes first. At all such dates specified, POIs are considered expired and any previously approved instructional material must be reapproved, by each applicable Service/Component, prior to the continued conduct of any medical training, whether planned instruction or activities involve the use of animals or not, and regardless of any existing government contracts. To preclude potential interruption or cancellation of planned training events, an updated POI should be submitted, according to the above Service/Component specific instructions, at least 90-120 days prior to the POI or animal-use protocol expiration date. It is essential that re-approval(s) be obtained for **each** supported Service/Component (U.S. Army, U.S. Marine Corps, U.S. Air Force, or USSOCOM). Service/Component POI approval times may significantly vary depending on mission priorities and current workload. At this time, reciprocity for POI approval has not been established between Services/Components. Vendors unable to meet this requirement will be removed from all applicable Component-specific AVL’s on the POI (or animal-use protocol) expiration date, whichever comes first.

D. Additional requirements may be needed as specified in DoD and Service/Component policies, government solicitations and contracts, or as deemed necessary by Component Animal Use Oversight offices.

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Enclosure 1 Animal-Use Protocol and Program Review Documents

The following documents are required in your submission packet to initiate the animal-use protocol or compliance inspection. Additional information may be required and will be requested as deemed necessary. Submission guidance may be obtained from the respective Component Animal Use Oversight office.

1. Vendor's IACUC-approved version of the animal-use protocol, preferably in DoD standardized format. The standardized protocol template may be found in reference (4) or obtained by contacting any one of the Component Animal Use Oversight offices. Detailed instructions for completion are also provided in reference (4). **NOTE:** Although the DoD standardized template is not required, all requested information contained therein must be appropriately addressed, in sufficient detail, and included with submission of the IACUC-approved protocol.
2. Vendor's IACUC approval memo for the above animal-use protocol. **NOTE:** All amendments or modifications to the IACUC-approved protocol must be reviewed and approved by the vendor's IACUC, and subsequently by the respective Component Animal Use Oversight office, prior to any such changes being implemented. Any changes implemented without obtaining prior approval will be considered non-compliance and may result in immediate suspension of animal-use activities.
3. Documentation of continuing review of the above approved protocol by the vendor's IACUC. **NOTE:** Continuing reviews must be conducted by the vendor's IACUC at least annually.
4. When medical training involving the use of live animals is to be conducted within the U.S., provide a written statement indicating that animals will be or have been legally obtained from suppliers licensed by the USDA in accordance with sections 2133-2134 of reference (1), unless the supplier claims to meet established exemption criteria. If claiming exemption, provide the applicable documentation. When training is to be conducted outside of the U.S., provide a written statement indicating that animals will be or have been legally obtained from suppliers in accordance with current national policy of the applicable Host Nation.
5. Most recent USDA inspection report, unless vendor is exempt from inspection. All USDA inspection reports received during the period of the contract should be immediately submitted to the respective Component Animal Use Oversight office. **NOTE:** If a vendor is ever notified by the USDA that their Animal Care & Use Program is under investigation, such notification should be provided to all Component Animal Use Oversight offices within five (5) business days of receiving the notice. Any adverse event(s) having potential to impact DoD continued support of a government contract, regardless if subject to USDA investigation or not, should be immediately reported to the respective Component Animal Use Oversight office.
6. Two (2) most recent results of vendor IACUC's semi-annual program review and facility inspection, including the follow-up report provided to the Institutional Official (IO) signed by a majority of IACUC members. **NOTE:** Semi-annual program review and facility inspections must be conducted by the vendor's IACUC at least once every six (6) months.
7. Current IACUC membership roster. If the vendor's Chief Executive Officer (CEO) has granted delegated authority to the IO, such delegation should be specific and in writing. Provide documentation if applicable.
8. Minutes of the last three (3) IACUC meetings documenting member attendance and committee deliberations.
9. Documentation of training that all IACUC members have completed over the course of the past year in order to meet mandated training requirements as specified in references (1) and (2).
10. Current list of all IACUC policies and/or standard operating procedures (SOPs), including committee review, approval, and revision dates.
11. Emergency Preparedness and Response plan that includes disposition of animals.

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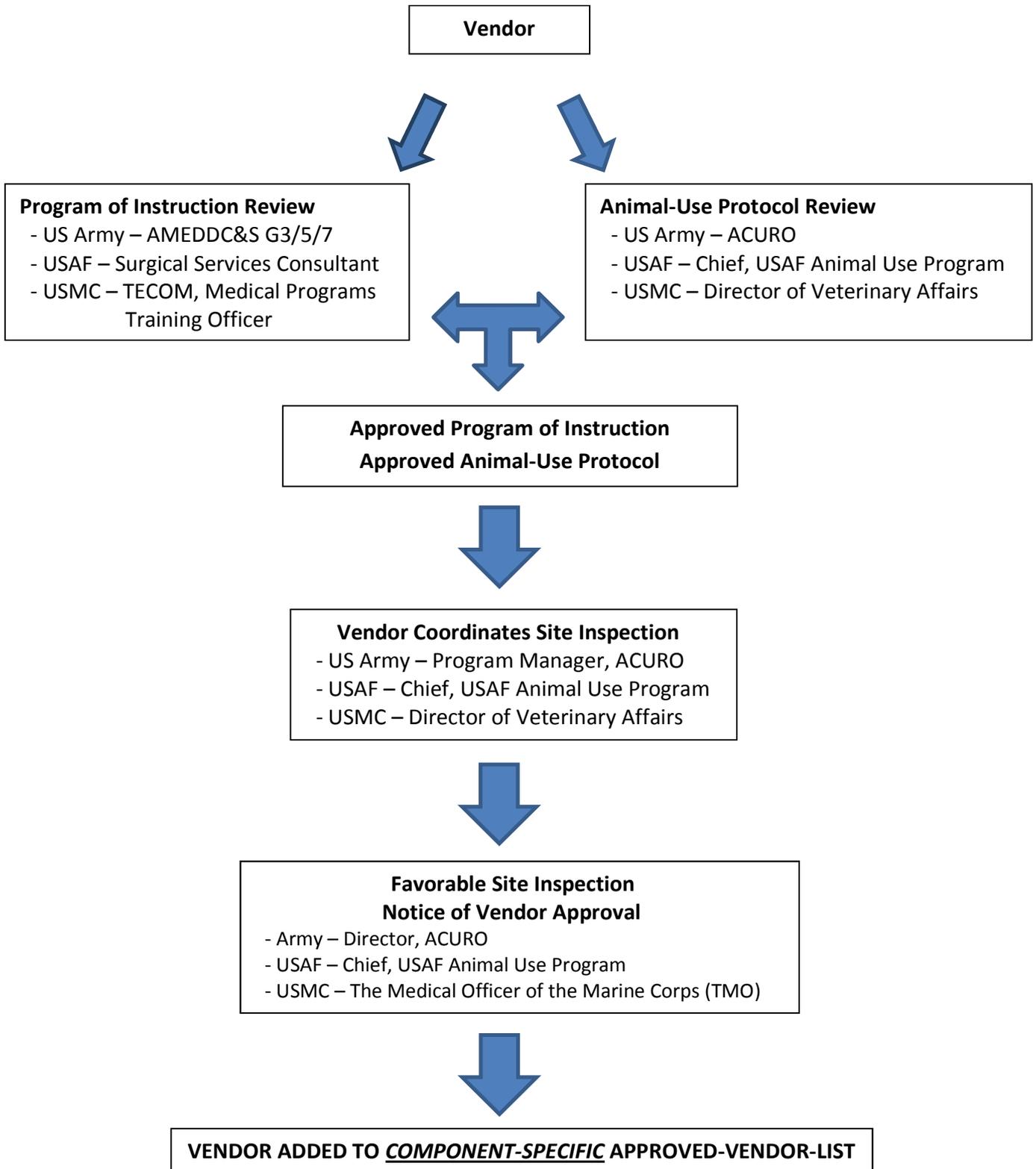
12. Detailed description, policy, or SOP of vendor's Occupational Health and Safety Program.
13. IACUC policy or SOP for the reporting of animal welfare concerns. In addition, provide copies of any final reports of non-compliant issues identified within the past year requiring notification to AAALAC, USDA, or any of the DoD Component Animal Use Oversight offices. **NOTE:** Any animal welfare concern(s) having potential to impact DoD continued support of a government contract should be immediately reported to the respective Component Animal Use Oversight office.
14. Most recent correspondence with AAALAC indicating current accreditation status. **NOTE:** If a vendor is ever notified by AAALAC of loss of program full accreditation, notification should be provided to the respective Component Animal Use Oversight office within five (5) business days.
15. Documentation of current registration with the USDA, unless exempt.
16. Most recent USDA Annual Report of Research Facility (APHIS Form 7023). **NOTE:** Annual reports should be submitted to the respective Component Animal Use Oversight office for the duration of any existing contract.
17. Documentation of current registration with the Drug Enforcement Administration (DEA).
18. Documentation of current veterinary licensure for the state/location where training is to be conducted.
19. IACUC policy or SOP on the appropriate supervision and use of DEA-regulated or controlled substances.
20. Current approved version of vendor's Program of Instruction (POI) with applicable Component-specific approval memo(s).

The following website may be used as a convenient method for sending the above listed information: <https://safe.amrdec.army.mil/safe2/>. Submission of all documents, however, should be as specifically directed above. AMRDEC's Safe Access File Exchange (SAFE) is an alternative program that allows for the ***secure transmission*** of much larger files (up to 2GB) than can normally be sent via regular e-mail. It permits encryption, is CAC-enabled, and allows for the creation of *.zip files. It does not fill up the recipient's inbox and can mark files "FOUO" or as "Privacy Act" data.

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Enclosure 2

(U.S. Army, U.S. Air Force, U.S. Marine Corps)



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Enclosure 3

U.S. Special Operations Command (USSOCOM)

