

**STRATTON VAMC ANIMAL RESEARCH PROGRAM**  
**Stratton Veterans Administration Medical Center**  
**Albany, New York**

**STANDARD OPERATING PROCEDURES**

- PART I – Institutional Animal Care & Use Committee**
- PART II – Animal Research Facility**
- PART III – Occupational Health & Safety & Animal Exposure**
- PART IV – Controlled Substances**

**FOLLOW-UP RESPONSIBILITY**

IACUC Chairperson and Stratton VAMC Research Program Management (ACOS/R and AO/R)

**RESCISSION**

None

**DISTRIBUTION**

All Principal Investigators Using Animals

**REFERENCES**

- Guide for the Care and Use of Laboratory Animals, Institute of Laboratory Animal Resources, 2011
- Public Health Service Policy on Humane Care and Use of Laboratory Animals, U.S. Department of Human Resources, Public Health Service, NIH. Revised 1986
- Animal Welfare Act (PL 89-544) and all subsequent amendments
- VHA Handbook 1200.07 “Use of Animals in Research”
- USDA AWAR, 9 C.F.R. §2.32(a); Principle 8, U.S. Government Principles for The Utilization And Care Of Vertebrate Animals Used In Testing, Research, And Training
- Guide for the Care and Use of Laboratory Animals, U.S. Department of Health and Human Services, Public Health Service, (2011), and subsequent revisions.
- M-3, Part I, Chapter 12, Animal Subjects in Research
- Occupational Health and Safety in the Care and Use of Research Animals NRC, National Academy Press, Washington, DC 1997
- VA Directive 7700 - Occupational Safety and Health, dated February 11, 2009
- Occupational Health and Safety for Veterinary Medical Units, VHA Program Guide 1200.5

## **PART I – IACUC SOP**

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## PURPOSE

- To provide guidelines for the Institutional Animal Care and Use Committee (IACUC) at the Stratton VA Medical Center as defined in VHA HANDBOOK 1200.7, USE OF ANIMALS IN RESEARCH. The IACUC is a subcommittee of the Research and Development (R&D) Committee.
- To assure institutional compliance with federal regulations and guidelines and with the Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC) standards for the care and use of laboratory animals.
- To provide guidelines for adequate training of all research personnel in the proper handling of research animals, and all research techniques involving animals including, but not limited to, survival surgery .

## POLICY

- The IACUC must perform review and oversight functions required by Public Health Service (PHS) Policy, the Animal Welfare Act (AWA), the *Guide for the Care and Use of Laboratory Animals* (the *Guide*), the Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC) and VA Central Office mandates.
- The IACUC is responsible for review and oversight of all proposed research and teaching activities utilizing live vertebrate animals when such activities are conducted on VA premises or in affiliated laboratories, and those activities are supported by VA or the VA non-profit research foundation administered funds.
- The IACUC is responsible for review and oversight of training activities of anyone who performs procedures and manipulations in animal research.
- No experiments involving vertebrate animals may begin (or animals ordered) prior to the following: full written approval of ACORP and all appendices by the IACUC; full written approval by the R&D and Biosafety committees; and documentation that the PI and all research staff listed on the ACORP have completed all required training.
- The IACUC has authority to approve or disapprove proposed research activities involving the use of animals. The Institutional Official (s) may not approve activities that the IACUC has disapproved.
- No member of the IACUC may be excluded from participating in any IACUC activity. All members will be notified in a reasonable amount of time (at least one week whenever possible) of all IACUC activities in order to allow them the opportunity to participate.
- The IACUC membership must meet the following criteria:
  - The IACUC will consist of not less than five voting members, and must include at least the following:
    - One Chairperson
    - One doctor of veterinary medicine who has training or experience in laboratory animal science and medicine, and who has direct program responsibility for activities involving animals at Stratton VA Medical Center; this is a voting member whose appointment is *ex officio*

- One practicing scientist experienced in research involving animals
- One member whose primary concerns are in a non-scientific area (e.g. ethicist, member of the clergy)
- One member who is not affiliated with the Stratton VA Medical Center other than as a member of the IACUC and who is not part of the immediate family of a person who is affiliated with the medical center and who is not associated in any other way with the laboratory animal or research field; this person must be appointed to represent the general community interests in the proper care and treatment of animals.
- At least one member of the IACUC must be a member of the parent R&D Committee.
- One member of the IACUC needs to be a member of the Subcommittee on Research Safety & Biosafety
- Animal Research Facility (ARF) Supervisor is an *ex officio* member without voting authority.

The IACUC Chair, in consultation with the R&D committee, must forward the name(s) of nominees for the IACUC to the Medical Center Director. The Medical Center Director must officially appoint members in writing and specify the length of the appointments.

Members who are not *ex officio* serve three years for their first term and reappointments or additional terms can be indefinite. The Chair of the committee is appointed annually by the Medical Center Director, and may not simultaneously chair another subcommittee.

- Quorum - A quorum is required in order to convene a meeting of the IACUC, and approval of any aspect of the IACUC responsibility requires a majority vote. In special circumstances, the IACUC may review non-animal related items electronically and approval requires a majority of members to vote. Committee members are allowed one week to respond to electronic voting items. If one voting member has specific concerns or votes negatively, the item will be brought before the next committee meeting for full review.
- Conflict of Interest - The ACOS for R&D and Administrative Officer (AO) for R&D do not serve as voting members on the IACUC, and when in attendance, are attentive to the occurrence or appearance of conflict of interest relative to their supervisory, managerial, or fiscal authority. They will avoid intervention or participation in deliberations involving entities in which they have financial or economic interests, except to provide information as requested by the IACUC.
  - No IACUC member may participate in the IACUC review or in the approval of a research project in which the member is personally involved in the project, except to provide information requested by the IACUC. The IACUC is responsible for ensuring that the protocol review process is not compromised by conflicts of interest arising from members participating in animal research reviewed by the IACUC.

- IACUC members should not participate in the IACUC review or approval of a research project in which the member has a financial conflict, except to provide information requested by the IACUC prior to the deliberations.

## DEFINITIONS

- Animal Component of Research Protocol (ACORP): The ACORP, the official VA animal protocol form, is the set of questions that must be considered during a review of animal protocols. It must be used by VA Institutional Animal Care and Use Committee (IACUC) when a project involving animal research is submitted for consideration of VA funding or the animal research will be performed on VA premises.
- Activity (involving animal care and use): Any element of research, testing, training or teaching procedures that involves the care and/or use of animals.
- IACUC Chair: The voting member of the IACUC who performs the functions and responsibilities of Chairperson for the committee. This cannot be the Veterinary Medical Officer or the non-affiliated member. An individual appointed by the Medical Center Director as the Chair of the Subcommittee; this person has usually served on an IACUC for at least one year.
- Institutional Animal Care and Use Committee (IACUC): The IACUC is the committee that is legally responsible for ensuring that all animals used in activities covered by federal guidelines and regulations are cared for and used in a humane manner and that all activities are in compliance with all federal regulations and guidelines.
- Institutional Official: The Medical Center Director is authorized to legally commit resources on behalf of the research facility, to ensure that the requirements of the PHS Policy, the Animal Welfare Act and VHA 1200.7 are met.
- Major Change: A protocol modification that deviates significantly from the original animal use protocol. Major changes may include a change in pain category, change from terminal to survival procedure, a request for an increase in the number of animals that exceeds 15% of the number originally requested, change in endpoint criteria that would increase the amount of time animals may experience pain or distress, addition of previously untested or unknown test articles or substances, change in species or change in PI.
- Major (significant) compliance deficiency: Any infraction that is or may be a threat to the health or safety of the animals. A major (significant) deficiency may include, but is not limited to, neglect or cruelty to animals, conducting animal research outside of regulatory oversight, non-adherence to specific and previously agreed upon policies and guidelines, non-adherence to the written protocol, inadequate record keeping, inadequate training of all participants involved with animal experimentation, repeated minor infractions.
- Memorandum of Understanding (MOU): A memorandum detailing how research projects that are conducted at another institution using VA or VA non-profit research foundation funds are monitored, approved, and performed, in order to ensure compliance with all applicable laws and regulations. This must be

approved by the IACUCs at both institutions and signed by the Institutional Officials of both institutions.

- **Minor Change:** A protocol modification that cannot be defined as a major change. Minor changes may include a change in choice or dose of anesthetic, analgesic or antibiotic (with veterinary approval), a change in support personnel, a change to a similar strain of rodent, or any reduction in or a small increase ( $\leq 15\%$ ) in the total number of animals used, or a change in the experimental treatment regime of the animals that will not alter the health or pain level of the animals in any way.
- **Minor compliance deficiency:** Any infraction that cannot be defined as a significant deficiency. A minor deficiency can include, but is not limited to, inadequate record keeping, inadequate training of personnel, unapproved minor changes in procedures and unapproved changes in personnel.
- **Principal Investigator (PI):** A research scientist performing animal research on Stratton VA Medical Center property or using VA or VA foundation funds to perform animal research at an institute with whom the Stratton VA Medical Center has a Memorandum of Understanding (MOU).
- **Protocol:** The written research activities by an individual investigator.
- **Qualified IACUC Member:** Any member of the IACUC who has completed mandatory IACUC training.
- **Quorum:** A majority (more than 50 percent) of voting members. For voting purposes, a member directly associated with a protocol or issue cannot be considered part of the quorum.
- **Vice-Chair:** The voting member of the IACUC who performs the functions and responsibilities of Chairperson in their absence. This cannot be the Veterinary Medical Officer or the non-affiliated member. An individual appointed by the Medical Center Director as the Vice-Chair of the Subcommittee; this person has usually served on an IACUC for at least one year. When no Vice Chair has been named, then one may act on an ad-hoc basis when the IACUC Chair's absence is unplanned or emergent.

## RESPONSIBILITIES

### **Institutional Official/Medical Center Director**

- Ensures that the animal research program has the resources and support necessary to comply with all federal regulations and guidelines that govern animal research.
- Appoints IACUC members.
- Reviews and approves the facility inspection and program review reports.
- Establishes the institutional climate and provides institutional commitment to humane animal care and use through the IACUC.
- Reviews and signs annual reports to regulatory and accrediting bodies.
- The facility Director is responsible for ensuring that the animal research conducted at the VA facility is monitored by an effective IACUC of Record, that adequate resources are available for the animal research program and that IACUC members, IACUC support staff, veterinarians and animal care staff have

adequate opportunities to receive continuing education. The Director must also ensure that adequate support for animal research is provided by other Services of the facility (e.g. completion of work orders by the Engineering Service) as needed.

### **IACUC Chair**

- Has the primary responsibility for presiding over IACUC meetings.
- Appoints subcommittees of at least two voting members when necessary for special issues, such as compliance or SOP review.
- Reviews all new protocols, protocol modifications, renewals and personnel changes prior to meetings.
- Has the authority, along with the veterinary consultant, to accept minor changes in protocols in an expedited manner. The changes will be reported in writing (“For the Minute Record” item) at the next scheduled Full Committee meeting.
- Works with the Research Compliance Officer to resolve noncompliance issues.
- Receives requests and reviews justification for designated member review items.
- Participates in 6-month facility inspection and program review.
- Represents the IACUC to VA Office of Research & Development (VACO/ORD), Office of Research Oversight (ORO), Office of Laboratory Animal Welfare (OLAW), AAALAC, and US Department of Agriculture (USDA).
- Verifies that the IACUC Coordinator has ensured that all personnel involved in animal research receive and satisfy training and continuing education requirements.

### **IACUC**

- Review all new protocols, protocol modifications, renewals and personnel changes prior to the meetings as specified in the Public Health Service (PHS) Policy, the Animal Welfare Act (AWA), the *Guide for the Care and Use of Laboratory Animals* (the *Guide*), the Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC) and VA Central Office mandates.
- Assist in noncompliance issues when needed.
- Participate in 6-month facility inspection and program review.
- Perform IACUC procedures as listed in Section 5 below (PROCEDURES).
- Verify through review of submission documents that all Principal Investigators and staff listed on the main ACORP have completed the mandatory annual training.

### **Research Compliance Officer (RCO)**

- Conducts random inspections and audits of animal use and housing areas, protocols, records and procedures involving animal use, and in house breeding colonies.
- Presents reports at IACUC meetings involving compliance activities for that reporting period.
- Audits, 5% or minimum of 5 IACUC records, as part of the semi-annual program

review.

### **Veterinary Medical Officer (VMO, attending or consulting veterinarian)**

- Maintains full delegated responsibility for the overall operations of the animal program.
- Provides veterinary review of all animal use protocols, renewals, modifications and personnel changes prior to distribution to IACUC members. If the VMO has questions regarding any protocol, the VMO may attempt to resolve any veterinary issues with the principal investigator prior to the IACUC meeting.
- Has the authority, along with the Chairperson, to accept minor changes in protocols in an expedited manner. The changes would be reported to the Full Committee at the next scheduled meeting.
- Presents reports at IACUC meetings involving animal health issues or issues relevant to the IACUC for that reporting period.
- Evaluates animals involved in reports of animal welfare concern and/or noncompliance and participates in investigating issues pertaining to animal welfare.
- Assists in investigating noncompliance issues when requested by the Chair or RCO.
- Provides regular training sessions to investigators and research staff that perform procedures or manipulations on laboratory animals. Training topics will include animal usage, federal regulations, and other topics essential for the proper use of animals in research.
- May make recommendations to the Institutional Official regarding any aspect of the institution's animal program, facilities or personnel training.
- The VMO must meet the qualifications for a GS-15 VA veterinarian found in VA Handbook 5005, Staffing, Part II, Appendix F32.
- The credentials of each veterinarian must be approved by the CVMO (Chief Veterinary Medical Officer) prior to appointment to the position of VMO or VMC.
- ACLAM certification is preferred for veterinarians serving VA animal research programs.

### **IACUC Coordinator**

- Generates and provides written notification of the results of IACUC reviews including protocol renewal, modification, approval, and miscellaneous letters to the PIs.
- Generates IACUC agendas and records IACUC minutes.
- Maintains Protocol, Personnel, and IACUC Membership Training Databases.
- Maintains all IACUC records.
- Distributes information to all IACUC members in regard to meeting dates and agenda packets with all business items including reviewer assignments for all new protocols (VHA Hbk 1200.7) essential for the activities of the IACUC Committee. Packets must be provided to members no later than 3 business days before the IACUC meeting.

**Principal Investigator (PI)**

- Ensures that all protocols, renewals, modifications and other documents that require IACUC review are submitted to the IACUC in a timely manner and contain all information related to proposed animal experiments. The PI is responsible for ensuring the use of current IACUC forms available on the research website.
- Assures all active protocols and study procedures involving the use of animals have been reviewed and approved by the IACUC and R&D prior to the initiation of research.
- Maintains approved ACORP, appendices, protocol, amendments, approval letters and correspondence from R&D and IACUC committees and keeps records properly stored and secured on VA premises. These records can be scanned and kept electronically on a secured VA drive or password protected file. Research records are to be kept indefinitely.
- Supervises laboratory staff and ensures that all personnel conduct research in accordance with the approved protocol and follow all policies, SOP's, laws and regulations applicable to the research.
- Reports problems, complications and/or concerns about the use of laboratory animals to the VMO and/or Chairperson.
- Ensures and provides documentation to the Research Office that all personnel, including the PI, have completed all mandatory training such as the web based training "Working with the VA IACUC" and the species specific training appropriate for the studies being performed. In addition, the PI is responsible for ensuring that all personnel, including students, are fully trained in all aspects of the animal activities in their lab. This includes, but is not limited to, training in hazardous agent use, Animal User Orientation, Occupational Health & Safety Training, and Stratton VA Medical Center mandatory training.
- Corrects deficiencies and infractions in a timely manner and in accordance with the schedule of corrective action as specified by the IACUC.

**PROCEDURES****Meetings & Submissions**

The IACUC will meet at a minimum every other month and more often as necessary. The committee reviews new protocols, protocol modifications, protocol renewals, and personnel changes of all research proposals when such research includes the use of vertebrate animals.

- The Principal Investigator must consult with the Veterinary Consultant during the planning stages of each research study - this should be performed prior to submission to the Research Office. This consult may take the form of a face-to-face meeting or a written review of a draft of the ACORP form. Verification of the discussion should be submitted with the proposal.
- The Principal Investigator will request review of the research by submitting a New Protocol Submission Form to the Research Office, with the appropriate number of copies of all supporting documents per the animal protocol submission checklist.

- The IACUC Coordinator verifies all education and training is completed for everyone listed on the protocol.
- The IACUC Coordinator checks the original submission for completeness and accuracy and enters the submission into the database. If any items are missing, the coordinator will notify the Principal Investigator or the designated contact person.
- The Chair or designee is notified electronically and has 7 calendar days to review the new protocol submission. All new submissions will be reviewed and presented for committee vote at a fully convened meeting.
- Any ACORP that contains multiple survival surgeries or procedures that produces pain and suffering in animals that do not receive analgesics must be reviewed by the full committee.
- New ACORPs (Initial and 3-year renewals) are given an internal tracking number used by the VMU Supervisor and the Principal Investigator, such as 10-01(calendar year 2010, 1<sup>st</sup> ACORP of the year).

### **Research Proposal Review**

Public Health Service Policy on the Humane Care and Use of Laboratory Animals and the Animal Welfare Regulations permit only two methods of Animal Study Proposal (ASP) and proposed significant changes review:

- Full committee review (FCR) at a convened meeting of the Animal Care & Use Committee
- Designated member review (DMR) in lieu of FCR at a convened meeting

### **Full Committee Review at a Convened Meeting Description:**

The standard or default method for review and approval of ASPs by the IACUC is through the deliberative process during convened meetings. For those meetings, a quorum must be present for the IACUC to conduct business. Copies of or a list of new or renewal ASPs or proposed significant changes are distributed to the IACUC members for their review prior to the convened meeting. The members are asked to identify ahead of time any ASPs which they feel must be reviewed and deliberated only by FCR. It is further understood that any ASP initially subjected to FCR may require modification and the adequacy of that modification may be assessed by either the return of the modified ASP to the full committee, or in the absence of a call for FCR, return of the modified ASP to the DMR process (see below).

IACUC members having a conflict of interest with any particular ASP (or proposed significant change) may participate in questions and answers regarding the ASP, but must recuse themselves during deliberation and voting on that action. During that deliberation, the member(s) in conflict of interest must not be counted as part of the quorum, which must still be present to render a decision.

### **Designated Member Review In Lieu of a Convened Meeting Description:**

When an expedited review is required, DMR can be proposed by the IACUC Chair. The actual Policy description of this method is as follows: "If full committee

review is not requested, at least one member of the IACUC, designated by the Chairperson and qualified to conduct the review, shall review those research projects and have the authority to approve, require modifications in (to secure approval) or request full committee review of those research projects.” The process is addressed later in this SOP.

This method is equally acceptable for use by IACUCs when conducting protocol review, but it must proceed as outlined in the PHS Policy. Using this method, all IACUC members receive a list of proposed research projects and access to the necessary information on the protocol to be reviewed. If any member feels that this protocol should go before a full committee, then its review must be deferred to the next full IACUC meeting. Any member can make the decision to send the protocol to full-committee review at any time during the time period designated for providing this opportunity. The IACUC will allow a 5 days, during which members may indicate which method of review is preferred. If no member calls for a full-committee review, then the Chair can refer the protocol in question to a designated reviewer. The Chair may select one or more members, qualified to review this specific protocol, who will act on behalf of the entire IACUC to approve the protocol, request additional information from the PI to approve it, or refer it for full review. The designated reviewer does not have the power to withhold approval, however, but must in such cases refer the protocol for full-committee review.

The designated-reviewer approval has equal validity to full-committee review approval and does not require subsequent re-approval or notification by a convened meeting. It is always possible for the IACUC to discuss protocols approved by either method in future meetings as a form of continuing review or in response to animal welfare concerns. The Stratton VAMC permits the use of designated member review for initial reviews except with ACORPs containing multiple survival surgeries or procedures that will produce pain and suffering in animals that do not receive analgesics require a full committee review.

### **Modifications to Protocols**

The IACUC must review and approve, require modifications in (to secure approval), or withhold approval of all research proposals involving species and activities included within the definition of an “animal” (see 1200.7). Minor administrative changes - typographical or arithmetic errors, misspellings, incorrect room or telephone numbers, etc., are not considered substantive. While these corrections must be made, additional IACUC review is not required. Substantive information - the information the IACUC needs to evaluate the proposal for humane animal care and use in accordance with the requirements of the PHS Policy at IV.C.1., and in adherence to provisions of the Guide. All research projects involving animals must be approved by the IACUC and then by the R&D Committee prior to commencement. The date of continuing review is based on the date of IACUC approval.

The IACUC must review proposed research at convened meetings at which a quorum (a majority of voting members) is present. In order for the research to be approved, it must receive the approval of a majority of those voting members present at the meeting. A quorum must be maintained for each vote to occur. If a quorum is not maintained, the proposal must be tabled although suggestions for review may be recorded and communicated to benefit the investigator with such decisions, contact the Chief Veterinary Medical Officer (CVMO), who may recommend further consultations with OLAW or USDA. The IACUC needs to consider the following topics in the preparation and review of animal care and use protocols (see 1200.7):

- Rationale and purpose of the proposed use of animals.
- Justification of the species and number of animals requested. Whenever possible, the number of animals requested should be justified statistically.
- Availability or appropriateness of the use of less-invasive procedures, other species, isolated organ preparation, cell or tissue culture, or computer simulation.
- Adequacy of training and experience of personnel in the procedures used.
- Unusual housing and husbandry requirements.
- Appropriate sedation, analgesia, and anesthesia.
- Unnecessary duplication of experiments.
- Conduct of multiple major operative procedures.
- Criteria and process for timely intervention, removal of animals from a study, or euthanasia if painful or stressful outcomes are anticipated.
- Post-procedure care.
- Method of euthanasia or disposition of animal.
- Safety of the working environment for personnel.

If procedures are proposed that may cause more than momentary or slight pain or distress to the animals, it is mandated that an investigator consult the VMO, VMC, or designee, during the planning stages of a project (USDA AWAR; see 9C.F.R. §2.31(d)[iv][B]). Because it is often difficult for an investigator to predict which procedures might cause more than momentary pain or distress without consulting a laboratory animal veterinarian, this consultation needs to be performed prior to IACUC review of a protocol. The veterinary consult may take the form of a face-to-face meeting, or a written review of a draft form by the VMO or VMC. No protocol may be given final approval until a veterinary consult by the VMO or VMC has been performed. (1200.7)

NOTE: The review of a protocol by the VMO or VMC during an IACUC meeting does not satisfy this requirement.

## REVIEW PROCEDURES

### Designated Member Review Process

Designated Member Review may be utilized, only after all members have been provided the opportunity to call for a full-committee review. The IACUC Chair or designee assigns 2 voting members as Designated Member Reviewers from the committee who are not participating in the research. These Designated Member Reviewers act on behalf of the entire IACUC to approve the protocol, request additional information or changes from the PI, or refer it to full committee review. The Designated Member Reviewers do not have the power to withhold approval, however, must in such cases refer the protocol for full review. Designated Member Reviewers receive the abstract, main ACORP, appendices, protocol, Research Protocol Safety Survey and committee member review form electronically.

- 1 If the Designated Member Reviewers do not indicate a full committee review, but have a request for a minor modification regarding the research project then their request is forwarded to the PI by the IACUC Chair or designee.
  - The PI responds to the IACUC Chair or designee with a letter containing a complete listing of the requested minor modifications within 5 business days of the notification.
  - The IACUC Coordinator will forward the letter and the modified documents to the designated member reviewers for review and approval by the Designated Member Reviewers.
  - Once the IACUC Coordinator verifies that designated member reviewers are satisfied with the requested minor, the IACUC Chair or designee signs the designated member review approval letter and applicable forms.
- 2 If the Designated Member Reviewers find the protocol submission acceptable, their reviewer forms are forwarded to the IACUC Chair or designee for an approval letter.
- 3 After all approval signatures are obtained, the original approval letter and copies of the ACORP and applicable appendices are sent to the Principal Investigator.
- 4 A copy of the approval letter and the original ACORP and applicable appendices are filed in the Research Office.
  - The designated member reviewer approval has equal validity to full committee review approval, and does not require subsequent re-approval or notification by a convened meeting; however, the IACUC is notified of the approval of the research in the agenda of the next scheduled IACUC meeting.

### Initial Full Committee Review Process

Any IACUC member may request full committee review of research distributed to them for review.

All ACORPs containing multiple survival surgeries or procedures that will

produce pain and suffering in animals that do not receive analgesics require a full committee review. If a full committee review is indicated or requested upon review of the research, the review must take place at a fully convened meeting with a quorum present. The following steps will take place:

- 1 The IACUC Chair or designee assigns 2 primary reviewers who are not participating in the research and who are knowledgeable with the research subject matter. The IACUC may, at its discretion, invite individuals with expertise beyond, or in addition to, that which is not available on the IACUC to assist in the review of research. This person will not have a vote on the IACUC. The entire committee receives the abstract, main ACORP, appendices, and committee member review form per the delegated subcommittee reviewer system. Primary reviewers receive the same documents in addition to the protocol and Research Protocol Safety Survey form if applicable. Reviewers are provided with a primary reviewer form to record their comments.
- 2 Primary reviewers may contact the PI with any questions or concerns. PI may make any suggested changes and resubmit documents to the Coordinator prior to the approval meeting.
- 3 The PI responds to the IACUC Chair or designee with a letter containing a complete listing of the modifications made and 3 copies of all modified signed documents within 30 days of the notification.
- 4 The IACUC Coordinator will forward the letter listing the modifications and the modified documents to the primary reviewers for review prior to the next scheduled IACUC meeting.
- 5 The IACUC Coordinator will include the revised documents in the agenda packet for the next scheduled meeting.
- 6 The IACUC Chair will lead the discussion of the research and revised documents at the next scheduled meeting. The Principal Investigator will be invited to the IACUC Committee meeting as a guest to answer any questions members may have regarding the research project.
- 7 The votes for, against, abstaining, recused, and excused will be recorded. IACUC Members with a conflict of interest must recuse themselves from voting and leave the room during deliberations and voting.
- 8 Minutes will record discussion of the research protocol submission.
- 9 When information is lacking from a protocol or the committee may have questions requiring a response from the PI, the IACUC may take the following actions:
  - If **all** members of the IACUC **are** present at a meeting, the committee may vote to require modifications to secure approval and have the revised research protocol reviewed and approved by designated member review (DMR) or returned for FCR at a convened meeting.
  - If all members of the IACUC are not present at a meeting, the quorum that is present at the convened meeting have the authority to vote to have the modified protocol reviewed via the DMR process.
- 10 After approval has been received, all approval signatures are obtained. The

- original approval letter and copies of the ACORP and applicable appendices are sent to the Principal Investigator.
- 11 A copy of the approval letter and the original ACORP and applicable appendices are filed in the Research Office.
  - 12 The approval date is the date the IACUC Chair or designee signs the approval letter. Please note: research cannot begin until the R&D acknowledgement letter is obtained.

### **Amendments**

Principal Investigators may request a revision to the research by submitting a "Animal Research Amendment Form" for Revision/Amendment with a copy of all revised documents.

- 1 The IACUC Chair or designee and the Veterinarian Consultant/Veterinary Medicine Officer (VMO) review the request to determine if the changes are minor or major.
- 2 Revisions that represent a minor change may be reviewed and approved by Designated Member Review.
- 3 After all approval signatures are obtained, the original approval letter and copies of the ACORP and applicable appendices are sent to the Principal Investigator.
- 4 A copy of the approval letter and the original ACORP and applicable appendices are filed in the Research Office.
- 5 The IACUC is notified of the approval of the revision in the agenda of the next scheduled IACUC meeting.
- 6 If the IACUC chair or designee and the VMO/ Veterinary Consultant determine the changes to the protocol to be major, then the amendment must go through the full committee review process.
  - Major changes to research include, but are not limited to, changing animal species, adding a surgical component, change in Principal Investigator, or adding/removing test substances. All major revisions must go through a full review process.
- 7 The IACUC Chair or designee assigns 2 primary reviewers from the committee who are not participating in the research. The IACUC may, at its discretion, invite individuals with expertise beyond, or in addition to, that available on the IACUC to assist in the review of research. The entire committee receives the abstract, main ACORP, appendices, and committee member review form electronically per the delegated subcommittee reviewer system. Primary reviewers receive the same documents in addition to the protocol. They are provided with a primary reviewer form to record their comments.
- 8 Comments from the primary reviewers and committee members will be forwarded to the PI by the IACUC Chair or designee. Process continues with the steps noted above. The PI responds to the IACUC Chair or designee with a letter listing the modifications and 3 copies of all modified signed documents within 30 days of the notification.

**Amendments to add or remove research personnel from protocols**If you are adding research staff, please do the following:

- 1 Send the IACUC Coordinator the name of the person (this can be done via e-mail);
  - include all contact information including address, phone number and e-mail address; the name and identification number of the protocol or protocols that they will be assigned to work on; copies of completed mandatory training certificates (e-mail or fax)
- 2 To ensure that the WOC and VetPro process is complete before submitting new personnel name and contact information to the Coordinator. Staff will not be added to protocols until the Research & Development office receives letters from the appropriate credentialing office (HR or VetPro) that staff member may begin working at the Stratton VAMC.
- 3 Once process is completed, an e-mail notification will be sent by the Coordinator notifying the PI that the new staff member may begin research.

If you are removing research staff, please do the following:

- 1 Have the staff member check out with the Research Office Room 637D and hand in their VA badge to the Police Department
- 2 Send the IACUC Coordinator the name of the person (this can be done via e-mail) including all contact information: address, phone number and e-mail address; include the name and identification number of the protocol or protocols that should be removed from.
- 3 Once process is complete, the IACUC Coordinator will send a Notification via e-mail notifying the PI that the staff member has been removed from the protocol/s.
- 4 All correspondences and notifications will be filed in the appropriate protocol files, as well as a copy or the original e-mail request will be placed in the Research Staff member's folder.

**Please Note: Any person found working in a research lab and who has not been processed properly through the Research & Development Office and Human Resources will be removed from the facility and may be prohibited from gaining future research access to the facility.**

Transfer of animals from one year to next year

- 1 Principal Investigators may request a transfer of use of animals from one year to the next year by submitting a Protocol Review Request Form for Revision/Amendment.

- 2 The IACUC Chair or designee and the Attending Veterinarian (VMO) review and approve the request.
- 3 Once the IACUC Coordinator verifies the IACUC Chair or designee and the Attending Veterinarian approved the request, the IACUC Chair or designee will sign the expedited review approval letter.
- 4 The original approval letter is sent to the Principal Investigator, and a copy of the letter is filed in the Research Office.

### **Annual Review of Research**

- 1 Approximately 1 month before the date of the IACUC meeting at which annual review is scheduled, the IACUC Coordinator sends an Annual Review form, cover memo, and protocol education report to the Principal Investigator.
- 2 Upon receipt of the signed completed annual review form and applicable attachments from the Principal Investigator, the IACUC Coordinator stamps it with the date of receipt.
- 3 The IACUC Coordinator verifies that all personnel listed on the ACORP have completed their mandatory educational training. An Annual Review approval letter is prepared and sent to the IACUC Chair or designee for review and approval.
- 4 If the IACUC Chair or designee finds the report and training acceptable, the Annual Review Form and approval letter are signed.
- 5 The original signed approval letter and copies of applicable forms are sent to the Principal Investigator. A copy of the letter and original applicable forms are filed in the Research Office.
- 6 The IACUC is notified of the approval in the agenda of the next scheduled IACUC meeting.

### **3-Year ACORP Renewal**

- 1 Approximately 1 month before the date of the IACUC meeting, at which annual review is scheduled, the IACUC Coordinator notifies the Principal Investigator that this is a 3 year renewal which requires a complete new ACORP and protocol submission. The IACUC Coordinator sends a 3 year renewal review form, cover memo, and protocol education report to the Principal Investigator.
- 2 The Principal Investigator must submit a new updated ACORP, protocol, and applicable appendices for review. The documents will be reviewed and processed as described above for a "Initial Full Committee Review Process," or "Designated Member Review," based upon the opinion of the IACUC Chairperson and VMO.

### **Facility Inspection and Review of Animal Care and Use Program**

- 1 At least once every six months, the IACUC will inspect all facilities,

including animal housing and study areas and review the institution's program for humane care and use of animals using the Animal Welfare Act and the Guide as a basis for evaluation. This report will include:

- IACUC Policies and Responsibilities
  - Reporting Requirements
  - Records Requirements
  - Personnel Qualifications and Training
  - Occupational Health and Safety Program
  - Veterinary Medical Care
  - Laboratory Policies and Responsibilities
  - Physical Facilities
- 2 The IACUC Coordinator will distribute the semi-annual review inspection forms to committee members identified by the IACUC Chair. Members will complete the review of their assigned sections by the deadline identified and return the completed forms to the IACUC Coordinator.
  - 3 IACUC randomly reviews IACUC records representing at least five percent of the total active projects (a minimum of five). (per 1200.7.8d(1)(b))
  - 4 The IACUC Chair or designee will conduct a review of the animal research facility with at least three committee members prior to the next scheduled meeting.
  - 5 The semi-annual program and facility reviews will be discussed at the next scheduled IACUC meeting.
  - 6 Form 2, Table of Program and Facilities Deficiencies, will be drafted at the IACUC meeting, and a timetable for corrective action will be identified. A majority of all voting IACUC members must approve the report at this meeting. The IACUC Coordinator and ARF Supervisor will coordinate work order requests for deficiencies.
  - 7 Form 3, Post-Review Documentation, will be completed and signed by all appropriate individuals, including a majority of all voting IACUC members. The ACOS R&D and IACUC Chair will meet with the Medical Center Director to review the document for signature. The Semi-Annual Report cannot be altered by any local official once a majority of voting IACUC members has voted to approve the report.
  - 8 A signed copy of the complete report (including Forms 1,2 3) must be sent through the ACOS R&D and Medical Center Director to the CVMO within 60 days of the self-assessment date.
  - 9 A copy of the report should be submitted to the R&D Committee for review. R&D approval is not required before submission of the final document to the CVMO.
  - 10 The original signed complete report must be retained for at least 3 years.

### **Closure of research**

- 1 To request closure of animal research, the Principal Investigator must

- submit all appropriate subcommittee and R&D documentation requesting closure to the IACUC Coordinator.
- 2 Since the animal portion of the study does not require a formal closure process, the R&D Committee will close the study once all other applicable subcommittee closure requests have been reviewed and approved.
  - 3 The IACUC Coordinator will report the final study closure to the IACUC as a "for minute record" item.

### **Record Keeping**

- 1 Minutes of IACUC meetings are kept in the Research Office indefinitely.
- 2 All records of IACUC correspondence are maintained in the applicable research file for each study.

## **AUTHORITY, OVERSIGHT & REPORTING**

### **Noncompliance and Suspension of Activities**

- 1 Noncompliance is defined as any of the following:
  - Activity of animal use prior to written IACUC, SRS&B, and R&D approval.
  - Proceeding with changes in activities without written IACUC approval or failure to adhere to the activities as described in an approved protocol ("protocol violation").
  - Research activity involving animals that is not associated with an approved and current ACORP.
  - Any violation of the animal care and use provisions of the Animal Welfare Act, the PHS Policy on Humane Care and Use of Laboratory Animals, the NIH Guide for the Care and Use of Laboratory Animals, or any applicable Stratton VA policies or SOP's.
- 2 Upon notification of an incident of non-compliance (major or minor), the IACUC reviews the incident/s of noncompliance in accordance with all appropriate regulations and guidelines, at a convened meeting of a quorum and will determine if the noncompliance incident represents a major or minor infraction.
  - The IACUC has the authority to immediately suspend the activities of any research, which in their opinion is in non-compliance and/or places animals at risk of pain or suffering with the vote for suspension to be approved by the majority of the quorum present.
  - If the IACUC suspends an activity involving animals, the Institutional Official in consultation with the IACUC shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to OLAW, ORO, USDA and AAALAC .
  - Animal welfare will be the main priority if a suspension occurs.
  - Provisions will be made to maintain the care and welfare of the animals in accordance with The Guide.

- The IACUC will contact the PI in writing listing the infractions in detail.
  - The PI must respond within 7 days to the itemized infractions and provide a written corrective action plan with timetable, if appropriate.
  - Research may continue only when the PI is notified in writing that all non-compliance issues have been resolved in a satisfactory manner.
- 3 Data that are collected during a period of noncompliance, whether major or minor, will be reviewed by the committee to determine the significance of the data collected and the appropriate action that the PI must take in regards to that data.
  - 4 The IACUC coordinator will maintain complete documentation of non compliance incidents and all notifications to Principle Investigators and their responses in the study file.

### **Reporting Animal Concerns and Whistleblower Policy**

The Stratton VA Research Service is committed to the humane care and use of laboratory animals. To ensure that laboratory animals receive humane care and use or treatment in accordance with the highest ethical standards, laws, regulations and policies governing animal research, the IACUC must review and if warranted, address any animal-related concerns by the public or by Medical Center employees. The IACUC must review each concern in a timely and systematic manner and when necessary take prompt and appropriate corrective action.

- Reports of animal welfare concerns may be made anonymously, if desired. However, if the complainant would like to know the resolution of the investigation, he or she must provide a name. All reports will be handled confidentially, although anonymity cannot be guaranteed.
- Any concerns or deficiencies in the care and/or treatment of animals or any activities related to animal care that may be improper or inhumane, may be reported. Concerns may be reported to one's direct supervisor, the Attending Veterinarian, the ACOS/R&D, the IACUC Chair or the ARF Supervisor. Reporting may be done verbally, in writing or by e-mail. When reporting, as much factual information as possible should be included.
- Protection from retaliation is a very important issue. If one believes that they have been retaliated against for whistleblowing, a formal complaint can be filed with the Human Resources Department of the Medical Center.
- There are numerous signs throughout the ARF explaining the facility's whistleblowing Policy and the steps for reporting concerns.

### **Mandated Reporting of Deficiencies and Reports to outside agencies and headquarters**

As a condition of extending the privilege of conducting animal research to individual medical facilities, the Stratton VAMC expects that the IACUC and

institutional administrators will avoid any appearance of hiding or suppressing deficiencies. **NOTE:** *This goal is best achieved by prompt reporting of deficiencies before others outside of the program do so. Consistent with NIH Notice NOT-OD-05-034 dated 2/24/05, "Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals," facilities are to notify appropriate agencies by phone immediately that a full, written account of a reportable deficiency is forthcoming.*

- The main categories of deficiencies that must be reported to outside authorities and the elements needed in the report are as follows:
  - Any serious or continuing non-compliance with PHS Policy (including any serious deviation or continuing non-compliance with the provisions of the Guide, as required by the PHS Policy) or USDA AWA. The report needs to include:
    - When and how the IACUC became aware of the problem.
    - When the investigation was performed to determine facts and detail the circumstances that led to the non-compliance.
    - The results of that investigation, and
    - What corrective actions the IACUC approved to stop the noncompliant activity and prevent future recurrences.
  - Suspensions of protocols previously approved or suspensions of procedures or studies never given approval. The report needs to include:
    - When and how the IACUC became aware of the problem.
    - When the investigation was performed to determine facts and detail circumstances that lead to the non-compliance.
    - The results of that investigation.
    - When the IACUC convened a quorum to suspend the activity.
    - What corrective actions the IACUC approved to prevent recurrences.
  - Failure to correct a significant deficiency (identified during a semi-annual IACUC program or facility self-assessment review) according to the schedule approved by the IACUC. The report needs to include:
    - The date when the IACUC identified the deficiency.
    - The timetable and plan approved for correction.
    - Why the correction(s) could not be completed according to the timetable.
    - The revised timetable.
    - The plan to finish the correction(s).

\* The USDA AWAR (see 9 CFR 2.31(c)(3)) states that the failure to correct a significant deficiency must be reported in writing within 15-business days of the self-imposed deadline by the IACUC, through the IO, to USDA and any Federal agency funding that activity. This required 15-business day reporting period is extended to cover all categories of reportable deficiencies. **NOTE:** *Consistent with NIH*

*Notice NOT-OD-05-034 dated 2/24/05, "Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals," facilities should notify appropriate agencies by phone immediately that a full, written account of a reportable deficiency is forthcoming.*

- Although an ORD veterinary hold is not considered an IACUC suspension, it must be reported to other Federal agencies if the IACUC and Institutional Official (IO) find that information in the ACORP represents a reportable deficiency as defined in this SOP.
- Deficiencies meeting any of the criteria defined above must be reported in writing within 15 business days through the ACOS for R&D and the medical facility Director to the following agencies and offices:
  - ORD (by contacting the CVMO's office).
  - OLAW, as required by PHS Policy.
  - The Animal Care Section at USDA APHIS, as required by AWAR, if the deficiency involves a species meeting the definition of an animal in the AWAR, or if the deficiency impacts the care or use of such a species.
  - AAALAC, as required by AAALAC rules of accreditation.
  - The VA ORO, as required by ORO policy.
  - Any Federal agency (other than VA) funding an activity that has been suspended.

### **Post-Approval Monitoring**

The IACUC has the responsibility to monitor experimental animal procedures particularly when there is a potential for producing pain or distress to animal subjects. This responsibility can be met in three ways:

- Performance of random protocol audits and unannounced inspections of laboratories and/or areas where animals are used or housed.
- When requested by the IACUC, VMU Animal Health Staff will observe specific procedures and/or observe animals post-procedure and report to the IACUC an evaluation of training competency and or pain/distress level of the animals.
- The IACUC provides continuing review of all animal use protocols at least once annually.

**Sentinel Animals and Educational Use of Animals Review**

- Proposed use of animals for instructional or educational purposes must be reviewed and monitored by the IACUC following the same process as that employed for research proposals.
- Sentinel animals are used to monitor and determine the overall health of the general animal population, not for experimentation.

**Reporting of Hazardous Material**

- The IACUC provides the Chemical Hygiene Officer, Biosafety Officer and Radiation Control Officer with a list of hazardous materials used in animal protocols.
- Each lab must follow applicable Stratton VA Medical Center safety guidelines.

**IACUC Member Training**

- New IACUC members receive orientation by the IACUC Chair or Vice-Chair in areas of protocol review, inspection procedures, IACUC responsibilities and reporting requirements.
- All IACUC members must complete the VA version of the web based "CITI" training course and exam entitled "Essentials for IACUC Members".
- All IACUC members will receive continuing education in relevant animal use/care topics during the IACUC meeting or at facility Research program wide meetings. The content of the education is determined by the IACUC Chair, Vice-Chair, and Attending Veterinarian and Research Program Office management.
- Additional Training opportunities may include:
  - One-on-one training with the Chair, VMO, RCO or other qualified IACUC member.
  - Individually review federal, state, local or institutional laws, regulations, policies or SOP's.
  - Complete web based training courses available from VA Office of Research and Development, the OLAW (PHS Policy on Humane Care and Use of Laboratory Animals tutorial), the Animal Welfare Information Center Workshop and others.
  - Participate in PRIM&R IACUC courses.
  - Educational seminars provided by the VMO, ORO or ORD.

**Investigator, Research Staff, and ARF Staff Training:**

- Prior to approving a protocol, the IACUC will ensure that all staff listed on each protocol have been adequately trained (see: USDA Animal Welfare Act and Regulations (AWAR), 9 C.F.R. §2.32(a); Principle 8, U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used In Testing, Research, And Training). As a minimum, the training utilized will cover all topics listed in USDA AWAR, §2.32(c).

- The Office of Research and Development (ORD) has developed free web-based training that helps meet mandatory training requirements for research staff – this is a “CITI” based training called “Working with the VA IACUC.” This ORD approved web-based training will be utilized on an annual basis to demonstrate compliance with Federal animal research training mandates, unless alternate and equivalent annual training approved by the CVMO has been adopted. Education goals for web-based training will be considered met when personnel are able to pass an exam that covers important topics in the training. The exam must be of sufficient difficulty to provide some assurance that important concepts have been learned.
- Investigators are required to take "Working with the VA IACUC" web course and must pass the exam. Investigators **and** research staff listed on the main ACORP are required to take species-specific web courses that covers the species proposed for use and pass the exam (can be found at: <https://www.citiprogram.org>).
- Individuals wishing to utilize alternate web-based, didactic, or other types of training in place of ORD web-based training must document in writing to the CVMO that the alternate training covers all areas required by USDA Animal Welfare Act Regulations on an annual basis. If documentation is not deemed adequate, ORD web-based training, or more stringent alternative training must be adopted as approved by the CVMO.
- The VA also has mandatory training requirements for Investigators and Research Staff. The VA has developed free web-based training that helps meet mandatory training requirements accessible to research staff. Investigators and research staff listed on protocols are required to take the following VA course:
  - Information Security 201 for Research and Development
  - VHA Mandatory Training for Trainee’s VII, found at <https://www.ees-learning.net/librix/loginhtml.asp?v=librix>

If the Investigator or research staff has access to the VA computer network system, they are also required to take the following courses:

- VA Privacy Policy
- VA Information Security Awareness

### **VA and Affiliate IACUCs**

Stratton VAMC does not have an affiliate IACUC and as such does not address related issues. Should such an affiliation be established, this SOP will be addressed to meet all of the relevant requirements.

### **Initiating New Programs**

Stratton VAMC will not initiate a new animal program, or restart dormant programs utilizing laboratory animals for research, testing, or training unless approved by the CRADO, in consultation with the CVMO and the affected ORD Service Directors.

## **PART II – Animal Research Facility Standard Operating Procedure**

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## **INTRODUCTION**

The Stratton VA Medical Center Animal Research Facility (ARF) maintains full accreditation with the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC). The Medical Center actively supports the use of animals in research, teaching and testing. However, the use of animals in VA research is a privilege granted with the understanding and expectation that such research is conducted according to the highest ethical and legal standards. These policies are written to set forth the principles and procedures that govern research activities involving laboratory animals in the Stratton VA Medical Center Animal Research Facility.

## **GENERAL STAFF POLICIES**

The general policies for all staff working within the Animal Research Facility are as follows:

- The introduction of food and/or beverage into the ARF is strictly prohibited except in designated areas. Designated areas are offices and the break room only. The disposal of food and beverage refuse will only occur in these areas.
- Smoking is not allowed in any area of the ARF. This policy is strictly enforced.
- Personal entertainment devices, such as stereos, radios and televisions are prohibited in all animal care areas. Special permission may be granted by the Associate Chief of Staff for Research and Development (ACOS/R&D) to use these devices in the operating room, necropsy room or procedural rooms. These devices are allowed in offices and the break room.
- To protect the health of the animals housed in the ARF, non-research animals are prohibited from all areas of the ARF. This prohibition includes pets of any species.
- Any behavior by research personnel that threatens the health and well-being of the research animals is regarded as a serious infraction and will be reported to the proper authorities.
- All research personnel must have their identification cards displayed while working in the ARF.
- Any injuries or illnesses that occur to research personnel in the ARF, as a result of animal contact or exposure, must be reported to their Supervisor and the The Occupational Health Service .
- Unauthorized persons will not be allowed in the ARF without proper ID and/or permission of the ARF supervisor.

### **Reporting Animal Concerns and Whistleblower Policy**

The Stratton VA Research Service is committed to the humane care and use of laboratory animals. To ensure that laboratory animals receive humane care and use/treatment in accordance with the highest ethical standards, laws, regulations and policies governing animal research, the Institutional Animal Care and Use Committee (IACUC) must review and if warranted, address any animal-related concerns by the public or by the Medical Center employees. The IACUC must review each concern in a timely and systematic manner and when necessary take

prompt and appropriate corrective action.

Reports of animal welfare concerns may be made anonymously, if desired. However, if the complainant would like to know the resolution of the investigation, he or she must provide a name. All reports will be handled confidentially; however, anonymity cannot be guaranteed.

Any concerns or deficiencies in the care and/or treatment of animals or any activities related to animal care that may be improper or inhumane, should be reported. Concerns may be reported to one's direct supervisor, the Attending Veterinarian (VMO), the Associate Chief of Staff for Research and Development, the IACUC Chair, or the ARF Supervisor. Reporting may be done verbally, in writing or by e-mail. When reporting an incident, factual information should be detailed in the report.

The Notification and Federal Employee Antidiscrimination and Retaliation (No FEAR) Act protects individuals from retaliation for whistle blowing. If an individual believes that they have been retaliated against for whistle blowing, a formal complaint can be filed with the Human Resources Department of the Medical Center. There are numerous signs throughout the ARF detailing the Medical Center's No Fear Act/Whistle Blowing Policy and the steps for reporting concerns.

## **SECURITY IN THE ANIMAL RESEARCH FACILITY**

Vulnerability of the Animal Research Facility and staff is of high priority and constant assessment is done to help assure a safe and secure workplace for personnel and animals used in research. These measures include:

- Background checks on new research personnel by Human Resources.
- Identification card swipe system on all external doors of the ARF. Whenever a person swipes into the facility, the Police Unit can instantly identify the card that is being used.
- Safety screens are located on all windows. In addition, these windows have alarms that detect movement of the window and loud noise levels in the area of the window. These alarms go directly to the Police Unit.
- There are five emergency buttons located in the hallways of the ARF. These buttons can be pushed for any emergency or potential threatening situation. The Police Unit will respond immediately to any incident in which a emergency button is pressed.
- All ARF's external doors are equipped with security hinges to prevent the door from being removed from the frame.
- A security camera is located on the main building directed at the two main entrances of the ARF. The Police Unit is responsible for monitoring the security camera.
- The Police Unit is responsible for verifying all external doors are secure during non-tour duty hours during each police shift.

## **PER DIEMS AND SPACE**

All investigators utilizing animals in the ARF are charged a per diem rate for the daily care of each individual animal. The per diem charge includes feed, bedding, changing pans and cleaning cages, the veterinary technician's time to perform these duties and the veterinarian costs. The rates are determined by the type of funding the Investigators are receiving: VA Funded or Non-VA Funded research.

All Non VA Funded investigators are charged for space used at the Animal Research Facility. This includes the rooms that are used to house their animals, as well as laboratory and office space. Investigators are charged a monthly fee per square foot for all support areas. Rooms that are used for the housing of animals are assessed for the capacity of animals that requiring housing before the Investigator is charged. The investigator is charged per square foot, pro-rated according to the percentage of space used for animals in the housing areas. These calculations are done on a daily basis and are charged to the investigator monthly.

## **STAFFING**

The Animal Research Facility has one part-time animal technician, and the ARF supervisor. They provide full coverage for the facility during the weekdays, weekends and holidays. The ARF supervisor's regular tour of duty is Monday-Friday. The regular tour of duty for the caretaker includes weekends and holidays. The VMO makes visits to the facility every two weeks and is accessible via phone or e-mail at all times. The names and home phone numbers of the ARF supervisor, VMO and local/alternative veterinarian for emergencies are posted prominently in the facility. After hours emergencies are handled through Police and Security Service, notification to the Research Department will occur through the use of the Research Emergency Cascade.

## **TRAINING OF STAFF**

The ARF Supervisor is responsible for training of all animal care personnel working in the Animal Research Facility. This will be done with the assistance and guidance of the attending veterinarian. Training will consist of direct hands on training with the ARF supervisor or veterinarian, the reading and understanding of research policies and ARF SOPs as well as required web based training on the specific species housed in the ARF. Continuing education for animal care personnel will consist of yearly required web based training, research staff training and attendance at local lab animal meetings or symposiums.

The ARF Supervisor and VMO or alternate VMO must also complete yearly web based training and attend research staff training sessions. The ARF supervisor and attending veterinarian will be expected to attend some lab animal meetings or symposiums as part of their continuing education. The attending veterinarian provides training twice a year at research staff meetings.

## **SAFETY AND THE USE OF PROTECTIVE CLOTHING**

Standard Precautions are used by animal care personnel working in the ARF and annual training is provided in compliance to these standards.

Material Safety Data Sheets (MSDS) sheets (paper and electronic) are located in the ARF Breakroom for all chemical agents used by animal care personnel. There are several signs in the ARF announcing the location of the MSDS sheets.

There are 9 emergency eyewash stations and 3 emergency shower pull stations located in the Animal Research Facility. Eyewash stations are tested weekly by the Facility Maintenance Service (FMS) and recorded on the card attached to the eyewash station. Shower stations are tested monthly by Engineering Service personnel and recorded on the card attached to the shower stations.

There are 12 fire extinguishers and 4 fire alarm pull stations in the ARF. All fire extinguishers and fire pull stations are clearly marked. All fire extinguishers are checked monthly by the Safety Office. In case of an emergency, all exit doors are clearly marked.

All ARF research staff must follow the VA's policy on the proper use and disposal of needles and syringes. Needles are not to be recapped. Syringes with attached uncapped needles must be dropped into puncture proof containers for disposal. When containers are full, they are placed in the hazardous waste area for pick up by private contract personnel. Adequate animal restraint is used to reduce the chance of accidental needle sticks. This may involve proper restraining devices and the use of anesthetics.

The ARF has 5 stationary chemical hoods that may be used for tasks involving hazardous or dangerous materials. Hoods are certified once a year to help ensure that they are functioning properly.

All animal care personnel working in the ARF must wear clean scrub suits daily, except under certain circumstances such as non-animal contact assignments, in which case the technician may wear a full length, buttoned lab coat over his or her clothing. Dedicated steel toed shoes are worn by animal care personnel while performing tasks in the ARF. Additional protective clothing is used by animal care personnel for various assigned duties. These would include safety eyewear, gloves, ear protection, respirators, aprons and gowns. Disposable gloves are used whenever animal contact procedures are done and when handling animal wastes.

All other research personnel working in the ARF, including visitors must wear full length, buttoned lab coats during their stay in the ARF. Uniforms used in the ARF are NOT to be worn outside of the facility or taken home. Laundry facilities are located in the ARF for washing and drying of all lab coats and scrubs.

Signs are posted throughout the ARF to bring attention to the animal species that are used in the facility. This is to prevent or reduce the exposure of individuals who may be allergic to one or more species of animals in the facility. The signs instruct them to report to the The Occupational Health Service for further evaluation.

### **PHYSICAL PLANT MAINTENANCE AND REPAIR**

Work Orders. Work orders for repairs in the VMU should be completed in a timely manner. Logs of work order submission and status must be reviewed as part of the IACUC semiannual evaluation of the animal care and use program. Any delays that have the potential to affect the health and well-being of animals or humans should be communicated to the IACUC as potentially reportable deficiencies.

### **WASTE DISPOSAL**

All soiled bedding and refuse are treated as hazardous waste and are packed in biohazard boxes. The boxes are picked up by EMS personnel every two weeks and shipped by a hazardous waste company to be destroyed. Animal carcasses are red bagged and transported in accordance with regulatory requirements. Animal carcasses are stored in a freezer. EMS personnel pick up and box carcasses every two weeks and a hazardous waste company will ship boxes to be destroyed.

Radioactive wastes are stored in radioactive barrels by the Radiation Safety Officer and later shipped by the radiation safety officer.

### **PEST CONTROL**

The object of the Animal Research Facility's pest program is to control arthropods and rodent pests utilizing mechanical control techniques in conjunction with a sanitation program and minimal application of approved insecticides if applicable. All chemical pest control substances must be approved by the attending veterinarian and the ARF supervisor for animal safety.

The ARF supervisor is responsible for the facility's pest control program. Rodent pest levels are monitored by examination of the facility for rodent excrements and chewing on feed bags as well as examination of sticky traps. Arthropod pests are monitored using roach traps. Traps are placed in rooms and are counted monthly. The ARF supervisor keeps a record of these numbers in the ARF office. If a severe case of vermin infestation is noted in an animal room, the room will be emptied and exterminated. Currently there are no insecticides used in the ARF.

### **ANIMAL PROCUREMENT**

All animal purchases must be approved by the ARF Supervisor. The reasons for this are:

- Animal care staff must have housing and care available when animals arrive.
- Animal care staff must provide disease surveillance and vaccinations on arrival.

- It ensures that someone is available to receive and provide proper attention to newly arrived animals at all times as required by provisions of the Animal Welfare Act.
- It ensures that there are an adequate number of animals available for that particular Animal Component of Research Protocol (ACORP) in a given study year.

### **Animal Procurement Procedures**

Any laboratory animal used in the Animal Research Facility must be acquired in accordance with Federal laws, regulations and policy. All deliveries of live animals must be made directly to the Animal Research Facility unless special arrangements have been made and approved by the Associate Chief of Staff for Research and Development.

The procedures for ordering animals are as follows:

- 1 Prior to ordering animals, an email must be sent to the ARF supervisor and IACUC Chairperson for verification that there is space available in Animal Research Facility to house the animals being requested and to confirm that the number of animals requested are available for use, according to the approved ACORP.
  - The email must contain the number of the approved ACORP.
- 2 Once a positive response is received from the ARF supervisor and IACUC Chairperson, the purchase order may be placed. For VA and Albany Research Institute orders, the purchase order form must contain the title and number of the approved ACORP. Orders will not be placed until both authorizations have been obtained. This is necessary to ensure that there are no deviations from the protocol.
- 3 If any animals arrive to the Animal Research Facility without prior approval, they will be refused and returned to the vendor at the expense of the Principal Investigator. All instances of non-compliance will be presented to and addressed by the IACUC.
- 4 After the arrival of approved animals, the ARF supervisor will track the number of animals for the particular study to ensure that the study does not exceed the allotted animals according to the ACORP.

### **Approved Vendors**

All animal purchases will be made through approved vendors, unless otherwise noted and approved by the IACUC Committee. The current list of approved vendors is as follows:

RABBITS – Millbrook Labs, Harlan and Covance.

RATS – Harlan, Charles River and Taconic.

MICE – Charles River, Taconic, Jackson Labs, and Harlan.

GUINEA PIGS – Charles River and Elm Hill.

### **ANIMAL RECEIVING PROCEDURES**

All deliveries of animals will be through the receiving Room #126. After animal lab

personnel have verified a shipment of animals, they will notify Research Budget and Fiscal Assistant. After a shipment of animals has been received, the room and equipment must be disinfected before receiving additional animals. The technician is responsible for having all cages of animals identified appropriately. Identification will include species, strain, date received, weight or age, sex, investigator, source and protocol number. The U.S.D.A. form will be verified against the animal numbers for species under the Animal Welfare Act and will be filed in the Supervisor's office. These forms will be maintained for the period required by law. All incoming animals are to have a quarantine period, unless animals received are pathogen-free and from the same source. The length of the quarantine period will vary depending upon the species, vendor source, and health status of the animal and will be determined at the time of ordering.

### **Rodents**

Box shipment of rodents will be placed on a table or cart. The animal lab employee receiving the animals will verify the accuracy of the shipment before signing the invoice. The boxes containing the rodents will be taken directly into an available quarantine room and placed into the appropriate type of cages and labeled with the following information: Investigator, date received, birth date, strain, vendor, sex, weight when received and protocol number. The employee will check rodents for nasal or ocular discharge, as well as general overall health. The empty shipping boxes will then be taken directly to the trash dumpster, located directly outside of the Animal Research Facility. Rodents with an unknown health status will be quarantined for a minimum of two weeks. Rodents from an approved vendor source with a known health status will be placed in an existing colony from the same vendor source. A stabilizing period of five days is encouraged for those rodents from an approved source.

### **Rabbits**

Rabbits are received in the ARF and will be placed on a table or cart, initially. Animal lab personnel receiving the animals will verify the accuracy of the shipment before signing the invoice. When rabbits are received they will be examined for ear mite infections, nasal or ocular discharge, diarrhea and skin lesions. The animal is then weighed. Animals are then taken directly to an available quarantine room and are placed into the appropriate cage and labeled with the following information: Investigator, date received, strain, vendor, sex, weight when received and protocol number. Shipping boxes are then taken to the trash dumpster, located directly outside of the Animal Research Facility. Rabbits from the same vendor source may be placed directly into the animal room or otherwise quarantined in an available room. Rabbits with an unknown health status will be quarantined for a minimum of two weeks.

## **IDENTIFICATION OF ANIMALS HOUSED IN THE ANIMAL FACILITY**

All animals are to be clearly identified upon receipt of shipment or at the time of birth. Unique numbers are assigned to animals larger than rodents.

**Methods:** All animals are identified by attaching a cage card to the cage or box. The following information must be supplied on the cage card where applicable:

- Protocol Number
- Investigator's Name
- Source
- Strain
- Date Received
- Species
- Weight or Age on Arrival
- Sex

It is the responsibility of the animal care staff to properly identify the animals and make sure the identification is legible. It is also their responsibility that the animals have the proper identification on them at all times. Any missing identification cards should be reported to the ARF supervisor as soon as possible.

#### **Identification Cards for Animals Being Bred**

Animals that are bred in the facility are identified by an attached cage card to the cage or box. The following information is required on the cage card where applicable.

- Identification
- Date of birth
- Number of animals
- Parents
- Sex
- Source
- Investigator's Name
- Protocol Number
- Date of Receipt
- Species and Type

#### **ANIMAL HOUSING**

The primary enclosure of a cage or box provides the limits of an animal's immediate environment, so this area must allow for the normal physiologic and behavioral needs of the animal, such as urination, defecation, maintenance of body heat, etc. The housing requirements for species used in the ARF are as follows:

Animals	Weight, g	Floor area/animal, in. (cm)	Height in. (cm)	Comments
Mice in groups	< 10	6 (39.7)	5 (12.7)	Larger animals may require more space to meet the performance standards.
	Up to 15	8 (51.6)	5 (12.7)	
	Up to 25	12 (77.4)	5 (12.7)	
	>25	≥ 15 (≥ 96.7)	5 (12.7)	
Mice, Female + litter		51 (330)	5 (12.7)	Other breeding configurations may require more space and will depend on considerations such as number of adults and litters, and size and age of litters
	Recommended space for the housing group			
Rats in groups	<100	17 (109.6)	7 (17.8)	Larger animals may require more space to meet the performance standards.
	Up to 200	23 (148.35)	7 (17.8)	
	Up to 300	29 (187.05)	7 (17.8)	
	Up to 400	40 (258.0)	7 (17.8)	
	Up to 500	60 (387.0)	7 (17.8)	
	> 500	≥ 70 (≥ 451.5)	7 (17.8)	
Rats, Female + litter		124 (800)		Other breeding configurations may require more space and will depend on considerations such as number of adults and litters, and size and age of litters
	Recommended space for the housing group			
Hamsters	<60	10 (64.5)	6 (15.2)	Larger animals may require more space to meet the performance standards.
	Up to 80	23 (148.35)	6 (15.2)	
	Up to 100	29 (187.05)	6 (15.2)	
	> 100	40 (258.0)	6 (15.2)	
Guinea Pigs	Up to 350	60 (387.0)	7 (17.8)	Larger animals may require more space to meet the performance standards.
	> 350	≥ 101 (≥ 651.5)	7 (17.8)	
Rabbits	< 2	1.5 (0.14)	16 (40.5)	Larger rabbits may require more cage height to allow animals to sit up.
	Up to 4	3.0 (0.28)	16 (40.5)	
	Up to 5.4	4.0 (.37)	16 (40.5)	
	> 5.4	≥ 5.0 (≥ 0.46)	16 (40.5)	

### Stratton VAMC General Housing Practice

- Mice – Polycarbonate boxes, at least 7.5”x 11”x 5” with a maximum of five animals per box.
- Rats – Polycarbonate boxes, 10.5”x19”x 8’ with a maximum of 3 animals per box.
- Rabbits – Stainless steel or plastic cages with 1 animal per cage.
- Guinea Pigs – Polycarbonate boxes, 10.5”x19”x 8”, with one guinea pig per box.

### SOCIAL ENVIRONMENT AND ENRICHMENT

Animals housed in the Animal Research Facility require a certain degree of social interaction and/or enrichment to reduce boredom as well as encourage healthy and normal habits. When possible, social animals are housed in groups to stimulate social interaction. In cases where animals are housed alone, such as in rabbits or guinea pigs, enrichment toys are used to encourage interaction. Mice, rats and guinea pigs are all

given Nylorbones. Mice are given toys that encourage nesting. Rabbits are given Jingle Balls as well as Bunny Blocks which they interact with.

### **RABBIT CARE AND FEEDING**

The ARF staff should clearly observe all rabbits in the rooms that they are assigned. Particularly notice appetite, changes in attitude, amount and makeup of feces, etc. Any changes should be brought to the attention of the ARF supervisor, investigator and the veterinarian.

Rabbits are housed in individual cages. The size of the cage is mandated by the Animal Welfare Act and The Guide, and must be adhered to.

If rabbit feed is kept in the animal room it is to be placed in vermin-proof containers that have tight-fitting lids. Periodically such containers are to be completely emptied and sanitized. When feed is emptied out of the bag and placed in these containers, the technician will write the date this is done and the milling date of the feed on a tag, located on the side of the container.

Pans are changed twice weekly. At the time of changing, clean pans are covered with about ¼ inch layer of hardwood Sani-Chip. Rabbit cages are changed and sanitized on a two week schedule.

Unless required by experimental protocol rabbits are fed ad libitum a regular commercial rabbit feed. Feed hoppers are checked daily and refilled as needed. Water is provided with attached water bottles. Water must be checked daily to insure adequacy and cleanliness. Water bottles may be "topped-off" using the water source within the animal room. Bottles must be returned to the same cage when "topping" them off. However, water bottles are sanitized at least weekly. Diet is not fed beyond 180 days after milling date.

When moving rabbits to a new cage, the ID card is first moved to the new cage followed by the particular animal. This is done to avoid misplacing or incorrect identifying animals. Caution must be used in handling rabbits during changing of cages, so that none are injured. The technician should observe the rabbit for general health, malocclusion, overgrown nails and signs of ear mites. These problems will be taken care of by the technician and brought to the attention of the veterinarian. On a monthly basis, nails are checked or trimmed and rabbits weighed and weights recorded on the back of the cage card by the ARF staff. When rabbit cages are changed, the technician must be sure that the proper cage card is placed on the clean cage.

When the technician has completed servicing the rabbit room, the floor will be swept and hosed down daily. At least once a week the floor will be mopped using a clean mop head. The mop water will contain two ounces per gallon of a quatricide disinfectant added according to the label directions. Mops, brooms, dustpans, and mop buckets are dedicated to particular rooms. Trashcans in the rooms are lined with plastic bags and

will be emptied regularly.

Rooms are completely emptied and sanitized every three months using two ounces per gallon of a quatricide, with the use of a pressure sprayer.

### **Feeding Schedule for Newly Acquired Rabbits**

When newly acquired rabbits are received and placed in their individual cages, they are not offered food until approximately 24 hours after receipt. The amount of food is then increased over a five day period, starting with about 25 grams on day one to about 125 grams by day five. Water is available ad libitum.

First 24 hours ----No Food

Day 1 -----25 grams

Day 2 -----50 grams

Day 3 -----100 grams

Day 4 -----125 grams

Day 5 -----125 grams

### **RODENT CARE AND FEEDING**

The animal technician should clearly observe all rodents in rooms for which they are responsible for with particular attention to: appetite, changes in attitude, coughing, hair coat etc. Any changes should be brought to the attention of the ARF supervisor, the investigator and the veterinarian.

Rodent caging at the Animal Research Facility consists of solid bottom plastic cages with wire lids. Rodents are normally housed in groups, unless the protocol deems otherwise. Rats are housed up to three per cage and mice up to five per cage. The size of the cages is mandated by the Animal Welfare Act, and must be adhered to. There are some specialized metabolism cages which may be used on occasion.

If rodent feed is kept in the animal room it is to be placed in vermin-proof containers that have tight-fitting lids. Periodically such containers are to be completely emptied and sanitized. When feed is emptied out of the bag and placed in these containers, the date this is done and the milling date is written on a tag, located on the side of the container. A standard rodent diet will be given ad libitum to all rodents unless a different feed type or schedule is required by the investigator. Feed hoppers will be checked daily and filled as necessary. Diet is not fed beyond 180 days of milling date. Water will be provided ad libitum unless another schedule is required by the investigator. Water will be checked daily. Pint bottles will be used for all rodent cages. When rodents are housed in plastic cages care must be taken to insure that sipper tubes are long enough, and no curved sipper tubes are used.

Water bottles may be topped off using the water source within the animal room. Topped off bottles must be returned to the same cage. All water bottles must be changed and sanitized at least once weekly for mice and rats.

Plastic boxes will have approximately 1/2" layer of Care-Fresh placed in the bottom of the boxes. Boxes used for rats will be changed twice weekly and for mice once per week. Wire lids are sanitized weekly. Racks holding rodent boxes are to be sanitized once every two weeks. Ventilated racks are changed and sanitized on a monthly basis.

When changing cages, first remove the ID card from the dirty cage and place it on the clean cage. Then remove the rodents and place them into the clean cage. This is done to avoid misplacing or incorrectly identifying the animals. When plastic cages are changed, the wire lids may be transferred from one cage to the next, but at least once every week the lids should be changed and sanitized. When rodents are transferred from one cage to another, they should be observed closely for any abnormality.

Every day, each animal room will be checked and serviced. The rooms will be swept once a week or daily, depending upon need. The floor will be mopped at least weekly using a clean mop head. The mop water will include two ounces per gallon of a quatricide disinfectant added according to label instructions. Mops, brooms, dustpans, and mop buckets are dedicated to individual rooms. Trash cans in rooms will be lined with plastic bags and emptied regularly.

Rooms are completely emptied and sanitized every three months using two ounces per gallon of a quatricide disinfectant with the use of a pressure sprayer.

### **GUINEA PIG CARE AND FEEDING**

The animal technician should clearly observe all the Guinea Pigs in the rooms for that they are responsible for with particular attention to changes in appetite, hair coat, activity and vocalization. Guinea Pigs are housed individually in solid bottom cages with wire lids. The cage size is mandated by the Animal Welfare Act, and must be adhered to (See chart above).

Guinea Pig boxes are changed three times a week. Cages will have approximately 1/2 inch of Care Fresh placed in the bottom. To change Guinea Pigs cages, first remove the ID card from the old cage and place it on the clean cage, followed by the movement of the Guinea Pig to the new cage. This is done to avoid misplacing or incorrectly identifying the animals. Wire lids are changed and sanitized weekly. Racks holding cages are changed every other week.

Guinea Pigs are fed a standard guinea pig diet ad libitum in stainless steel feeders. The feeders are changed weekly and sanitized. Each feeder is completely filled at each feeding. If Guinea Pig feed is kept in the animal room, it is to be placed in vermin-proof containers that have tight fitting lids. Periodically such containers will be emptied and sanitized. When feed is emptied out of the bag and placed in containers, the date this is done and the milling date is written on a tag located on the side of the container. Diet is not fed beyond 90 days from milling date (Guinea pig food is fortified with Vitamin C, which breaks down after this period).

Water bottles are changed and sanitized daily. Topping off of Guinea Pig bottles is not permitted.

Each day, after a room has been checked and serviced, the floor will be swept. The floor will be mopped at least twice weekly, using a clean mop head. The mop water will contain two ounces per gallon of a quatricide disinfectant added according to label instructions. Mops, brooms, dustpans and mop buckets are dedicated to individual rooms. Trash cans are lined with plastic bags and are emptied regularly.

Rooms are completely emptied and sanitized every three months using two ounces per gallon of a quatricide disinfectant with the use of a pressure sprayer.

### **RECOMMENDED RELATIVE HUMIDITY, DRY-BULB TEMPERATURE for COMMON LABORATORY ANIMALS**

Animal	Relative Humidity(%)	Dry-Bulb °C	Temperature °F
Mouse	30-70	18-26	64.4-78.8
Rat	30-70	18-26	64.4-78.8
Hamster	30-70	18-26	64.4-78.8
Guinea pig	30-70	18-26	64.4-78.8
Rabbit	30-70	16-21	60.8-72.0

#### **Temperature and Light Monitoring of the Animal Rooms**

Monitoring of the animal room environment is an essential tool for controlling the environment.

High, low, and present temperatures (Fahrenheit) of each animal room are recorded daily. Min/Max thermometers are to be used for monitoring. The temperatures over the previous 24 hours should be recorded during the same time period each day. The time of the recording is noted. In addition, Data Loggers are used in the facility to spot check temperature, humidity and light cycles in specific rooms and generate reports of this activity. The Data Log System is a computer based software system that uses satellite sensors that are placed in animal rooms for a determined period. These sensors take environmental readings at pre-determined time intervals and store this information. Afterwards, the sensor is connected to a special adaptor in the computer located in the ARF Supervisor's Office. The environmental data is then electronically processed in the computer and a report is generated of the continuous temperature, humidity and light cycles in the room for that period. Temperatures recorded outside the ranges listed above for the various species must be reported to the Engineering Service. Monthly reports must be on file in the facility office and available for review upon request. A 12-hour light, 12-hour dark cycle is maintained unless otherwise requested by the investigator.

**Animal Room Environmental Logs**

Current animal room environmental records are maintained in each animal room. It is a check list for the technician assigned to the room to complete daily. The log consists of columns for the technician to mark off the critical elements of daily husbandry, such as feeding and watering have been done. There is an additional area to record the high, low, and present temperatures and humidity. Time, date and the technician's initials are recorded on the log after the work is completed. Completed animal room environmental records are maintained in the Animal Research Facility office for at least three years (current VACO records retention rules require that these are kept indefinitely).

**Room Activity Log**

Current room activity logs are maintained in each animal room. It consists of a check list for the technician assigned to each room to be filled out daily. There are columns to check off for the cleaning of sinks, feed barrels, floors and surfaces, the changing of animal pans, boxes and cages and room sanitation. The technician will initial the room activity log after completion of duties in the room. Completed room activity records are maintained in the Animal Research Facility office for at least three years (current VACO records retention rules require that these are kept indefinitely).

**HANDLING SICK, DEAD, ESCAPED OR UNIDENTIFIED ANIMALS**

Animal Technicians are to observe their assigned animals for signs of disease or abnormal behavior at the beginning of each workday. If any animal appears to be sick or dead, or has escaped or is unidentified the following steps should be taken for each respective situation.

**Sick Animals**

A sick animal report sheet will be filled out with the date, time, species, animal ID, room number, cage location, investigator and symptoms. The ARF supervisor will be notified and will check the animal. The investigator and the staff veterinarian will then be notified. The name of the person notified will be recorded. Only in exceptional cases will the veterinarian initiate treatment without investigator knowledge. All observations, medications, and treatments given will be recorded on the sick animal report sheet and will be reviewed by the veterinarian.

**Dead Animals**

A dead animal report will be filled out with the date, time, species, animal ID, room number, cage location, investigator and date arrived. The ARF supervisor and the veterinarian will be notified, as well as the investigator. Upon request of the investigator, dead animals will be necropsied by the veterinarian or the ARF Supervisor. All necropsy findings, as well as possible cause of death, will be recorded on the dead animal report and reviewed by the veterinarian. Dead animals will be stored in the carcass freezer of the Animal Research

Facility. EMS personnel will pick up and box the carcasses every two weeks and a hazardous waste company will ship boxes to be destroyed.

### **Escaped or Unidentified Animals**

Animals do escape from their cages. If such an animal is found free or unidentified in a room, it will be placed in a new cage and identified as "FOUND." Each investigator with animals in that room will be notified in writing. Unclaimed animals will be euthanized 7 days after they are found. Escaped animals found by investigators or staff should not be placed in any cage except an empty cage. If an animal is found loose, the ARF supervisor must be notified.

## **ANIMAL ROOM SANITATION**

### **Rabbit Rooms**

Rooms are swept and hosed down daily during the week. The rooms are mopped weekly with two ounces per gallon of quatricide using a freshly laundered mop. Every three months, rabbit rooms are completely emptied and all walls, floors, and fixtures are sanitized using two ounces of a quatricide disinfectant with the use of a pressure sprayer.

### **Rat and Mouse Rooms**

Rooms are swept daily as needed but at least once weekly. The rooms are mopped weekly with two ounces per gallon of a quatricide, using a freshly laundered mop. Every three months, rat and mouse rooms are completely emptied and all walls, floors and fixtures are sanitized using two ounces of a quatricide disinfectant, with the use of a pressure sprayer.

### **Guinea Pig Rooms**

Rooms are swept daily and mopped twice weekly with two ounces per gallon of a quatricide disinfectant using a freshly laundered mop. Every three months, all guinea pig rooms are completely emptied and all walls, floors and fixtures are sanitized with two ounces per gallon of a quatricide disinfectant with the use of a pressure sprayer.

### **Mopping Procedures**

2 ounces per gallon of a quatricide is applied to the floors of the room and left for ten minutes. The mop is rinsed of detergents and the floor is wet-mopped with fresh water.

### **Room Breakdown**

For rodent and rabbit housing rooms, once every three months, all animals' dedicated implements and feed barrels are removed. All surfaces are cleaned with two ounces of a quatricide disinfectant with the use of a pressure sprayer and then rinsed with water.

### **HVAC Filters**

For rodent housing rooms, filters are changed at least once a month by EMS personnel.

For rabbit housing rooms, filters are changed at least twice monthly by EMS personnel.

## **EQUIPMENT WASHING**

The cage washer is used to clean most non-surgical equipment, including cages, pans, boxes, water bottles, etc. The cage washer is operated for dirty items, while clean items are placed in the clean cage storage area of the room in which the cage washer resides.

At the start of cage washer operations, the fan hood in the rack washing area is started. This ensures a proper airflow pattern. Dirty items are to be brought into the room only through the double door at the corridor C-50 (South Corridor)

### **Machine Operations**

Most non-sterile equipment is sanitized in a Northstar R620 Cage & Rack washer. It is a floor-mounted, stainless steel, single door unit with a 6 foot ramp for loading and unloading large animal cages and racks. Its rotary spray design is also capable of cleaning boxes, bottles and utensils used in the care and housing of research animals. All operations are programmed by computer and the user only needs to turn the machine on and select pre-set wash and rinse cycles. There is also an acid cycle used for the removal of urine scale. The detergent used for the rack washer is Alka Det2 and for scale removal, Acid Power is used. Both products are manufactured by Pharmecal Research.

The cage and rack washer has scheduled maintenance quarterly from an outside company, LBR Scientific. Records of all work performed on the washer are kept in the ARF Office.

Temperature strips are used to verify that the water temperature reaches the required 180 degrees. They are attached to an item being washed during each use of the machine. These strips are placed on monthly calendars and are on file in the ARF Office.

Every two weeks, the rack washer screens are taken out and cleaned of debris by the ARF staff. This is done by removing the slotted stainless steel floor panels of the machine and then removing the four wire mesh screens located underneath. These screens are hosed down in the washroom of all debris and replaced in the rack washer.

### **Cage & Rack Washing**

Dirty items to be sanitized are brought into the washroom corridor C-50 (South Corridor). Pans and boxes containing dirty bedding are dumped into infectious

waste boxes located under the fan hood, near the C-50 corridor. Cages and racks are then pushed into the washer via solid 6 foot ramp. Boxes, pans, bottles and utensils can also be loaded on special racks and then placed in the washer. At this time, the temperature strip is placed on an item in the washer. The technician, after closing the stainless steel door, will select which wash and rinse cycles that are needed to sanitize the items inside. The different cycles used in various equipment cleaning are clearly displayed on the control panel of the rack washer. The start button is then pressed for the machine to start filling and the cycles to begin. When items in the washer are finished, the technician will unload the machine and take the clean material out of the north end washroom door into the clean cage area of the facility. Equipment is dried and stored in this area. Boxes and pans are filled with bedding there as well.

Technicians are supplied with safety equipment such as gloves, eyewear, steel toed shoes, ear protection and aprons for use while working in the washroom.

Boxes containing soiled bedding are picked up by EMS personnel and then transported by a waste removal company for disposal. New boxes for soiled bedding are made on site as needed.

At the end of each day, the following shall be accomplished:

- 1 The power switch is turned off on the Cage and Rack washer.
- 2 The floor wetted down, detergent put on floor and the floor brushed down.
- 3 The floor is then hosed down completely.
- 4 All floor drains will be emptied of debris daily.
- 5 No dirty equipment should be left overnight unless absolutely necessary. This is to prevent vermin infestation. When equipment is left overnight it may be stored in the "dirty" end of the washroom and the washroom doors are closed
- 6 The exhaust fan will be shut off at the end of the day, unless there is dirty equipment in the washroom.
- 7 Microbial evaluation will be done monthly by randomly sampling equipment taken out of the rack washer. A sterile culture swab is used for sampling and then brought to the VA Microbiology Lab for testing.

### **FEED AND BEDDING HANDLING, STORAGE AND PREPARATION**

Standard animal diets and bedding will be purchased from known suppliers using regular VA purchase procedures. The types of diets and bedding used will be recommended by the ARF supervisor and approved by the consulting veterinarian. Orders will be placed with Supply Service early enough that feed and bedding are always available.

Our standard diets and bedding are currently being purchased from Scott's Distributing Inc., Hudson, NH. Rabbit, rodent and guinea pig feeds are Purina Pro-Lab diets. Contact bedding is Presspak Care Fresh. Non-contact bedding is Hardwood Sani-

## Chips.

Special diets and ingredients for diets will be ordered by the responsible investigator after discussion with the ARF supervisor and consulting veterinarian. ARF personnel should keep the investigator informed concerning the amounts on hand and the need to reorder. Particular attention should be paid to feeds or ingredients ordered through Albany Medical College or Albany College of Pharmacy to allow adequate time for delivery.

All feed, bedding and ingredients will be received through the receiving foyer. Items will be checked against the Purchase Order for completeness. Damage will be noted and feed and/or bedding delivered in damaged containers will not be accepted. Signs of contamination or spoilage will be checked and dated items will be verified to assure currency.

Bulk animal feed and bedding will be placed in dedicated feed rooms and stored in the original sacks, bags, etc. Feed will be rotated to assure freshness. Feed not date coded will have the date of receipt written on the bag.

Ingredients for diets which need to be refrigerated will be stored in one of the facility refrigeration units. Care must be taken that such ingredients are not stored with materials that could cause contamination of the ingredients.

Feed may be transferred into bins or cans when available and these may be kept in the animal room. The containers should always be kept tightly closed to prevent vermin infestation and periodically the container should be emptied and cleaned. These containers will not be transferred from room to room, and when the original bag is not in the container, the type of feed will be identified on the top of the container lid. The milling date and date the feed is placed in the container will be plainly marked on the tag located on the side of the container

If ARF personnel are to prepare diet for investigators, it will be the responsibility of the investigator to request such service in advance, and instruct ARF personnel in the proper preparation of the diet.

## **QUARTERLY SEROLOGY TESTING ON RATS & MICE**

Health monitoring and serology testing are done on mice and rats housed in the ARF four times per year by the ARF supervisor. Virus-antibody free (V AF/Plus) animals are placed in the same room as the appropriate research animals for at least six weeks and then are anesthetized, bled (via cardiac puncture) and sacrificed. The blood is then allowed to separate and the serum is sent to Charles River Laboratories for determination of the presence of any viruses, mycoplasmas or bacteria that have been contracted from research animals. At that time, fecal flotations and skin samples will also be taken from the sentinel animals to check for internal and external parasites by the attending veterinarian or ARF supervisor. After the results are forwarded to the

Animal Research Facility, the ARF supervisor will prepare a report for the attending veterinarian, who will evaluate the report and take whatever steps necessary to ensure the proper health status of animals in the facility.

During the six-week period, the sentinel animals will have contact with the dirty bedding or where possible be housed directly in the same cages as the research animals. The sentinel animals will be anesthetized with Ketamine (90 mg/kg)/Xylazine (10mg/kg) mixture until they reach a surgical plane of anesthesia. After blood is collected via cardiac puncture, euthanasia is achieved by an overdose of Ketamine/Xylazine. The blood is allowed to coagulate at room temperature and is then centrifuged at 2000-3000 RPMs for 15 minutes. The samples are then measured and diluted with Phosphate Buffered Saline (PBS) by mixing 1 part of serum to 4 parts PBS. The samples are then packed with an ice pack and shipped via overnight service to Charles River Labs.

The number of animals used for monitoring purposes shall be no less than 24 mice and 20 rats per year and will be broken up into 4 groups, three months apart. The numbers will depend on the number of animals being housed and the number of rooms currently in use. A range of 1 sentinel animal per 8 to 10 research animals will be used. Upon the recommendation of the attending veterinarian, these numbers may be altered based on the serology reports, visible signs of infection or other health issues involving the ARF.

The type and strain of sentinel animals will be as follows:

- Mice: Swiss Webster, 13-15 grams, male and female, age range of 6 months plus. The vendor will be Charles River Labs.
- Rats: Sprague Dawley (CD) 175-200 grams, male and female, age range of 6 months plus. The vendor will be Charles River Labs.

This procedure is required in order to maintain a high quality animal care program and healthy animals.

## **EUTHANASIA**

Euthanasia of animals used in the Animal Research Facility must be performed in a manner that minimizes stress and discomfort to the animals as well as reducing the undue distress to the persons performing this task. All methods of euthanasia follow the recommendations of the AVMA panel on euthanasia and any exception to these recommendations must be project-specific, based on scientific necessity and require advanced approval from the IACUC. The veterinarian, ARF supervisor and trained animal care staff can carry out euthanasia procedures. Investigators and their staff will have prior training and/or experience verified by the IACUC upon review of the ACORP. If not, they must consult the veterinarian prior to the procedure.

### **Approved Methods of Euthanasia for Mice, Rats and Guinea Pigs**

- Carbon dioxide inhalation.
- Cervical dislocation under anesthesia for mice and small rats.
- Decapitation of anesthetized animal.

- General anesthesia followed by causation of death without regaining consciousness with the administration of barbiturate euthanasia solution.
- Intraperitoneal administration of pentobarbital at 3x the anesthetic dose.

#### **Approved Methods of Euthanasia for Rabbits**

- Carbon dioxide inhalation with prior sedation.
- General anesthesia followed by causation of death without regaining consciousness with the administration of barbiturate euthanasia solution.

The use of carbon dioxide, compressed CO<sub>2</sub> in cylinders, will be the only source of CO<sub>2</sub> used for euthanasia purposes. Death must be verified by the person administering the euthanasia prior to disposal of the animal.

### **SURVIVAL RODENT SURGERY**

Survival surgery on rodents does not require a special facility, but must be performed using sterile instruments, surgical gloves, and aseptic procedures to prevent clinical infections.

Instruments are to be sterilized by use of a cold sterilant (solutions containing gluteraldehyde) or by autoclaving with steam or ethylene oxide.

Surgical procedures will be performed in a designated area. The area should not be cluttered to allow for easy cleaning. The area should be cleaned prior to the procedure, as well as after completion of the surgical procedure with a quaternary ammonia solution or other equivalent solutions by the investigators or their technical staff.

The operative site on the animal should be prepared for surgery in order to remove as many bacteria as possible without harming the skin or interfering with wound healing. Skin cannot be sterilized; however, bacteria can be reduced to a relatively safe level for surgery by removal of hair, mechanical scrubbing, and the effective use of surgical scrub and germicidal solutions. Hair removal may not always be necessary dependent upon species or surgical site.

Hair should be clipped well beyond the margins of the incision. If the animal is cooperative, the hair can be removed prior to anesthesia. A number 40 clipper blade will remove most hair satisfactorily. If additional hair needs to be removed, moisten the area with a soap solution and shave with a straight razor. Hair can be removed close to the skin when clipped in a direction opposite to that in which it grows. The clipper blade should be checked prior to use for broken teeth, as these cut and abrade the skin. The blade should be held flat and not used in a raking motion, as this can injure the skin. Occasionally, the blade will become hot, and it should be checked frequently to prevent clipper burns. When the hair has been removed, the animal should be thoroughly cleaned of loose hair.

A selection of compatible scrub and germicidal solutions is important to achieve

maximum effectiveness. The limitations of the solutions need to be recognized. Alcohol solutions are not effective against bacterial spores. A commonly used surgical scrub and germicidal solution combination is povidone-iodine and 70 percent ethyl alcohol.

Povidone-iodine scrub should be applied with friction, followed by a thorough rinsing with warm water. A more thorough preparation should be performed after the animal is positioned on the operating table. The surgical preparation should begin at the incision line and in a circular motion proceed outward toward the periphery.

Discard the sponge when reaching the periphery or when either hair or rectum has been touched. Alternate surgical scrub and germicidal solutions at least three times and until the sponge with germicidal solution remains clean after prepping. The last application of germicide should be allowed to dry on the operative site for maximum effectiveness.

The animal should be draped by the surgeon after gloving using sterile technique. Draping should be done prior to instrument arrangement.

### **Preparations of the Surgeon**

The objective of any scrub is to remove as many bacteria as possible by mechanical scrubbing and the use of chemical antiseptics without harming the skin. Many techniques are used so that every surface, from the nails to the elbow, is thoroughly scrubbed. The time and number of brush strokes may vary depending on previous scrubs and on the type of solutions used. Scrubbing times of 5 to 15 minutes and 10 to 20 brush strokes per surface have been advocated. The combination of scrubbing time and thorough brush strokes is the key to an effective surgical scrub. A guideline for the thoroughness is 10 minutes or 10 brush strokes per surface. Each scrub will include two scrubs and two rinses.

Fingernails should be short and free of nail polish. Rings and jewelry should be removed. The scrub begins with a general soaping and rinsing with warm water. The nails should be cleaned with a disposable nail pick. The hands should be held higher than the elbows to prevent contamination from water running off the elbows and dripping onto the hands.

Skin surfaces should be scrubbed in a definite pattern of strokes in order to reach all surfaces. Start the scrub at the fingertips, proceeding to the surfaces of the fingers, the palms, the top of the hands, and then to the arm surfaces. After one scrub is complete, the hands and arms should be thoroughly rinsed. Discard the brush and acquire a new one for the second scrub. The process is then repeated.

Drying the hands and forearms is necessary to prevent moisture from becoming a possible source of contamination. Gloves can be donned more easily with dried surfaces. Toweling should start at the fingers, then proceed to the hand, and with a twist motion, dry the wrist and forearm up to the elbow. It is important that a

clean portion of the towel be used for each section (i.e., right hand and arm, left hand and arm).

### **Gloving**

Before gloving, lubricants can be applied to the hands to allow gloves to slide on more easily. Powders have been replaced by gloving cream in an effort to minimize dust particles in the operating room.

Gloves that are commercially pre-powdered, making additional lubricants unnecessary, may be used. The outside of the gloves should not be touched during the gloving.

## **ASEPTIC SURVIVAL SURGERY IN ANIMALS OTHER THAN RODENTS**

### **Patient Preparation**

The surgical patient should be prepared for surgery by withholding food for at least 12 hours prior to surgery. Water should be allowed until preoperative medication is given. Prophylactic antibiotics may be required in a patient that has a risk of infection.

### **Cleaning & Disinfection of the Operating Room & Its Equipment**

Each morning prior to surgery, the operating room should be damp dusted with a 2 percent quatricide solution. Walls, table surfaces, kick buckets, chairs, and surgery lights should regularly receive, depending on surgery schedule, a thorough disinfection. The surgery lights should not be overlooked. Their positioning directly over the surgical field can be a prime source of contamination. Wheels of equipment and various foot pedals (i.e., power equipment suction, electro-surgical unit) should be cleaned and disinfected. Places such as door ledges, cabinet tops, towel dispensers, view boxes, and the underside of equipment should not be overlooked.

Equipment such as the heating pad, the ECG, and the suction unit should be checked and ready for use. Instrument packs and supplies should be assembled. A wheeled cart can be used for transporting packs and supplies if they are stored outside the operating room.

Soiled instruments and discarded materials should be promptly removed from the operating room. Tables, kick buckets, stands and heating pads should be cleaned and disinfected after each case. Suction tubing and bottles should be replaced with clean units. The floors should be mopped with a 2 percent quatricide solution.

All furniture and equipment in the operating room should be moved at the end of the day for cleaning and disinfecting. A mop and bucket should be reserved for the operating room and marked "surgery only." The mop should be cleaned and

disinfected daily by being laundered or soaked in a clean disinfectant for 30 minutes. Dry mopping, sweeping, and dry dusting should not be done in the operating room as they tend to increase air currents and the spread of organisms. After surgery, the scrub sinks should be thoroughly cleaned and disinfected to remove oily deposits that are left by the scrubbing process. The soap dispensers and foot pedals should also be included in the cleaning and disinfecting procedure. If the scrub brushes are reusable, they should be cleaned and re-sterilized.

Monthly: Sterile supplies should be dated at the time of sterilization, and this dating should be inventoried each month. All cloth or paper articles are double wrapped and considered sterile for one month. Articles in heat-sealed plastic are considered sterile for one year.

### **Operating Room**

The operating room is an area requiring the utmost cleanliness and constant effort is required in maintaining asepsis. As persons entering the operating room are potential sources of contamination, policies regulating attire must be maintained. Surgical caps and masks must be worn when surgery is being performed. Cleanliness and good personal hygiene should be habits of everyone who enters the operating room.

Visitors should be given clean observation gowns and disposable shoe covers to be worn over their street clothes and shoes. Outer articles of clothing, without additional gowns, should not be permitted in the operating room.

The clothing of operating room personnel should be simple in design and comfortable. Scrub tops and pants or scrub dresses are acceptable; however, tops should be tucked in and dresses should fit closely. Loose clothing can accidentally touch sterile surfaces. Cotton clothing is preferred over silk, nylon, or other synthetics because of the explosive hazard created by static electricity. Light blue, jade green, or misty green colors produce less glare than white. If a separate pair of shoes for surgery is impractical, shoe covers should be worn. All shoes must be cleaned of blood and debris daily.

All hair must be covered. The type of hat worn is determined by the amount of hair that needs to be covered. Those with short hair may wear the standard cap. Others with fuller and longer hair should wear the bouffant hat. Beards and sideburns can be effectively covered by surgeon's hood.

A properly applied mask should fit snugly around the nose and chin. Loosely fitting or improperly worn masks are of little value in preventing exhaled organisms from entering the operating room. The mask should be comfortable and easy to breathe through. Coughing, sneezing, and talking increase moisture in the mask and moisture decreases the filtration of organisms and allows their escape into the operating room. A moist mask is ineffective and must be

replaced by a dry one.

The operative site should be prepared for surgery in order to remove as many bacteria as possible without harming the skin or interfering with wound healing. Skin cannot be sterilized; however, bacteria can be reduced to a relatively safe level for surgery by removal of hair, mechanical scrubbing, and the effective use of surgical scrub and germicidal solutions. The best solution and technique remain controversial. Hair removal and skin preparation should take place in the designated animal preparation area.

Hair should be clipped well beyond the margins of the incision. If the animal is cooperative, the hair can be removed prior to anesthesia. A number 40 clipper blade will remove most hair satisfactorily. If additional hair needs to be removed, moisten the area with a soap solution and shave with a straight razor. Hair can be removed close to the skin when clipped in a direction opposite to that in which it grows. The clipper blade should be checked prior to use for broken teeth, as these cut and abrade the skin. The blade should be held flat and not used in a raking motion, as this can injure the skin. Occasionally, the blade will become hot, and it should be checked frequently to prevent clipper burns. When the hair has been removed, the animal should be thoroughly vacuumed.

A selection of compatible scrub and germicidal solutions is important to achieve maximum effectiveness. The limitations of the solutions need to be recognized. For example, hexachlorophene loses its effectiveness when regular soap or alcohol is applied afterwards. A commonly used surgical scrub and germicidal solution combination is povidone-iodine and 70 percent ethyl alcohol.

The initial cleansing of the operative site should take place outside the operating room. Povidone-iodine scrub should be applied with friction, followed by a thorough rinsing with warm water. A more thorough preparation should be performed after the animal is positioned on the operating table. The preparation solutions should be applied with sterile gloves or sterile sponge forceps. The surgical preparation should begin at the incision line and in a circular motion proceeding outward toward the periphery.

Discard the sponge when reaching the periphery or when either hair or rectum has been touched. Alternate surgical scrub and germicidal solutions at least three times and until the sponge with germicidal solution remains clean after prepping. The last application of germicide should be allowed to dry on the operative site for maximum effectiveness.

The patient is draped by the surgeon after scrubbing, gowning, and gloving. The patient should be draped prior to other preparation responsibilities (i.e. arranging instruments, accepting sterile supplies, etc.) in order to prepare a sterile field in which to work. This prevents contamination of the gown by brushing up against the non-sterile table edge.

The fenestrated drape should be large enough to cover the table and the opening should be slightly larger than the length of the incision. A single drape is unfolded and, by looking through the opening, is placed directly over the incision site. Regardless of the method used, drapes should never be dragged to the incision site. In four corner draping, four drapes are applied with a double thickness of about 10 inches toward the line of incision, with two drapes parallel to the patient and two perpendicular to the patient. The first and second drape should be placed parallel to the patient with the first drape applied closest to the person draping in. A towel clamp may be used to temporarily secure the drape to the patient. The third drape should be placed perpendicular and cranial to the patient and secured with towel clamps. The fourth drape should be placed perpendicular and caudal to the patient with the end of the drape connecting to the Mayo stand. Towel clamps should be used to secure the fourth drape to the patient and the Mayo stand.

### **Preparations of the Surgical Team**

The objective of any scrub is to remove as many bacteria as possible by mechanical scrubbing and the use of chemical antiseptics without harming the skin. Many techniques are used so that every surface from the nails to the elbow is thoroughly scrubbed.

### **Technique**

The technique for a complete surgical scrub remains controversial. The time and number of brush strokes may vary depending on previous scrubs and on the type of solutions used. Scrubbing times of 5 to 15 minutes and 10 to 20 brush strokes per surface have been advocated. The combination of scrubbing time and thorough brush strokes is the key to an effective surgical scrub. A guideline for the thoroughness is 10 minutes or 10 brush strokes per surface. Each scrub, however, should include two scrubs and rinses.

Fingernails should be short and free of nail polish. Rings and jewelry should be removed. The scrub begins with a general soaping and rinsing with warm water. The nails should be cleaned with a disposable nail pick. The hands should be held higher than the elbows to prevent contamination from water running off the elbows and dripping onto the hands. The scrub suit top should be tucked in and the body bent slightly at the waist to allow dripping to run off into the sink and not onto the scrub suit.

Skin surfaces should be scrubbed in a definite pattern of strokes in order to reach all surfaces. Start the scrub at the fingertips, proceeding to the surfaces of the fingers, the palms, the top of the hands, and then to the arm surfaces. After one scrub is complete, the hands and arms should be thoroughly rinsed. Discard the brush and acquire a new one for the second scrub. The process is then repeated.

**Toweling**

Drying the hands and forearms is necessary to prevent moisture from penetrating the gown and becoming a possible source of contamination. Gloves can be donned more easily with dried surfaces. The towel should be grasped at the top and allowed to unfold. The body should be bent at the waist to prevent the loose end of the sterile towel from brushing against the scrub suit. Toweling should start at the fingers, then proceed to the hand, and with a twist motion, dry the wrist and forearm up to the elbow. The dried hand should grasp the free end of the towel and proceed to dry the opposite hand and arm. It is important that a clean portion of the towel be used for each section (i.e., right hand and arm and left hand and arm).

**Gowning**

The sterile gown should be opened prior to scrubbing by the surgeon or other operating team members. The gown should be fan folded with the inside facing outward. The entire gown should be grasped by holding the inside edge of the neckband and allowed to unfold. Care should be taken to prevent contamination of the gown by brushing against the counter edge or other non-sterile objects. The hands should now be slipped into the armholes in an upward motion. Avoid standing too close to the counter edge or near a wall, as the sleeve edges and gown front could easily be contaminated. Once the gown has been slipped on, it should be tied at the neck by an assistant.

**Gloving (Closed Method)**

Closed method gloving reduces the potential for contamination, because the bare hands never touch the gloves or gown sleeve edge. Before gloving, lubricants can be applied to the hands to allow gloves to slide on more easily. Powders have been replaced by gloving cream in an effort to minimize dust particles in the operating room. Gloves are commercially pre-powdered to make additional lubricants unnecessary.

Bare hands do not touch the gloves or the gown. Therefore, when gowning do not allow fingers to go beyond the sleeve edge but pick up the right glove through the gown with left hand. Place right glove on the arm with the fingers pointing toward the shoulder and the thumb down. Through the gown, use fingers to spread the cuff of the glove around the entire right gown sleeve edge. Pull cuff back over sleeve edge. Slide hand into glove by grasping the gown and pulling back. Repeat for the left glove.

**Post Operative Care**

It is the responsibility of the investigator to assure appropriate post-surgical care of animals. Special post surgical care arrangements can be made in advance with the veterinary technical service staff. This care includes such procedures as maintenance of adequate fluid balance, administration of antibiotics, analgesics, or other drugs whenever indicated, the recording of rectal temperature, respiration rate and pulse rate, and care of the surgical incisions, emergency treatment, and similar clinical procedures. The duration of the post-surgical care

will vary with the type of surgery performed and the condition of the animal, but it must be provided whenever it is needed, day or night. Post-operative care should include the following items:

- Pulse and respiration determined every 5 minutes until the animal is extubated.
- Pulse and respiration every 10 minutes until animal is sternal.
- Body temperature every 30 minutes until animal is standing.
- Extubation once swallowing reflex has returned and when there is no longer a need for either ventilatory support or oxygen administration.
- To reduce hypostatic congestion animals should be turned every 30 minutes, unless this manipulation is contraindicated by the surgical procedure.
- Post-operative medications:
  - Continuation of fluids and antibiotic therapy where indicated.
  - Animals will be given analgesics routinely until there are no signs of any discomfort or obvious pain.
- Records should contain the above information, and should indicate food and water intake, urination, defecation, and care of the surgical wound. Standard post-operative records forms provided by the ARF should be used.
  - Records of post-operative care must be maintained and should be available for inspection if necessary. Post-operative records must become affixed to the animal's clinical record sheet and returned to the ARF upon termination of the animal.
  - Clinical observations must be recorded daily until sutures are removed or animal is fully recovered from the operation.
  - Post-operative record keeping is done by the Principal Investigator and/or the technician.
  - The records of surgery and post-operative surgery are located in the ARF supervisor's office

## **PART III – Animal Exposure Surveillance and Occupational Health Program (OHSP) Standard Operating Procedure**

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## OVERVIEW

### **Regulatory Authorities:**

The program is designed to comply with the recommendations made by the Committee on Occupational Safety and Health in Research Animal Facilities, Institute of Laboratory Animal Resources, Commission on Life Sciences, National Research Council. These recommendations have been published in the *Guide for the Care and Use of Laboratory Animals* (NRC, National Academy Press, Washington, DC, 1996) and the *Occupational Health and Safety in the Care and Use of Research Animals* (NRC, National Academy Press, Washington, DC 1997).

This Standard Operating Procedure (SOP) is modeled after the document developed by the Occupational Medical Service (OMS), the Occupational Safety and Health Branch (OSHB) and the Veterinary Resources Branch (VRB). This program is offered in compliance with Occupational Safety and Health Administration (OSHA) regulations defining medical surveillance programs for employees potentially exposed to hazardous materials. It is also understood that all individuals working in the Stratton VAMC animal research program and facilities will follow the Stratton VAMC Research Safety and Biosecurity Plan; this plan provides detailed instructions to protect staff safety.

### **Opportunity to Participate**

All Federal employees, without compensations (WOC), and other non-Federal personnel who work with animals or unfixed tissues used in VA research must be given the opportunity to participate in the OHSP at the VA facility at no charge. In addition, the following individuals who have intermittent contact with animals or the animal facility must also have the opportunity to enroll at no charge:

- IACUC voting members (including the non-affiliated and non-scientist member) and non-voting participants who enter the animal facility as part of the IACUC semi-annual evaluation of the animal care and use program and facilities.
- Maintenance, engineering, and housekeeping personnel who enter the VMU intermittently.
- Other personnel such as VA Police or security personnel who could have need to enter the VMU in an emergency. Such personnel should be identified in consultation with occupational health medical professionals.

### **Right to Decline Services**

Personnel may decline to receive those services not required by VA facility to protect the health of the animals or other personnel (e.g., TB testing or chest radiography). Personnel who decline optional services are considered to be enrolled in the OHSP as long as the VA facility documents that they were given the opportunity to receive these services.

**Frequency of interaction with the OHSP**

As allowed by the Office of Laboratory Animal Welfare (OLAW), the frequency of interaction with the OHSP required for each person will vary with the risks and durations of exposure to animals, unfixed animal tissues, and allergens. Personnel with higher risk may need annual or more frequent interaction with the OHSP, while personnel with limited risk may need less frequent interaction.

**Responsible Parties:**

- The Occupational Health Service will have responsibility for administration and oversight of the program. The Occupational Health Service will also be responsible for the medical aspects of the program including maintenance of the medical records.
- The ACOS-R&D and Principal Investigators will be responsible for providing employee identification, education, training and documentation of the policies related to the Animal Exposure Surveillance. If applicable and when animals in section IIIC and IIID are used in the Animal Research Facility.
- The Research Office will supply, on a quarterly basis, a current list of all WOC employees assigned to the Animal Research Facility and a current list of all active projects involving animal studies (list to include: Principal Investigator, title of the study and the species being studied).
- The Safety Office will supply the Occupational Health Service names of all other individuals having episodic contact with the Animal Research Facility.
- In the event that there is an incident, accident or injury to personnel related to animal care or use, the Principal Investigator (supervisor) should be notified by employee/The Occupational Health Service to investigate and provide recommendation for program revision or correction.

**PROGRAM DESCRIPTION****Goal:**

The Animal Exposure Surveillance Plan (AESP) is designed to monitor and support the health of personnel having direct exposure with a variety of vertebrate animals, animal tissue, body fluids, wastes or living quarters. These personnel may be exposed to occupational hazards such as bites, scratches, or Zoonotic diseases. Personnel may also be allergic to animal proteins or latex.

**Participants:**

Personnel required to participate in the medical surveillance under this program include medical center employees (including Without Compensation employees), students, volunteers or visitors who:

- Have direct exposure to vertebrate animals, animal tissues, body fluids, wastes or living quarters.
- Work with Zoonotic disease agent(s).
- *Exception:* Personnel involved in isolated, one-time contact will be informed of

specific health precautions and appropriate inoculation or medical constraints. Isolated, one-time contact will not require participation in the medical monitoring program.

## PROGRAM ENROLLMENT

### Baseline Health Assessment

All applicants that receive a pre-employment physical exam are routinely questioned regarding anticipated occupational exposure to animal exposure to animals. In addition, other personnel identified by the Research Office that will have exposure to animals will be referred to the Occupational Health Service for enrollment.

Surveillance will depend upon the type of animal contact: small animals (rodents, rabbits), large animals (cats, dogs, livestock), or non-human primates (marmosets, monkeys, apes).

### Routine Testing

All participants in the Medical Surveillance Program will receive the following for pre-employment:

- Physical Exam including chest x-ray, if warranted (e.g., past history, clinical presentation, known TB or (+) PPD), by appointment, through Personnel Health.
- Tetanus prophylaxis
- Tuberculosis screening
- Hepatitis B Screening/immunization
- Measles/mumps/rubella/varicella screening

If the above screenings have been performed in the last year at another facility, please provide documentation to the Occupational Health Service .

**Large Animal Contact Category Employees** (if applicable) In addition to the routine testing, individuals who will have contact with large animals will be offered:

- Rabies Prophylaxis. For individuals working with the rabies virus, large animals (cats, dogs, livestock) or wild animals, exposure to potentially infected animal body organs, or perform post-mortem examinations on animals with a history of poorly defined neurological disorders. (Since every type of rabies vaccine has shown adverse reactions in some individuals, the use of this vaccine is not mandatory).
- Q Fever Risk Counseling. For Individuals who have direct contact with the organism *Coxiella Burnetti* in a research capacity or those who handle or use products from infected sheep, goats or cattle.
- Toxoplasmosis Titer and Counseling, which is of particular interest to any female of childbearing capacity. Gestating employees who work directly with cats or their feces are at risk.

**Non-Human Primate Contact Category Employees:** (if applicable) In addition to the routine testing

- Purified Protein Derivative (PPD) TB skin test every six months
- Periodic chest x-rays for employees with PPD reaction based on The Occupational Health Service clinician discretion
- TB contact study in the event of a work exposure to active TB according to established infection control guidelines
- Rubella: documented proof of immunity or titer
- Rabies Vaccine: working with non-human primates in quarantine
- Hepatitis A for at risk employees
- Herpes virus simiae (B-virus) counseling – paramount for those working with rhesus, cynomolgus and other Asiatic monkeys of the genus Macaca
- Serum storage

**Allergies (Animal & Latex)** - Anyone entering the ARF is alerted by a sign warning that animals are housed in the facility (see attached):

- Animals – if a participant in the AESP develops signs and symptoms of an animal allergy, they should be encouraged to report to the Occupational Health Service for evaluation and consultation and administrative/clinical intervention.
- Latex – If a participant in the AESP develops signs and symptoms of a latex allergy, they should be encouraged to report to the Occupational Health Service for RAST testing. If positive, then administrative and clinical intervention is indicated, including evaluation by a dermatologist.

### **Follow-up Health Assessment**

Participants are encouraged to have an Annual Examination through the Occupational Health Service to include an optional physical exam and optional laboratory tests as appropriate:

- PD TB tests (recommended annually)
- Tetanus immunization/diphtheria booster (at least every 10 years for employees handling animals)
- Annual audiogram (hearing test) for personnel exposed to noise in the rack washer room or loud animals.

**Note:** Participants who have had rabies immunization must receive serologic monitoring annually

### **Emergency Care**

In the event of an accident, (e.g. animal bite, scratch or cut) or occupational illness, standard procedures should be followed. The individual should report to Personnel Health or the Emergency Room and if time allows, notify their immediate supervisor about the accident/incident or exposure. The immediate supervisor must accompany them to the Occupational Health Service (Room 512C) or the Emergency Room if the Occupational Health Service is closed. If the immediate supervisor is not available, the Research Administrative Officer should be notified to accompany employee during working hours. During off-hours, the Administrative

Officer of the Day (located in the ER) would accompany the employee and notify the immediate supervisor if possible. Emergency medical care will be provided.

**\*Note:** Animal bites and scratches are hazards common to animal facility personnel. All cases should be documented. Tetanus prophylaxis should always be considered and, depending on the species, rabies prophylaxis and antibiotics arranged. (From NIH Publication No. 92-3415 Section C-3.)

## **PART IV - CONTROLLED SUBSTANCE PROCEDURES IN THE ANIMAL RESEARCH FACILITY (ARF)**

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## **RESPONSIBILITIES**

Controlled Substances (Schedules I-V, as defined in 21 USC Sec. 812 of 22 January 2002) may be used for animal research. They must be stored in a double-locked cabinet in a double locked cabinet in a room of the Animal Research Facility (ARF) (currently room 123). The supervisor of the ARF or designee will have access to the cabinet and dispense all controlled substances.

- The Associate Chief of Staff for Research (ACOS/R) or designee is responsible for ensuring compliance with the controlled substance procedures for animal research.
- Each dispensed controlled substance has a corresponding green sheet (VA form 10-2638) that is issued by Pharmacy Service. It must be used to record usage of the drug. Once a day, at the end of tour of duty, the ARF supervisor will inventory all controlled substances in the cabinet and check the drugs dispensed and the corresponding green sheets for accuracy.
- When the ARF supervisor is unavailable, the ACOS/R and Administrative Officer for Research (AO/R) will have access to the keys, will dispense drugs according to the procedure outlined below. An Alcoholics and Narcotics Inventory and Certification Record Sheet (VA Form 10-1043) is then signed certifying the accuracy of the contents in the cabinet.
- The expiration dates of the drugs will be checked against either the stamped dates on the vial or expirations noted in the product inserts. The label of the reconstituted drug will show the user's initials, the date when the solution was reconstituted, and expiration date indicated by the package insert once reconstituted. The facility will not use any expired drugs for animal research. Disposal of all expired drugs will be initiated by the ARF Supervisor and returned to Pharmacy Service.
- To ensure compliance with the VHA Handbook 1108.2, the Controlled Substance Coordinator (CSC), appointed by the facility Director, will conduct unannounced monthly inspections in the ARF.

## **PROCUREMENT AND DELIVERY OF CONTROLLED SUBSTANCES**

All controlled substances must be ordered and received through the Research Office. Investigators must submit a VA purchase order to the Research Office for processing. No other sources may be utilized to procure or attain controlled substances for research. Specific procedures will be followed within the Research Office to procure and receive these drugs as indicated below:

- 1 The ARF Supervisor notifies the Research Budget clerk upon receipt of a request for purchase of a controlled substance.
- 2 A written VA prescription form (VA form 10-2577F) will be submitted to the Pharmacy Service.
- 3 The pharmacy processes the order and completes the Drug Enforcement Agency (DEA) form 222 (if applicable) utilizing the Research DEA Certificate for any C2 drugs.

- 4 After receipt of the controlled substance, the pharmacy will contact the ARF Supervisor for delivery of the substance(s) and corresponding green sheet.
- 5 The ARF Supervisor will electronically sign for receipt of the controlled substance(s) after verifying the identity of the controlled substance, strength, and quantity, via the electronic green sheet VISTA program or equivalent.
- 6 The product and corresponding green sheet will be given to the ARF Supervisor for placement in the Animal Facility Narcotic Area of Use (NAOU).

## **DISPENSING OF CONTROLLED SUBSTANCES**

The ARF supervisor, or designee, will dispense all controlled substances to investigators and approved designees. Investigators or their designees will be responsible for the accuracy of the recorded usage of such drugs on the corresponding green sheet.

- 1 The investigator or approved designee will request the controlled substance from the ARF Supervisor.
- 2 The ARF Supervisor either dispenses the controlled substance or allows the investigator or designee to take possession of the controlled substance.
- 3 The ARF Supervisor will make a copy of the green sheet to keep in his possession if the investigator maintains possession of the original green sheet and controlled substance.
- 4 The Investigator or approved designee will sign and date the copy of the green sheet when they take possession of the drug. The controlled substance should never be left in an unsecured location when not in use while in possession of the investigator.
- 5 The species, protocol number, date, time, dose and balance shall be recorded on the green sheet at the time of each use, and the investigator or designee shall sign the document.
- 6 When the drug and corresponding green sheet are returned, the ARF supervisor will verify the amount of drug remaining and secure the original green sheet and drug in the locked cabinet in the (NAOU).

## **DISPOSAL OF EXCESS OR EXPIRED CONTROLLED SUBSTANCES**

- 1 The ARF Supervisor will coordinate product pick-up with the Pharmacy.
- 2 The Pharmacy will contact the contractor for non-prime vendor that is responsible for disposal.

## **RECONCILIATION OF GREEN SHEETS**

### **Green sheets with zero balance (no controlled substance remaining):**

- The ARF Supervisor will flag green sheet as “ready for pick-up by pharmacy” by computer entry.

- ARF supervisor disposes of empty containers.

**Green sheets with a balance (controlled substance remaining) and expired controlled substances:**

- The ARF Supervisor will coordinate product pick-up and green sheet transfer with a pharmacy representative.

**Green sheets with discrepancies:**

- 1 ARF supervisor and investigator will attempt to resolve the discrepancy and notify the CSC.
- 2 The investigator will submit corrective action plan to the ACOS/R&D and the CSC.
- 3 Any discrepancies unresolved will be forwarded to the ACOS/R&D and CSC for an investigation.