

## NIH POLICY MANUAL

### 3044-2 - PROTECTION OF NIH PERSONNEL WHO WORK WITH NONHUMAN PRIMATES

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1. **Explanation of Material Transmitted:** This chapter outlines the policy for protection of National Institutes of Health (NIH) personnel who work with or around nonhuman primates. Requirements are established for training, supervision, use of personal protective equipment, medical surveillance, accident reporting, and wound care.
2. **Filing Instructions:**
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#### **A. Purpose:**

Established under this chapter is the NIH policy for protection of NIH personnel who work with or around nonhuman primates. The policy describes the requirements for training, supervision, compliance, personal protective equipment, medical surveillance, accident reporting, and wound care. The intent of this policy is to minimize the overall number of injuries, specifically bites and scratches, sustained by NIH employees, special volunteers, and visitors who work with nonhuman primates or enter nonhuman primate rooms. Contractors engaging in activities with nonhuman primates must have a program in place with policies and procedures equivalent to the program described

herein. Project Officers for such contracts shall ensure that all contracts contain the equivalent components.

## **B. Policy and Procedures:**

*Training.* Each individual regularly entering a nonhuman primate room shall have received introductory training prior to entry. Transient visitors will be supervised by someone with appropriate training. Those individuals having hands-on interaction with nonhuman primates must also have additional training in approaching and handling nonhuman primates. Certification by the first line supervisor that a basic level of performance has been achieved is required. The Training Coordinator, Office of Animal Care and Use (OACU/OD), is responsible for the development and management of the program for training intramural personnel to work safely and humanely with nonhuman primates.

*Supervision and Compliance.* All NIH employees, including special volunteers, guest workers, visitors, and contract personnel shall comply with procedures set forth in this policy statement. Immediate supervisors are responsible for ensuring that their employees follow established policy. Corrective action shall be taken by the immediate supervisor for failure to comply with the provisions of this policy.

Continued failure to comply with requirements set forth in this policy shall be reported to the Scientific Director and/or Institute Director and may result in suspension of the privilege to use nonhuman primates in research protocols or other disciplinary action. The Institutional Official for Animal Welfare Assurance (i.e., Deputy Director for Intramural Research) shall be informed of such infractions and disciplinary actions taken.

*Personal Protective Equipment.* All individuals entering a nonhuman primate room must wear appropriate personal protective clothing and equipment which meets or exceeds the guidance established by the NIH Animal Research Advisory Committee (ARAC) (Appendix 1). Guidance on the selection and use of personal protective equipment for selected protocols will be provided upon request, by the Occupational Safety and Health Branch, Division of Safety (OSHB, DS). The NIH Institutional Biosafety Committee (NIH IBC) shall advise on appropriate protective measures, as needed, at the request of the Division of Safety. Individuals participating in protocols involving infectious disease agents must meet or exceed practices and procedures recommended in the CDC/NIH publication entitled Biosafety in Microbiological and Biomedical Laboratories and any additional stipulations placed on the protocol by the NIH IBC. Copies of THE CDC/NIH publication may be obtained by calling 496-2346. All support personnel, who have not been appropriately trained, (e.g. building engineers, pest controllers, safety and health personnel, etc.) entering nonhuman primate rooms must be accompanied by a responsible facility staff member who is knowledgeable in the behavior and handling of nonhuman primates.

*Medical Surveillance.* All persons having direct contact with nonhuman primates in the course of conducting research and all persons providing care must participate in the NIH Animal Exposure Surveillance Program (AESP). Transient visitors, who are

required to enter a room housing nonhuman primates but do not have direct contact with the animals, are not required to participate in the AESP but are to wear single-use dust/mist masks in addition to other required protective clothing. All contractor employees having direct contact with nonhuman primates must participate in an AESP that is equivalent to that of the NIH and which shall be provided by their employer.

*Accident Reporting.* All accidents and injuries involving animals, animal wastes, or potentially contaminated equipment must be reported promptly to the first-line supervisor. An individual who sustains any injury must report to the Occupational Medical Service (OMS) as soon as possible. The Division of Safety will regularly review accident/injury reports and make accident information available to the Training Coordinator, OACU, who will ensure that training will address identified problem areas.

*Wound Care.* Each nonhuman primate facility manager or ICD veterinarian, as applicable, is responsible for maintaining an adequately stocked wound care kit. The kit includes materials for culturing a wound, inflicted by a nonhuman primate, for Herpesvirus simiae also known as Monkey B virus. The wound care kit must be located in an easily accessible area, and instructions for culturing wounds, first aid, and reporting to OMS must be prominently displayed. The facility manager or veterinarian, as applicable, is responsible for informing all research and animal care staff of the location of the wound care kit. The procedures to be followed in the event of a nonhuman primate bite or scratch are described in the NIH Animal Exposure Surveillance Program (AESP).

#### **C. Additional Information:**

For further information on this manual chapter, contact the NIH Office of Animal Care and Use (496-5424).

#### **D. Additional Copies:**

Copies of this manual chapter may be obtained by completing Form NIH 414-5 and submitting it to the P&RB, DSS, ORS, in Bldg 31, Room B4BN08.

### **Appendix 1 - Minimum Requirements for Protective Clothing in Nonhuman Primate Rooms**

### **Appendix 2 - Protective Clothing Requirements for Personnel in Nonhuman Primate Facilities**

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**PROTECTION OF NIH PERSONNEL WHO WORK  
WITH NONHUMAN PRIMATES  
Minimum Requirements for Protective Clothing in  
Nonhuman Primate Rooms**

Although research using animals entails some real and unavoidable risks, the goal of protective programs is to enable animal based research to go on in a safe and productive environment. Our goal is to provide a set of principles that can be applied to a variety of animal facilities. Two principles are at the base for all protective measures: accident avoidance based on understanding the physical risks entailed, as exemplified by avoiding bites, and scratches; and good personal hygiene based on knowledge of when contamination is most likely to occur, methods of avoidance, and decontamination, as exemplified by proper use of barrier methods and good hand washing practices.

For a protective program to be effective, workers must believe that the recommendations that are in place increase their safety significantly. The most important preventive strategy is education. Vigilance in animal handling, specific training of scientists and handlers in techniques for safe interaction with animals, proper use of protective clothing and equipment, and hand washing should be stressed. Any preventive measures that are put in place must be accompanied by an educational process that instructs all animal workers in the methods and rationale for each preventive measure. Protocols for emergency diagnosis and treatment of injury, especially possible B virus infection should be worked out ahead of time and all personnel instructed in their use. Workers who are knowledgeable about the risks and the protection offered by each device, article of clothing, and procedure should enthusiastically cooperate with the protection program.

All animal handlers, scientists, technicians and caretakers must be enrolled in the Animal Exposure Surveillance Program. This program classifies employees according to the species of animals to which they are exposed and provides appropriate surveillance and prophylaxis to these employees. Employees immunosuppressed by virtue of disease or treatment should be advised of their increased risks and should limit their exposure to animals.

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These requirements are not meant to cover all of the specific instances that might be encountered, or to limit the requirements of any facility, but to provide a framework of minimum standards for implementing a program tailored to the local conditions. Specific recommendations for a safe environment must be formulated to account for local conditions, and these may vary from one laboratory to the next even within a single facility. Exceptions to any of these requirements may be requested of the ICD ACUC. However, in these instances individuals must demonstrate adequate training and proficiency in appropriate techniques and the Division of Safety must concur with the exceptions. The NIH Institutional Biosafety Committee (IBC) will serve as the final review body, as needed. Specific minimum requirements for handling nonhuman primates have been extracted from the ACUC guidance document and are presented in Appendix 2.

PROTECTION OF NIH PERSONNEL WHO WORK  
 WITH NONHUMAN PRIMATES

Protective Clothing Requirements for Personnel in Nonhuman Primate Facilities

ACTIVITY	REQUIREMENTS
View animals in the primate room. No contact with the animals or the cages	Mucous membrane protection as appropriate*, street clothes covering, handwashing should be performed upon leaving the area and after any of the following activities.
Contact with a restraint device holding an awake animal	Mucous membrane protection as appropriate*, street clothes covering and light gloves
Transfer alert monkey using a stand-off method such as pole/collar technique or transfer cage	Mucous membrane protection as appropriate*, street clothes covering and light gloves.
Handling (e.g. hand catching or restraining) of an alert monkey.	Mucous membrane protection appropriate for high risk situations, street clothes covering and arm length bite protection gloves.
Physical contact with an anesthetized monkey.	Mucous membrane protection as appropriate*, street clothes covering and light gloves.
Cleaning cages.	Mucous membrane protection appropriate for high risk situations, dedicated clothing, dedicated shoes, and light gloves; dust-mist masks, if approved by OSHB, DS.
Physical contact with restrained alert monkey	Mucous membrane protection as appropriate*, street clothes covering and light gloves.
Physical contact with infant monkeys	Mucous membrane protection as appropriate*, street clothes covering and light gloves. As infants mature, heavier gloves may be required.
Perform portions of experiments in a laboratory that do not involve physical contact with monkey or body fluids.	Protection appropriate for non-animal aspects of research.
Handling awake New World Species	Mucous membrane protection as appropriate*, street clothes covering, protective gloves appropriate for the species and size of animal being handled. Larger species such as Cebus should be handled with the arm length bite protection gloves, while very small species such as marmosets may be handled with lighter weight protection.

\* Mucous membrane protection should be appropriate to the potential for splash hazard. The level of mucous membrane protection should be detailed in facility standard operating procedures (SOP's). SOP's are subject to review and approval by the ICD ACUC with the concurrence of the Division of Safety with consult by the IBC as necessary. The degree of risk involved in entering an animal holding room or working with awake animals varies with the design of the facility, the species involved and the nature of the task being performed. Examples of high risk situations include any procedures which may aerosolize NHP wastes or body fluids, e.g., hosing down animal rooms, dental work or tracheal intubation, especially of macaques. Lower risks are associated with fully restrained animals, anesthetized animals (However, Ketamine increases salivation which is a major source of potential B virus contamination from macaques.), and increased distance from animals. In very low risk situations, e.g., entering hallways through which animals in restraint devices may briefly pass, mucous membrane protection may not be required. The future definition and availability of SPF animals may alter these requirements.

## Additional Responsibilities and Training Requirements for Working With Nonhuman Primates

**Letter from Michael M. Gottesman, M.D. - Deputy Director for Intramural Research**

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1. Students and Trainees are defined, for the purpose of this policy, as those individuals who do not have documented training and experience in handling and working with nonhuman primates. In such cases, the Principal Investigator must assure that required training has been provided and that the student or trainee has demonstrated competency in performing all activities or procedures undertaken with any nonhuman primate. Minors (individuals under 18 years of age) may not work or be present for procedures or research activities involving awake nonhuman primates. Minors under 16 years of age may not enter a room containing a nonhuman primate.
2. Principal Investigators are responsible for the following:
  - specifying, in writing, each procedure and activity in which the student/trainee may participate involving an awake nonhuman primate
  - developing a training plan for the student/trainee including the length of time or number of procedures the student/trainee must perform under directly observed supervision by the Principal Investigator or qualified member of the staff designated by the Principal Investigator.
  - obtaining review of and concurrence with the training plan, for each student/trainee, from the ICD Veterinarian and the Occupational Safety and Health Branch (OSHB), DS, ORS (Note: the format for development of the training plan can be obtained from the OSHB)
  - instructing the student/trainee in the proper performance of any technique, procedure and/or manipulation of an awake nonhuman primate
  - documenting the student/trainee's progress
  - documenting the student/trainee's competency in the performance of any technique, procedure or manipulation involving an awake nonhuman primate prior to allowing the student/trainee to perform these activities in an independent manner
  - providing and documenting refresher training for any returning student/trainee (e.g., summer students)
3. Principal Investigators must provide all documentation and records, pertinent to a student/trainee's training and competency to perform work with awake nonhuman primates, upon request of the ICD ACUC and/or Division of Safety personnel.
4. Principal Investigators are responsible for insuring a student/trainee's compliance with all other provisions of NIH Manual Chapter 3044-2, Protection of NIH Personnel Who Work with Nonhuman Primates and any other special requirements or procedures specific to the facility within which they are working.

Michael M. Gottesman, MD

April 4, 1997

Deputy Director for Intramural Research

# **The National Institutes of Health**

## **Additional Responsibilities and Training Requirements for Working with Nonhuman Primate**

**Students/Trainees who will be working with nonhuman primates should:**

- participate in the NIH, OMS Animal Exposure Surveillance Program (AESP)
- receive a copy of MI 1340: NIH Occupational Safety And Health Management
- receive a copy of MI 3044-2: Protection Of NIH Personnel Who Work With Nonhuman Primates
- receive a copy of: Additional Responsibilities and Training Requirements for Working with Nonhuman Primates
- complete the training course: Safety with Nonhuman Primates, a program developed by the OACU and administered at the ICD level
- demonstrate the location of bite/scratch kits in their working area and how to use them .
- receive training on the procedures they will be performing.\*

Principal Investigators/Supervisors should provide an opportunity for discussion of the above documents and ensure that students/trainee understand the material content.

**Written SOP's must be developed for each procedure involving an awake NHP. The SOP should include but not be limited to the following:**

- step by step instructions on performing the procedure
- number of people necessary to perform the procedure
- equipment/supplies needed
- proper sharps techniques
- required personal protective equipment
- proper waste disposal
- name of person to consult when questions arise
- person to call in case of an emergency

\* See the sample form for training documentation developed by OSHB.

*Required Training: OSHB suggested format*

*April 1997*

Working with Awake Nonhuman Primates  
Required Training Documentation

Name: \_\_\_\_\_ Trainer: \_\_\_\_\_ Date of Initiation: \_\_\_\_\_  
(Trainee) (P.I. or P.I. Designee)

Procedure: \_\_\_\_\_ Risk Type: Bite \_\_\_\_\_ Scratch \_\_\_\_\_ Splash \_\_\_\_\_ Percutaneous \_\_\_\_\_

Specify the length of time or number of procedures the student/trainee must perform under the direct supervision of the Principal Investigator or a qualified member of the investigative staff designated by the P.I. \_\_\_\_\_  
(Length of time/# of procedures)

Training Progress\*:

Date \_\_\_\_\_ Duration \_\_\_\_\_ Trainer \_\_\_\_\_ Comments \_\_\_\_\_ P.I./Supervisor's Approval \_\_\_\_\_

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\_\_\_\_\_  
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\_\_\_\_\_  
\_\_\_\_\_

\*Length of time and number of training sessions to document proficiency will vary depending upon the type and complexity of the procedure.

**Proficiency Certification:**

I \_\_\_\_\_, hereby certify that \_\_\_\_\_ has demonstrated proficiency in the above  
(P.I./supervisor's signature) (date) (Trainee)  
named procedure on an awake NHP.

Note: This training record is to be maintained by the P.I./supervisor, and provided upon request to the IC ACUC or NIH Div. of Safety personnel.