

# NIH Policy Manual

## 3044-2 - Protection of NIH Personnel Who Work with Nonhuman Primates

**Issuing Office:** OD/OIR/OACU **Phone:** [\(301\) 496-5424](tel:3014965424)

**Approving Official(s):** DDIR

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### Transmittal Notice

- 1. Explanation of Material Transmitted:** This revised chapter outlines the policy for protection of National Institutes of Health (NIH) personnel who work with or around nonhuman primates (NHPs). It establishes requirements for training, supervision, use of personal protective equipment, medical surveillance, accident reporting, and wound care. This revision describes updated safety training requirements, updated procedures to the animal exposure and surveillance program, and includes revised definitions and new references.
- 2. Filing Instructions:**
  - **Remove:** NIH Manual 3044-2, dated 12/24/2015.
  - **Insert:** NIH Manual 3044-2, dated 08/19/2022.
- 3. PLEASE NOTE:** For information on:
  - Content of this chapter, contact the issuing office listed above.
  - NIH Policy Manual, contact the Division of Compliance Management (DCM), OMA on 301-496-4606, or: <https://oma.od.nih.gov/DMS/Pages/Manual-Chapters.aspx>

### A. Purpose

This policy provides requirements for training, supervision, compliance, personal protective equipment, medical surveillance, accident reporting, and wound care to minimize accidents, injuries, and exposures sustained by NIH employees, contractors, and other personnel who work with nonhuman primates (NHPs) or enter rooms and areas containing NHPs.

### B. Scope

- 1. Who this policy applies to:** This policy applies to all employees, contractors, and non-federal staff<sup>1</sup> in NIH facilities that conduct or support intramural activities

involving animals. This policy also describes training requirements for Special Volunteers and Transient Visitors planning to enter nonhuman primate facilities.

2. **Which facilities this policy applies to:** This policy applies to NIH facilities that conduct or support intramural activities involving nonhuman primates except for NCI Frederick.

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1 This includes students, trainees, fellows, guest-researchers, and volunteers.

## C. Definitions

Please see [Appendix 2](#) for a list of defined terms used in this policy.

## D. Policy

NIH intramural policy requires that each individual involved with the care and use of nonhuman primates be appropriately qualified and trained in the NHP procedures they conduct. Training must address the proper use of personal protective equipment (PPE), wound care, and reporting procedures for injuries and exposures.

All personnel including Transient Visitors, who have not been appropriately trained and will be entering facilities containing NHPs must be accompanied by a responsible facility staff member who is knowledgeable in the behavior and handling of NHPs. The facility staff member must be current with the required annual NIH training for users of live NHPs. Transient Visitors must meet the medical testing requirements established by the facility Animal Program Director prior to entering a NHP animal facility or room as noted in DOHS memorandum: [Medical Clearance of Transient Visitors into NIH Animal Facilities](#).

Minors at least 16 years of age whether employees or visitors ([defined in NIH Manual 3015](#)) may not work with or be present for procedures or research activities involving awake NHPs and may not work with human and/or nonhuman primate blood, body fluids, and tissues. Additionally, minors under the age of 18 are not permitted in nonhuman primate holding rooms or areas where procedures with awake nonhuman primates are conducted.

Each individual with direct contact with nonhuman primates or their tissues or body fluids must participate in the NIH Animal Exposure Program (AEP)<sup>2</sup>, or an equivalent program. The NIH Occupational Medical Service (OMS) determines what is an NIH AEP equivalent program. All injuries or exposures involving nonhuman primates, tissues, or waste must be reported to OMS immediately upon completion of wound care.

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2 If individuals are animal caretakers, technicians, or other facility staff, their immediate supervisor (IS) will maintain a record of their enrollment in AEP (or equivalent program). If

the individual is a researcher, their IC Animal Care and Use Committee (ACUC) coordinator will maintain a record of their enrollment in AEP (or equivalent program).

## **E. Responsibilities**

1. **The Principal Investigator (PI) or Immediate Supervisor (IS) is responsible for:**
  - a. Completing both components of the “Working Safely with Nonhuman Primates” course annually if NHPs are listed in their animal study proposals.
  - b. Ensuring their research staff members working with NHPs comply with the provisions of this Policy Manual (PM) and any other special requirements or procedures specific to the facility within which they are conducting NHP procedures. In addition, the PI/IS will take corrective action for failure to comply with the provisions of this policy.
  - c. Providing copies of all NHP training documentation to DOHS during routine safety surveys, during incident investigations involving NHP-related exposures, injuries or illnesses if requested.
  - d. Providing copies of all NHP training documentation to their IC ACUC if requested.
  - e. Describe all NHP awake procedures or provide the Standard Operating Procedure (SOP) number in the Animal Study Proposal(s) (to be reviewed and approved by the ACUC).
  - f. Ensuring a trainee’s competency in conduct of awake NHP procedures is appropriate and fully documented before allowing a trainee to perform these procedures independently.
  - g. Ensuring all personnel using pole and collar devices to move NHPs are briefed on the appropriate technique annually.
  - h. Ensuring research staff members receive training that direct hand to mouth feeding of Old World NHPs is prohibited. Please also refer to NHP user section 2f.
  - i. Ensuring trainees who have not performed NHP procedures and/or NHP awake procedures within the past 6 months document their re-take and document the initial NHP safety awareness and if applicable, the NHP awake procedures training before working with NHPs.
2. **The NHP user is responsible for:**
  - a. Adhering to all provisions of this Policy Manual.
  - b. Completing the annual NHP safety awareness training.
  - c. Completing any additional training that their PI/IS has established for them prior to attempting unsupervised, procedures on a NHP.
  - d. Documenting competency in conduct of NHP awake procedures as part of the ASP Training and Experience form. If additional training is needed, ensure this is documented as well.
  - e. Adhering to the requirement that the presentation of food, fluids, or research test agents to the mouths of Old World NHPs may only be conducted indirectly, e.g., using tongs, a utensil or research apparatuses.

3. **NHP Safety Trainers are responsible for:**
  - a. Conducting one or both components of the safety awareness training course: “Working Safely with NHPs” annually for NHP users within their ICs.
  - b. Ensuring documentation of trainees’ completion of the “Working Safely with NHPs” course is maintained by NIH.
4. **The OACU/OIR is responsible for:**
  - a. Developing and managing the materials for NIH IRP NHP safety training program.
  - b. Administering the Nonhuman Primate Train-the-Trainer Course to IC level NHP Safety Trainers and providing NHP Safety Trainers with the information and an outline to administer the “Working Safely with Nonhuman Primates” course.
  - c. Ensuring training addresses safe and humane NHP work practices, adheres to DOHS safety standards, and addresses DOHS-identified accident report trends of potential problem areas.
5. **The DOHS is responsible for:**
  - a. Providing general guidance on the selection and use of personal protective equipment for animal facilities, other areas that support animal research and in areas where NHPs are maintained and used. Specific PPE guidance shall also be provided to PIs and facility managers when NHP activities involve working with infectious diseases, hazardous chemicals, etc.
  - b. Selecting and approving occupationally required respirators if needed for NHP care and use.
  - c. Periodically reviewing NHP safety training documentation as part of their safety inspections and reviewing NHP safety training documentation as part of an incident investigation involving a NHP-related injury or illness.
  - d. Regularly reviewing NHP-related human injury and illness occupational reports and making accident information available to the OACU.
  - e. Providing appropriate medical support services for animal researchers including those researchers working with NHPs (e.g., pre-placement medical evaluations; risk assessment; AEP enrollment; care for work related injuries, exposures and illnesses; and Worker’s Compensation.)
6. **The IC ACUC is responsible for:**
  - a. Ensuring all individuals working with NHPs receive annual safety awareness training by completing the “Working Safely with Nonhuman Primates” course as outlined in section F2.
  - b. Ensuring all individuals at the IC and/or facility level who conduct one or both portions of the “Working Safely with Nonhuman Primates” training course take the required annual “Nonhuman Primate Train-the-Trainer” course provided by the Office of Animal Care and Use (OACU) as outlined in section F2.
  - c. Ensuring that all personnel using pole and collar devices to move NHPs are briefed on the appropriate technique annually.
  - d. Ensuring those individuals working with awake NHPs receive competency assessment and additional training (if needed).

7. **Animal program staff members are responsible for:**
  - a. Ensuring all NHP awake procedures are described and delineated in facility SOPs.
  - b. Documenting all training and experience related to performance of NHP awake procedures in the facility training records.
8. **Animal Facility Management is responsible for:**
  - a. Providing and maintaining wound flushing equipment, NHP Bite, Scratch, Splash, Exposure (BSSE) kits, and response instruction charts as described in the [NHP BSSE Guidelines](#).
  - b. Completing the Macaque Health Report form located in the NHP Bite, Scratch, Splash, Exposure (BSSE) kit for submission to OMS following a **macaque**-related accident, illness, or exposure.
  - c. Obtaining clinical samples from NHPs that are involved in personnel-related accidents, illnesses, or exposures—if requested by OMS.

## F. Procedures

1. **Personnel Restrictions:**
  - a. Transient Visitors and all personnel who have not been appropriately trained must be accompanied by a responsible facility staff member who is knowledgeable in the behavior and handling of NHPs.
  - b. Individuals less than 16 years of age may not be present in NHP holding rooms or where procedures or research activities involving NHPs or NHP blood, body fluids and tissues are ongoing. Minors are not permitted in nonhuman primate holding rooms or areas where procedures with awake nonhuman primates are conducted. Additionally, they may not work with human and/or nonhuman primate blood, body fluids and tissues.
  - c. Transient Visitors must meet the medical testing requirements established by the facility Animal Program Director prior to entering a NHP animal facility or room as noted in DOHS memorandum: [Medical Clearance of Transient Visitors into NIH Animal Facilities](#).
2. **Training:**
  - a. All personnel working directly with NHPs or regularly entering a facility containing NHPs shall complete the “[Working Safely with NHPs](#)” safety awareness training course and retake the course annually prior to unsupervised entry. Personnel interacting with awake NHPs may also need additional training<sup>3</sup> in approaching and handling NHPs. Certification is ensured by the Principal Investigator or immediate supervisor that a basic level of competency in performing awake procedures has been achieved. See PI/IS responsibilities paragraph in E1.
  - b. Personnel handling unfixed NHP tissues (i.e., no live animals) must complete both the Working Safely with NHPs, and [Working Safely with HIV and Other Bloodborne Pathogens for Non-Hospital Personnel](#) courses prior to working with the tissues; and thereafter annually complete the [Working Safely with HIV](#)

[and Other Bloodborne Pathogens for Non-Hospital Personnel](#) course.

- c. Transient Visitors who do not directly handle NHPs and/or infrequently enter a facility containing NHPs, must complete the second component of the “Working Safely with NHPs” safety awareness training course annually as described below in F.2.d. ii. The second component of the course addresses the facility’s PPE requirements, location of Bite, Scratch, Splash, Exposure kits, wound flushing, and eyewash stations as described in the [NHP BSSE Guidelines](#).
- d. The safety awareness training course: “[Working Safely with NHPs](#)” (NHP Course) consists of two components:
  - i. “Working Safely with NHPs” video/CD, quiz, and review of pertinent NIH Policy Manuals.
    - Trainers will maintain training completion records for their IC.
  - ii. The second component is a review of facility PPE requirements and location of Bite, Scratch, Splash, Exposure kits and eyewash stations.
    - Personnel entering multiple facilities where they work directly with NHPs or enter NHP facilities without supervision, must complete the second component of the training for each facility.
  - iii. Upon completion of both components of the “Working Safely with NHPs” course, the NHP Safety Trainer will document the trainee course completion either at the IC level or, if available, in a database maintained by the OACU.
  - iv. NHP Safety Trainers who wish to provide “Working Safely with NHPs” IC level training must take the “Nonhuman Primate Train-the-Trainer” course annually. This course is provided by the Office of Animal Care and Use (OACU). OACU will document completion of this training.

### **3. Personal Protective Equipment:**

- a. All individuals entering a NHP room must wear appropriate personal protective clothing and equipment which meets or exceeds the guidance established by the NIH Animal Research Advisory Committee (ARAC): [Guidelines for Personnel Protection](#) in Animal Facilities.
- b. Individuals participating in animal study proposals (ASP) which involve additional safety hazards such as infectious diseases or hazardous chemicals must consult the DOHS safety recommendations as written in the IC-approved ASP(s) or provided by a DOHS Safety Specialist.

### **4. Animal Exposure Program:**

- a. All persons having direct contact with NHPs and their tissues or body fluids must participate in the NIH Animal Exposure Program (AEP) provided by OMS or an equivalent program provided by the contractor.
- b. Transient Visitors are not required to participate in the AEP; however, prior to entering NHP holding and procedure areas, Transient Visitors will be required to comply with the facility health screening requirements) set by the facility’s Animal Program Director (e.g., provide proof of: TB testing, measles vaccination, measles titer or measles infection history).

**5. Employee Wound Care and Reporting Procedures for All NHP-related Injuries/Illnesses/Exposures:**

- a. **ALL** personnel involved in injuries and exposures involving NHPs, NHP wastes, unfixed NHP tissues or body fluids, or potentially contaminated equipment must immediately (within five minutes) initiate wound or mucous membrane first aid.
  - i. Contaminated skin and wounds should be thoroughly scrubbed and flushed continuously for 15 minutes with clean running water or normal saline solution, a sponge, and a cleansing agent such as povidone-iodine or chlorhexidine, provided on-site in the NHP bite/scratch (BSSE) kit.
  - ii. Contaminated eyes and mucous membranes should be irrigated at an eyewash station for 15 minutes using normal saline solution or clean running water.
- b. After initial wound or mucous membrane care is completed and appropriate medical treatment is sought, the individual must report the incident/exposure to their PI/IS and the animal facility management where the NHP is housed.
- c. Another individual may contact OMS, the animal facility management, and the individual's PI/IS to report the incident while the injured person is receiving first aid or seeking medical attention.

**6. Employee Wound Care and Reporting Procedures for Macaque-related Injuries/Illnesses/Exposures:**

- a. General wound care guidance for NHP bite, scratch or splash exposures and reporting requirements are found in the [NHP BSSE Guidelines](#).
- b. OMS must be contacted as soon as possible after the occupational exposure regarding any additional treatment and/or follow-up care instructions.
  - i. Ask to speak with the OMS provider-on-duty, and state: "I have had a nonhuman primate-related injury or incident." Notify the Bethesda Main Campus Clinic regardless of geographic location or NIH research campus.
  - ii. Call 301-496-4411 (Bethesda Main Campus Clinic), 7:30 am – 5:00 pm ET, Monday – Friday
  - iii. After-hours call 301-496-1211 (NIH Operator), 5:00 pm – 7:30 am ET, Monday – Friday, and on weekends & holidays.
  - iv. When possible, a co-worker should make the call to OMS while first aid is performed. Individuals unable to call OMS before completing scrubbing/flushing must call from their worksite immediately after scrubbing/flushing.
  - v. If instructed by the OMS provider, take the prescribed dose of valacyclovir orally, which is located in a sealed bag within the BSSE Kit or other pre-determined, easily accessible location.
  - vi. After completing first aid and calling OMS (numbers above, including after hours), immediately proceed to the closest OMS clinic for further evaluation, unless instructed otherwise by the OMS provider.
- c. The management staff for each NHP facility or laboratory using unpreserved tissues is responsible for maintaining adequately stocked Bite, Scratch, Splash,

Exposure kits. A list of the location of each kit will be provided to the Animal Program Director and the IC Safety Committee annually for their review and approval. An updated list for each facility must be sent annually to the ACUC of the lead IC, OACU, and the Animal Program Safety Manager (DOHS), for their information.

- d. The Bite, Scratch, Splash, Exposure kits must be located in an easily accessible area. Changes in locations and/or instructions related to these kits must be communicated to the NHP Safety Trainer and subsequently forwarded to all prior trained individuals.
- e. The facility NHP Safety Trainers are responsible for showing the location and contents of the Bite, Scratch, Splash, Exposure kits and the locations of the eyewash stations to the research and animal care staffs during the second component of the “Working Safely with NHPs” training.

#### 7. **Macaque Unfixed Tissue/Body Fluid Users:**

- a. **Macaque** monkeys and their tissues and body fluids are potentially infected with Herpes B Virus/*Macacine alphaherpesvirus 1*. To ensure safety and reduce injury, the below requirements must be completed:
  - i. Individuals at the NIH who will in any manner handle unfixed NHP tissues, blood, or body fluids must have documentation indicating they are current with these mandatory [DOHS safety training courses](#):
    - [Working Safely with HIV and Other Bloodborne Pathogens for Non-Hospital Personnel](#) for first time attendees, or
    - The annual [Bloodborne Pathogen Refresher Course \(Online\)](#)
    - The one time “[Working Safely with NHPs](#)” training before beginning work with unfixed tissues.

#### 8. **Institutional Biosafety Committee Registration for Macaque Unfixed Tissue/Body Fluid Users**

- a. NIH IBC Registration Determinations and Exemptions
  - i. Principal investigators (PIs) handling unfixed tissues, blood or body fluids from **macaques** (Rhesus, Pigtail, and Cynomolgus monkeys) are required to register and receive IBC approval their work and the experimental use of these materials with the NIH [Institutional Biosafety Committee \(IBC\)](#) via [PI-DASHBOARD](#) and receive IBC approval prior to handling **macaque** unfixed tissues, blood or body fluids. Research staff working with unfixed tissues, blood, or body fluids must be listed on the [registration](#).
  - ii. The NIH-IBC registration will incorporate/identify all associate investigators, technicians, and affiliated lab personnel who will in any manner handle the **macaque** tissues, blood, or body fluids regardless of their status on a given Animal Study Proposal.
  - iii. Changes to experimental work with unfixed **macaque** tissues, blood or body fluids already registered (and related to an already-approved registration) must be submitted as an amendment to the existing NIH-IBC

registration. Amendments are also required to update changes in personnel and location-of-work.

- iv. **Macaque** monkey tissues, blood or body fluids fixed and/or preserved in formalin, glutaraldehyde, or paraformaldehyde (and using well-documented, evidence-based methods shown to be effective in rendering samples non-infectious) are not considered ‘unfixed’ and do not require registration with the PI-DASHBOARD.
  - v. Work with unfixed tissue, blood, or body fluids derived from New World NHP species (e.g., squirrel monkeys, owl monkeys, Cebus monkeys, tamarins, marmosets, etc.) does not require an IBC registration.
  - vi. Veterinary care procedures performed by the veterinary or animal care staff within an animal research facility are exempt from NIH-IBC registration.
- b. Transfer of NHP Unfixed Tissue/Body Fluid
- i. If unfixed **macaque** NHP tissues, blood or body fluids are provided by a PI to another NIH laboratory or individual working outside of an ACUC-approved NHP animal research facility:
    - The receiving PI must hold an NIH IBC-approved registration to receive the material.
    - The NIH-IBC registration must be established prior to the transfer and receipt of the samples.
    - The transferring PI is responsible for ensuring the receiving PI holds an NIH IBC-approved registration for work with this material in NIH laboratories outside of ACUC-approved NHP animal research facilities.
  - ii. If unfixed **macaque** NHP tissues, blood or body fluids are provided by a PI to another laboratory or individual outside of the NIH, the transferring PI is responsible for ensuring that the receiving laboratory or individual:
    - Knows the human health related risks associated with the handling of unfixed **macaque** NHP tissues blood or body fluids, and
    - Understands their responsibility for compliance with their institution’s policies and procedures relating to the handling of potentially infectious material.
  - iii. Once a sample is appropriately transferred to another laboratory (i.e., research, clinical, pathology, etc.), the receiving PI and laboratory is responsible for the subsequent disposition of the transferred material in accordance with this policy.

## 9. Compliance:

- a. All NIH employees, contract personnel and other personnel working directly with NHPs or regularly entering a facility containing NHPs shall comply with procedures set forth in this Policy Manual.
- b. 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 NHPs in research protocols or other disciplinary action.

- c. The Institutional Official shall be informed of such infractions and may impose additional disciplinary actions.

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3 This training is performed at the IC and/or facility level and must be arranged through the facility manager or veterinarian. Detailed description of the expectations are in the [NHP BSSE Guidelines](#).

## **G. Records Retention and Disposal**

All records pertaining to this chapter must be retained and disposed of under the authority of [NIH Manual 1743](#), "Managing Federal Records," Appendix 4, Records Management Resources. These records must be maintained in accordance with current NIH Records Management and Federal guidelines. Contact your [IC Records Liaison](#) or the [NIH Records Officer](#) for additional information

## **H. Internal Controls**

The purpose of this manual is to establish requirements for training, supervision, compliance, personal protective equipment, medical surveillance, accident reporting, and wound care with the intent to minimize the overall number of accidents and injuries sustained by NIH employees, Special Volunteers, and Transient Visitors who work with nonhuman primates or enter nonhuman primate rooms.

1. **Office Responsible for Reviewing Internal Controls Relative to this Chapter:**  
Office of Animal Care and Use and the Office of Intramural Research.
2. **Frequency of Review (in years):** Ongoing with formal reports presented to the Animal Research Advisory Committee (ARAC) semiannually, annually, and triennially as described below.
3. **Method of Review:**
  - a. The procedures implemented by this chapter receive an ongoing review by the Office of Animal Care and Use via their interface with all IC-ACUC's on a continuous basis. Any significant changes in training policies or animal procedures are noted and acted upon as needed rather than at a specified time.
  - b. Semi-annually the IC-ACUC's perform a complete review of their animal care programs, a component of which is a review of the adequacy of IC training and experience. These semi-annual reports are filed with OACU. The OACU staff members review these reports, prior to their submission for review by the DDIR, and the OACU Director then provides a consolidated report to the ARAC regarding trends, concerns, etc. that affect the Intramural Animal Care

- and Use Program (ACUP).
- c. Annually the Division of Occupational Health and Safety compiles a report of bite and scratch injuries related to work with nonhuman primates and presents this to the NIH Occupational Safety and Health Committee and the ARAC. This report provides a basis for discussion of trends seen within this work arena and provides an avenue for both the NIH as well as the Intramural ACUC's to develop new guidance if concerns exist.
  - d. Triennially, the Intramural ACU program is visited by their accrediting organization, the Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC). Training and experience with NHPs is a part of AAALAC's extensive review of the NIH. AAALAC provides a report of their findings to NIH which in turn is presented to the ARAC for deliberation and resolution.
  - e. The Intramural Research Program (IRP) must make annual reports to both the United States Department of Agriculture and the NIH Office of Laboratory Animal Welfare (OLAW.) These agencies have regulatory authorities over the NIH IRP Animal Care and Use program. Per the PHS Policy, instances of significant noncompliance are required to be reported to OLAW.
  - f. In addition, the IC Directors or Scientific Directors participate in the Annual Intramural Self-Assessment of Management Controls, through completion of a set of comprehensive checklists of questions, several of which address concerns covered by this chapter. This process is managed by the Office of Intramural Research.
4. **Review Reports are sent to:** the Deputy Director for Intramural Research and the Deputy Director for Management.

## Appendix 1: References

1. [Guide for Care and Use of Laboratory Animals, 8th edition, National Research Council \(NRC\), 2011.](#)
2. [Occupational Health and Safety in the Care and Use of Research Animals, NRC, 1997](#)
3. [Occupational Health and Safety in the Care and Use of Nonhuman Primates, NRC, 2003](#)
4. [NIH Policy Manual 1340, NIH Occupational Safety and Health Management Program](#)
5. [NIH Policy Manual 3015, Admittance of Minors to Hazardous Areas](#)
6. [NIH Policy Manual 1743, Managing Federal Records](#), Appendix 4, NIH Records Schedule System.
7. [NIH Occupational Medical Service.](#)
8. [NIH Occupational Medical Service Animal Exposure Program.](#)
9. [Cohen, J.I., et al, "Recommendations for Prevention of and Therapy for B Virus Exposure \(\*Cercopithecine Alphaherpesvirus 1\*\)," Clinical Infectious Diseases, 2002, 35:1191-203.](#)
10. Centers for Disease Control and Prevention and National Institutes of Health. [Biosafety in Microbiological and Biomedical Laboratories \(BMBL\) 6th Edition](#), 2020.

11. Centers for Disease Control and Prevention and National Institutes of Health. [Biosafety in Microbiological and Biomedical Laboratories \(BMBL\) 6th Edition. Section VIII—Agent Summary Statements and Section VIII-E: Viral Agents.](#) Washington, DC: US Government Printing Office. 2020.
12. CDC National Institute for Occupational Safety and Health (NIOSH). [Hazard ID 5: Cercopithecine herpesvirus 1 \(B virus\) Infection Resulting from Ocular Exposure.](#)
13. [NIH Exposure Control Program for Non-Hospital Personnel, 2021.](#)
14. [NIH Delegations of Authority, Program: General No. 31, NIH Intramural Animal Care and Use Program.](#)
15. [Medical Clearance of Transient Visitors into NIH Animal Facilities, NIH Deputy Director for Intramural Research memorandum dated 7 May2015.](#)

## Appendix 2: Definitions

1. **Animal Exposure Program (AEP)** – That portion of the NIH occupational health program, specifically designed for NIH personnel who work in animal facilities and/or areas where research animals are housed or used, and/or NIH personnel who have significant contact with research animals or their unfixed tissues or body fluids (significant contact determined by the Principal Investigator or Immediate Supervisor). The AEP is directed and managed by the OMS, Division of Occupational Health and Safety (DOHS). NIH Institute and Center programs without OMS-DOHS directed AEP programs shall implement equivalent AEPs.
2. **Animal Facility Management** – An individual or individuals at each nonhuman primate (NHP) facility assigned direct responsibility for NHPs and/or facilities that may contain NHPs.
3. **Animal Research Advisory Committee (ARAC)** – A component of the NIH Intramural Animal Research Program whose members include the Chairs of each IC Animal Care and Use Committee (ACUC). The ARAC serves as an advisory body to the Institutional Official.
4. **ARAC Guidelines** – Guidelines developed and approved by the ARAC to assist the NIH Intramural Animal Research Program in providing consistent laboratory animal care and use across the NIH Intramural Research Program (IRP).  
<https://oacu.oir.nih.gov/animal-research-advisory-committee-guidelines>
5. **ACUC-approved Animal Research Facility** – An animal holding facility or special procedure area/facility and its personnel, which are overseen by an animal research program and its IC ACUC.
6. **Animal Study Proposal (ASP)** – Written plan for research involving animal models that must be reviewed and approved by the IC ACUC before animal activities can be conducted.
7. **Awake Procedures** – Activities and/or manipulations that place an individual at reasonable risk of contact with an awake NHP or its feces or body fluids. Examples of awake procedures include placing food in a NHP cage or feedbox, using a squeeze-back mechanism, jumping a NHP to another cage or transport device, pole and collar work, placing a NHP in a chair or other restraint device, or behavior recording within

a 2 foot radius.

8. **Awake Procedure Hand Feeding** – Direct hand to mouth feeding of Old World NHPs is prohibited. The presentation of food, fluids or research test agents to the mouths of Old World NHPs may only be conducted indirectly, e.g., using tongs, a utensil or research apparatuses.
9. **Contract Personnel** – Individuals employed by a contract company to provide services at NIH.
10. **Division of Occupational Health and Safety (DOHS)** – A component of the Office of Research Services (ORS). Serves as the NIH operational component in developing and implementing NIH-wide safety and health programs through surveillance, consultation, training and education.  
<http://www.ors.od.nih.gov/sr/dohs/Resources/Pages/Animal-Related-Personnel.aspx>
11. **Exposures** – The contact of a person’s skin or mucous membranes with NHP saliva, cells, or body fluids. Exposures include NHP bite, scratch or splash incidents.
12. **IC-Animal Care and Use Committee (IC-ACUC)** – A committee appointed via delegated authority from the Institutional Official by the Director or Scientific Director of the IC. The committee oversees the IC's animal research program, facilities, and procedures, including the key functions of reviewing and approving requests to use animals in Animal Study Proposals.
13. **IC Safety and Health Committee** – The Committee is composed of IC employees selected by the IC Scientific Director or their designee and serves as a conduit for communication between the IC employees, management, the Division of Occupational Health and Safety (DOHS) and the Division of Radiation Safety (DRS) concerning occupational safety and health matters. The objective of the IC Safety and Health Committee is to support the development, implementation, maintenance and improvement of a comprehensive Occupational Safety and Health Program that reflects NIH policy to:
  - a. Provide the highest practical degree of occupational safety and health for IC employees in all activities of the NIH;
  - b. Provide technical advice, assistance, and management-level support; recommend policies regarding occupational safety and health as authorized by the Director, NIH;
  - c. Minimize losses in human resources and property damage due to accident, injury or work-related illness; and
  - d. Comply with Public Law 91-596 (The Occupational Safety and Health Act of 1970), Executive Order 12196, and other regulations, standards and guidelines governing the occupational safety and health of HHS employees.
14. **Immediate Supervisor (IS)** – Individual with direct responsibility for personnel listed as trainees under this chapter. The IS can include facility managers, facility veterinarians, PI staff, contract managers, etc.
15. **Institution** – The NIH Intramural Research Program including its facilities and contracted, or subcontracted activities performed in accordance with NIH Policy Manual 3040-3 or other applicable acquisition regulations.

16. **Institutional Official (IO)** – The NIH Deputy Director for Intramural Research (DDIR). The Director, NIH, as the Chief Executive Officer of the institution, has delegated to the DDIR the authority and responsibility for compliance of the NIH Intramural Research Program with US Public Health Service Policy, the Guide for the Care and Use of Laboratory Animals, and the US Department of Agriculture Animal Welfare Act Regulations.
17. **Macaques** – A genus (*Macaca*) of NHPs commonly used in biomedical research at NIH, such as rhesus, cynomolgus and pigtail monkeys. **Macaques** are the natural host of the Herpes B Virus/*Macacine alphaherpesvirus 1*. Any tissues or body fluids derived from **macaques** are considered to be potentially contaminated with Herpes B Virus unless those **macaque** tissues or body fluids are fixed and/or preserved in formalin, glutaraldehyde, or paraformaldehyde and rendered non-infectious based on well-documented, evidence-based methods shown to be effective in rendering samples non-infectious.
18. **Minor** – A person under 18 years of age who may be an employee or visitor (please see [NIH Manual Chapter 3015](#) for detailed definitions).
19. **Mucous Membrane** – Epithelial membranes that line body cavities that open to the outside such as the mouth, nose, and eyes.
20. **Nonhuman Primate (NHP)** – Any member of a NHP species held or used for research at NIH. Examples of NHPs:
  - a. New World: marmosets, tamarins, squirrel monkeys, owl monkeys
  - b. Old World: rhesus, cynomolgus and pigtail/pig-tailed macaques, baboons, African Green monkeys
21. **NHP Safety Trainer** – Individuals at the IC and/or facility level who conduct one or both portions of the “Working Safely with Nonhuman Primates” training course and who take the required annual “Nonhuman Primate Train-the-Trainer” course provided by the Office of Animal Care and Use (OACU). These individuals may be animal care or research staff members. Typically, trainers are also involved with the oversight or daily care of the IC’s NHPs.
22. **NHP Facility** – Any buildings, rooms, or areas, including satellite facilities and lab spaces, where NHPs may be housed or held for research manipulations to include surgical manipulations and imaging.
23. **NHP Tissues and Body Fluids** – Any primary cells, tissues, blood, or body fluids derived from NHPs.
24. **Occupational Medical Service (OMS)** – A component of DOHS, Office of Scientific Resources (SR), Office of Research Services (ORS) that develops and implements the Animal Exposure Program. <https://ors.od.nih.gov/sr/dohs/YourRole/Pages/Animal-Related-Personnel.aspx>
25. **Personal Protective Equipment (PPE)** – Items of clothing (i.e. lab coats, shoe covers, face masks, gloves, etc.) or equipment (i.e. face shields, eye goggles, etc.) designed to prevent or limit exposure to potentially harmful agents to personnel. The hazards addressed by protective equipment include biohazards, physical, electrical, heat, chemicals, and airborne particulate matter. <https://www.osha.gov/personal-protective-equipment>

26. **Principal Investigator (PI)** – A scientist designated by the Laboratory/Branch Chief or the IC Director or Scientific Director who is responsible for conducting or managing an animal study in compliance with this policy, the Public Health Service Policy on Humane Care and Use of Laboratory Animals, the Guide for the Care and Use of Laboratory Animals, and the US Department of Agriculture Animal Welfare Act Regulations. The PI certifies acceptance of this responsibility by signing the Animal Study Proposal.
27. **Standard Operating Procedure (SOP)** – Detailed, written procedures that describe how to perform a particular task or overall duty/responsibility.
28. **Trainee** – Those individuals who will be receiving training on handling and working with nonhuman primates.
29. **Transient Visitors** – A category of animal facility visitors who are authorized to enter an animal room when accompanied by an escort trained in proper animal room entry procedures and practices. Transient Visitors are not authorized to have direct contact with animals. Transient Visitors may include but are not restricted to: federal employees and contractors, maintenance and construction workers, general public members, nonaffiliated ACUC members, Special Volunteers, guest workers, and visiting postdoctoral fellows.