University of North Carolina at Greensboro

INSTITUTIONAL ANIMAL CARE
AND USE COMMITTEE
(IACUC)

PROGRAM AND PROCEDURES

Spring 2015
# Table of Contents

Animal Care Overview..................................................................................................................6

Animal Supervisory Staff Responsibilities ..................................................................................6

The Institutional Animal Care and Use Committee: Lines of Authority and Responsibility

Institutional Official .........................................................................................................................8

Responsibilities and Authority of the Institutional Official ..........................................................8

Definition of a "Quorum": Requirements for All Official Actions and Granting Exceptions

Exceptions ........................................................................................................................................8

Exceptions to Voluntary Guidelines, Position Statements and Policies .......................................8

Exceptions to Federal Law and Regulations ..................................................................................9

General Overview of the IACUC Membership ..........................................................................9

Membership Terms and Membership Overlap .............................................................................9

Minimum Membership Requirements ...........................................................................................9

IACUC Titles and Responsibilities for USDA ...............................................................................10

IACUC Advisors/Consultants .........................................................................................................10

Appointment Terms .....................................................................................................................10

Alternate IACUC Members ..........................................................................................................11

Attending Veterinarian ..................................................................................................................11

IACUC Support through Office of Research Integrity (ORI) ......................................................13

IACUC Responsibilities .................................................................................................................14

Alternatives and Investigator Responsibilities .............................................................................14

Alternatives to Animal Testing AltWeb or PubMed ...................................................................14

Guidelines of Animal Research ....................................................................................................14

The “3Rs” of Animal Research ......................................................................................................14

Justification of Animal Use and Species Rationale .......................................................................14

Animal Numbers ...........................................................................................................................15

Animal Alternatives ......................................................................................................................15

Painful/Distressful or Potentially Painful/Distressful Procedures .................................................15

Non-Duplication ............................................................................................................................16

IACUC Review and Approval of Proposed Animal Use .................................................................16

Animal Use Activity Defined .........................................................................................................16

Purpose of IACUC Protocol Review and Approval Process ..........................................................16

Purpose of the IACUC Protocol .....................................................................................................17

Scientific Merit Review (Departmental Review) ..........................................................................18

UNCG Occupational Health Program ..........................................................................................18

Hazard Identification and Risk Assessment .....................................................................................20
<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Personnel Training</td>
<td>20</td>
</tr>
<tr>
<td>Personal Hygiene and Protection</td>
<td>20</td>
</tr>
<tr>
<td>Medical Evaluations</td>
<td>20</td>
</tr>
<tr>
<td>Renewal of Health Clearance</td>
<td>21</td>
</tr>
<tr>
<td>Use of Respirators</td>
<td>21</td>
</tr>
<tr>
<td>Principal Investigator Assurance</td>
<td>22</td>
</tr>
<tr>
<td>IACUC Initial Protocol Review</td>
<td>23</td>
</tr>
<tr>
<td>Stipulations for Additional Information</td>
<td>24</td>
</tr>
<tr>
<td>Approval Status</td>
<td>25</td>
</tr>
<tr>
<td>IACUC Approval Number</td>
<td>25</td>
</tr>
<tr>
<td>Approval Notification</td>
<td>25</td>
</tr>
<tr>
<td>IACUC Protocol Expiration</td>
<td>26</td>
</tr>
<tr>
<td>IACUC Review and Approval of Minor, Significant, and Highly Significant Amendments</td>
<td>26</td>
</tr>
<tr>
<td>Criteria for Minor, Significant, and Highly Significant Amendments</td>
<td>27</td>
</tr>
<tr>
<td>Failure to Obtain IACUC Approval of Significant Modifications</td>
<td>28</td>
</tr>
<tr>
<td>DeNovo Review</td>
<td>28</td>
</tr>
<tr>
<td>Official Request for IACUC Protocol Termination</td>
<td>29</td>
</tr>
<tr>
<td>IACUC Guidelines: General Animal Use and Specific Animal Techniques</td>
<td>29</td>
</tr>
<tr>
<td>IACUC-Approval of Protocols Originating from Non-UNCG Institutions and/or Conducted at UNCG</td>
<td>29</td>
</tr>
<tr>
<td>Criteria for IACUC-approval of Protocols from non-UNCG Institutions</td>
<td>29</td>
</tr>
<tr>
<td>Criteria for IACUC-approval of Protocols from UNCG and Conducted at non-UNCG institutions</td>
<td>30</td>
</tr>
<tr>
<td>Criteria for IACUC-approval of Protocols conducted at UNCG animal facility from non-UNCG institutions</td>
<td>30</td>
</tr>
<tr>
<td>Sub-granting of PHS Moneys to non-UNCG Institutions</td>
<td>31</td>
</tr>
<tr>
<td>Transfer of Animals</td>
<td>31</td>
</tr>
<tr>
<td>Intra-campus Transfer of animals</td>
<td>32</td>
</tr>
<tr>
<td>Criteria for IACUC-approval of Programs which Terminate in the Transfer of Animals to otherwise Unaffiliated Institutions</td>
<td>32</td>
</tr>
<tr>
<td>Animal Procurement, Animal Usage and Related-Issues</td>
<td>32</td>
</tr>
<tr>
<td>Biologic Materials</td>
<td>33</td>
</tr>
<tr>
<td>Display of the IACUC-Approval Number</td>
<td>33</td>
</tr>
<tr>
<td>Criteria for Initiating Research on Received Animals</td>
<td>33</td>
</tr>
<tr>
<td>19.1 Exceeding Animal Numbers Approved for Use</td>
<td>33</td>
</tr>
<tr>
<td>Retention of Research Animals under Expired IACUC-Approval Numbers</td>
<td>33</td>
</tr>
<tr>
<td>Transfer of Animals to other IACUC-Approved Programs</td>
<td>33</td>
</tr>
<tr>
<td>Criteria for Internal Transfers</td>
<td>33</td>
</tr>
<tr>
<td>Animal Usage Record Keeping Requirements</td>
<td>34</td>
</tr>
<tr>
<td>Animal Usage Record Keeping - Responsible Parties</td>
<td>34</td>
</tr>
</tbody>
</table>
Animal Usage Records ........................................................................................................34
UNCG’s Lab Animal Resources Protocol (LARP) ...................................................................34
Veterinary Medical Program .................................................................................................36
Overview of Animal Care and Use Facility Personnel Training .............................................37
Preventive Medicine .............................................................................................................38
Quarantine and Isolation Facilities and Procedures for Purpose Bred Animals .........................38
Periods for Physiologic, Psychological, and Nutritional Acclimation .....................................38
Program for Separation of Animals by Species, Source, and Health Status ..............................39
Surveillance, Diagnosis, Treatment, and Control of Disease Program ......................................39
26.1 Daily Observation of Animals and Responsible Personnel ..............................................39
Emergency Notification .........................................................................................................39
Medical Records - Maintenance Procedures ...........................................................................39
Sentinel Program - Quarterly Health Monitoring ......................................................................39
Disease Investigations ...........................................................................................................40
Diagnostic Reports ...............................................................................................................40
Diagnostic laboratory facilities, equipment and commercial services ......................................40
Annual Diagnostic Frequency .................................................................................................41
Study Records ......................................................................................................................41
Post –Approval Monitoring Program (PAM) ............................................................................41
IACUC Procedures for the Investigation of Animal Care and Use Concerns ...............................41
Procedures for the Review and Reporting of Animal Welfare Concerns ..................................42
Employee Voiced Animal Welfare Concerns ..........................................................................42
Public Voiced Animal Welfare Concerns ...............................................................................42
Animal Welfare Concerns and Guaranteed Anonymity ............................................................42
Personnel Training in the Handling, Notification and Documentation of Public Animal Welfare Concerns ..........................................................................................................................42
Review, Investigation and Documentation of Animal Welfare Concerns ................................43
ORI Policy on Investigation of Animal Use Concern and/or Potential Issue of Noncompliance ........................................................................................................................................43
Consequences of Noncompliance with IACUC Protocol, Policies, Procedures, or Decisions .................................................................................................................................44
Suspension of Protocol .........................................................................................................45
Reports to outside agencies of Noncompliance and Animal Activity Suspensions.............. Error! Bookmark not defined.
IACUC Suspension of On-Going Animal Activities ..................................................................45
Semi-Annual Facility Inspection ............................................................................................46
Standards for Facility Inspection ...........................................................................................47
Required Areas of Inspection* ...............................................................................................47
Inspection Participants .........................................................................................................48
Facility Inspection Preparation ..............................................................................................48
Semiannual Facility Inspection Checklist ..................................................................................48
The University of North Carolina at Greensboro (UNCG) is committed to the responsible and humane treatment of animals used in programs at or conducted in collaboration with the university.

First and foremost, and in accordance with U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used In Testing, Research, and Training, the university ensures that all of its animal activities are designed and performed “with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society”.

**Animal Care Overview**

UNCG animal care personnel are responsible for the continuous provision of appropriate animal environments, housing, and management. All animal care and use-related programs implemented by animal supervisory staff are developed, reviewed, evaluated and modified, as deemed necessary, in consultation with the Attending Veterinarian, and are reviewed and evaluated by the IACUC, at least semi-annually during program reviews and facility inspections.

**Animal Supervisory Staff Responsibilities**

The responsibilities of animal supervisory staff include, but are not limited to:

- To assist the IACUC in the oversight of animal care and use activities to ensure institutional compliance with all applicable federal, state and local animal welfare laws and regulations as well as relevant voluntary guidelines, company and IACUC policy
- To ensure that all animal supervisory staff are appropriately trained
- To ensure that animals are procured from only reputable and USDA-licensed sources (if applicable) and other reputable vendors (unregulated species).
- To monitor and document animal procurement to ensure animals are purchased only for use on current IACUC-approved activities and to help track numbers of animals (that animal numbers do not exceed those approved for use), including internal transfers between IACUC-approved programs
- To develop and implement appropriate animal procurement procedures
- To develop and implement the Animal Facility Manual for providing appropriate animal environment, housing, and management necessary to ensure the safety and health of research animals and the quality of the research program
- To oversee maintenance of laboratory animal facilities and equipment
- To ensure the availability of appropriate equipment and supplies to support all IACUC-approved animal use activities
- To develop and implement a program for monitoring the health of animals on a daily basis
- To develop and implement an appropriate health quality assurance program to ensure the continued health of animals
- To develop in consultation with appropriate health and safety personnel, and to implement, monitor and document participation in, an occupational health and safety program, designed to protect health and ensure safety of all personnel involved in animal care and use activities
To participate in the development an action plan in the event of facility problems during regular working hours, after hours, on weekends, on holidays.

To participate in the development of an animal facility disaster plan, in consultation with the ORI and Emergency Services, and as part of the overall safety plan for the animal facility, that takes into account both personnel and animals, in the event of a disaster.

**The Institutional Animal Care and Use Committee: Lines of Authority and Responsibility**

The Institutional Animal Care and Use Committee recognize that each member is appointed by the Chancellor of the University of North Carolina, Greensboro (UNCG) and consists of no less than five voting members. Efforts are made to appoint and maintain a diverse membership with a collectively broad spectrum of expertise and knowledge necessary to ensure a quality Institutional Animal Care and Use Program. With the exception of appointing IACUC members, the Chancellor has delegated their authority of Institutional Official to the Vice Chancellor of the Office of Research and Economic Development.

Appropriate lines of authority and responsibility for administering the program are critical for ensuring regulatory and voluntary compliance. There is a direct line of authority from The Institutional Official to the Institutional Animal Care and Use Committee (IACUC). The Attending Veterinarian, a voting member of the IACUC, reports directly to the Institutional Official via the Director of the Office of Research Integrity. (See table I below)

**DIAGRAM OF THE REPORTING CHANNELS FOR THE ANIMAL CARE AND USE PROGRAM AT THE UNIVERSITY OF NORTH CAROLINA AT GREENSBORO**
Institutional Official
The Institutional Animal Care and Use Committee recognizes that the Institutional Official (IO) is an individual of high-level authority within the institution and designated (documented in writing) the Institutional Official by the UNCG Chancellor. At UNCG, the Vice Chancellor of the Office of Research and Economic Development is the IO. The IO is authorized to legally commit on behalf of the institution that it is in compliance with the PHS Policy and the Animal Welfare Act. The IO has the administrative authority to promulgate, implement and enforce policies as well as the financial authority to approve necessary funding if required to meet the needs of the animal care and use program as recommended by the IACUC.

Responsibilities and Authority of the Institutional Official
The responsibilities of the Institutional Official include:

1. Authority to legally commit on behalf of the institution:
   - Authority to sign the UNCG's PHS Assurance, making a commitment on behalf of the institution that the requirements of PHS Policy will be met
   - Authority to sign the USDA research facility registration application and subsequent USDA annual reports (if applicable)
2. Direct oversight of the Institutional Animal Care and Use Program
3. Authority to administer the Institutional Animal Care and Use Program
4. Coordination of administration, IACUC, investigators and animal resources to ensure a clearly defined chain of authority
   (Note: The Institutional Official’s authority to formally appoint members to the IACUC is shared by the Chancellor).

Definition of a "Quorum": Requirements for All Official Actions and Granting Exceptions
A quorum of the IACUC is defined as a majority of the voting members, which shall not include any member who has a conflicting interest with the activity under review.

Requirements for All Official Actions
All official actions must take place at a convened meeting of a quorum of the voting IACUC-membership and upon a majority vote.

Exceptions
The IACUC may grant exceptions to its own voluntary guidelines, position statements and policies. Under special circumstances, it may be necessary for the IACUC to seek review and approval of exceptions to federal laws, regulations and policies from the appropriate agency.

Exceptions to Voluntary Guidelines, Position Statements and Policies
The IACUC may exercise its authority to grant exceptions to voluntary guidelines and its own established recommendations (position statements and policies), if the IACUC determines that such an exception is in the interest of animal health and well-being or if the exception can be scientifically justified and with due consideration to the cost-benefit to animal well-being and scientific advancement. Exceptions will be handled on a case-by-case basis and must be accompanied by written justification, supporting need. All
Exceptions must be approved by majority vote of a quorum of the IACUC and documented in the IACUC minutes.

Exceptions to Federal Law and Regulations
If an exception to federal animal welfare laws, regulations and/or policies cannot be clearly supported by satisfactory justification, the IACUC will seek the review and approval of the exception from the appropriate agency. If the federal agency approves the exception, the exception must be then be approved by majority vote of a quorum of the IACUC and documented in the IACUC minutes.

General Overview of the IACUC Membership
At a minimum, the IACUC membership will meet the applicable federal, state and local requirements including Public Health Service requirements, the Guide for the Care and Use of Laboratory Animals, 8th edition, USDA regulations 9CFR2.31 (if applicable), and institutional policy.

Membership Terms and Membership Overlap
Voting IACUC members are typically appointed for three-year terms with the option for renewal of additional terms thereafter. If possible, staggered terms, necessary to ensure at least one-half of the membership has a minimum of one to two years of experience at any given time, will be implemented. If possible, the mechanism of membership overlap will be implemented to permit a new member to serve as a non-voting member on the IACUC for a period of time prior to the resignation of a voting member as a means of training.

Appointment terms of non-voting members will be determined on a one-on-one basis, commonly dependent on IACUC needs and availability of qualified replacements.

Minimum Membership Requirements
At a minimum, the UNCG IACUC will consist of four (4) voting members including a:

- **Doctor of Veterinary Medicine** with training or experience in laboratory animal science and medicine, who has direct or delegated program authority and responsibility for activities involving animals at the institution

- **Unaffiliated Member** who is not affiliated with the institution in any way other than as a member of the IACUC, who is not a member of the immediate family of a person who is affiliated with the institution, and who represents community interests with respect to the use of animals in research; preferably, an individual whose primary expertise is in a non-scientific area and who is not a laboratory animal user

- **Practicing Scientist** with experience in research involving animals

- **Non-Scientist** with primary interests in a nonscientific discipline

As long as the committee meets the minimum membership of four members, an individual who satisfies more than one of the required qualifications may fulfill more than one requirement. For example, the unaffiliated member may fulfill the role of community representative and the role of non-scientist. However, based on USDA policy, the position of IACUC Chair, Veterinarian (V) and Non Affiliated Member (NAM) will be filled by three unique individuals.

Due to perceived undue influence over the IACUC, the Institutional Official will not be appointed to the IACUC.
IACUC Titles and Responsibilities
The Chancellor has appointed the following members with the following titles and responsibilities:

IACUC Chair
One individual is appointed IACUC Chair. This individual is selected based on their familiarity with the recognized standards for humane animal care and use, transgenic technology, and the role of animals in this process. The IACUC Chair serves to represent the institution, the IACUC and the animal research area, collectively. Because of the possibility of real or perceived potential conflict of interest, and based on USDA policy, the Veterinarian or the Nonaffiliated Member will not be appointed to the position of IACUC Chair.

Attending Veterinarian
The Doctor of Veterinary Medicine appointed to the IACUC is also the designated (or delegated) with expertise in the areas of laboratory animal medicine and science and direct or delegated animal care and use program authority and responsibility for activities involving animals. In the capacities of Attending Veterinarian and IACUC member, this member has a direct reporting line to the Director of the ORI and Institutional Official.

Non-Affiliated Member
The Non-Affiliated member (NAM) is selected based on his/her ability to represent an unbiased view of the community’s interests and concerns with regard to the care and use of animals in research. This individual is not affiliated with the institution in any way other than by their participation on the IACUC. This individual is not a research animal user.

Based on the IACUC’s enormous responsibility and substantial time-commitment, the IACUC membership will also include non-voting individuals and/or support staff to help alleviate the administrative burden on the committee by providing administrative support for IACUC activities.

IACUC Advisors/Consultants
The IACUC membership may include additional voting members or ad hoc (non-voting) advisors (e.g. regulatory consultants, legal representatives, biostatisticians, or safety officers) who bring additional expertise to the IACUC in the conduct of facility inspections, animal care and use program reviews and other IACUC activities. Additional voting members or ad hoc (non-voting) advisors may be necessary to help ensure committee effectiveness in the development and maintenance of a quality program customized to meet the unique needs of the institution while ensuring regulatory and voluntary compliance and desired program outcomes.

Appointment Terms
IACUC appointments for IACUC Advisors/Consultants will be indefinite, based on the needs of the committee.

The IACUC may appoint subcommittees to act on behalf of the IACUC and under clearly defined circumstances as deemed necessary to enhance the effectiveness of the IACUC in ensuring institutional compliance, research animal welfare and personnel safety and education (e.g. Animal Alternatives Subcommittees, Training, or monitor Occupational Health and Safety). However, in all cases, the IACUC will retain oversight and responsibility for all activities.
Alternate IACUC Members

The Chancellor may also appoint alternates to the IACUC membership if needed to ensure meeting quorum and/or for the purpose of training future full-voting IACUC members.

Each alternate must replace a specific IACUC member (a “primary” or full-voting) and be appropriately trained. More than one individual can be appointed alternate for the same primary member but only one alternate can be empowered with the vote during official business in the absence of their designated primary member. Similarly, one individual can be appointed alternate for more than one primary member, but can only represent one “absent” member (not multiple members) during official business. Each alternate must meet the criteria for the primary member’s specific role on the IACUC (i.e. practicing scientist replaces a practicing scientist; veterinarian replaces veterinarian; community member replaces community member). Alternates must vote their own conscience and not that of their primary member. Alternates cannot vote or contribute to the quorum unless their designated primary member or one of their designated primary members (if appointed as an alternate for more than one primary members) is physically or “technically” (due to conflict of interest) absent. Alternates must be appointed by the Chancellor in writing and each letter of appointment must be specific and one-to-one.

Attending Veterinarian

The Doctor of Veterinary Medicine appointed to the IACUC is also designated (or delegated) with expertise in the areas of laboratory animal medicine and science and direct or delegated animal care and use program authority and responsibility for activities involving animals. In the capacities of Attending Veterinarian and IACUC member, this member has a direct reporting line to the Director of the ORI and the Institutional Official. This authority and responsibility include, but is not limited to:

- Authorization via IACUC activities to contribute to the establishment of appropriate policies and procedures for ancillary aspects of veterinary care including, but not limited to, animal care and husbandry, animal health quality assurance, environmental and psychological enrichment programs for resident animals, exercise programs for canines, occupational health and safety programs for animal care and use personnel, animal facility disaster plans, and to conduct periodic evaluations of their associated outcomes, at least semiannually.

- Appointment as a full-voting member of the IACUC.

- As Attending Veterinarian and full voting member of the IACUC, the role of the Attending Veterinarian is vital to ensuring that the institution continues to maintain a program of adequate veterinary care including but not limited to the following provisions by semi-annual inspection and IACUC protocol review:
  - Appropriate facilities, personnel, equipment, and services are available to comply with federal animal welfare requirements.
  - Appropriate living conditions for each research animal species that contributes to their health and comfort.
  - Appropriate housing, feeding, and nonmedical care of the animals directed by the AV or other designated scientist(s) trained and experienced in the proper care, handling, and use of the species being maintained or studied.
  - Guidance to principal investigators, and other personnel, involved in the care and use of animals regarding handling, immobilization, anesthesia, analgesia, tranquilization, and euthanasia.
• Ensure the provision for pre-operative and post-operative care of the animals in accordance with established veterinary medical and nursing practices.
• Adequately qualified and trained personnel conducting procedures on the species being maintained or studied.
• Ensure that no animal is used in more than one major operative procedure from which it is allowed to recover unless satisfactorily justified for scientific reasons by the principal investigator, in the IACUC protocol.

• With respect to procedures that are potentially painful or distressful, the AV is authorized to:
  • Consult with research animal users to ensure the minimization of pain and distress during the conduct of animal research, and in particular, with regard to procedures that may cause more than momentary pain or distress.
  • Ensure that procedures which may cause more than momentary pain or distress are performed with appropriate pain relieving drugs unless withholding such drugs is justified for scientific reasons, in writing, by the principal investigator and will continue only for the necessary period of time.
  • Ensure that procedures that may cause more than momentary pain or distress are NOT performed with the use of paralytics without anesthesia.

• In addition, the AV will share the following responsibilities with the other voting members of the IACUC including, but not limited to:
  • Semi-Annual Program Evaluation including Program Review and Facility Inspections
  • Reports and Recommendations to the Institutional Official
  • Review and Approval of Proposed Animal Use Activities and Significant Modifications to IACUC-Approved Animal Use Activities
  • Suspension of On-Going Animal Activities (if warranted)
  • Assessment of Animal Care and Use Personnel Qualifications
  • Review of Institutional Training Programs for Animal Care and Use Personnel and the Institutional Animal Care and Use Committee
  • Provision of and participation in appropriate Occupational Health and Safety Programs and associated training for animal care and use personnel as well as others at risk
  • Reporting and Record Keeping Requirements
  • Provision of training in the recognition and reporting of animal care and use deficiencies or departures and the mechanism for voicing animal welfare concerns
  • Review and Investigation Animal Welfare Concerns
  • Endorsement of an Animal Facility Disaster Plan

• Authorized to ensure that adequate veterinary care is provided at all times.
  • Methods to control, prevent, diagnose, and treat diseases and injuries and the readily availability of appropriate weekend, holiday, and emergency care.
  • Daily or more frequent observations of all animals to assess health and well-being; if such observations are performed other than by the AV directly, a mechanism of direct and frequent communication must be in place to ensure the timely and accurate notification of the AV in the event of a problem or concern related to animal health.
  • Availability and provision of medical care for animals as necessary.
• Authorized to oversee the adequacy of all aspects of animal care and use for all animals.
• Responsible for developing and implementing the Veterinary Care Program

• With respect to procedures that involve surgery, the AV is authorized to:
  • Ensure the provision for pre-operative and post-operative care of the animals in accordance with established veterinary medical and nursing practices.
  • Ensure that all survival surgery is performed using aseptic procedures, including surgical gloves, masks, sterilized instruments, and aseptic techniques.
  • Ensure that all major operative procedures on non-rodents are conducted only in facilities intended for that purpose and that these facilities are operated and maintained under aseptic conditions.
  • Ensure that non-major operative procedures, and all surgery on rodents, are performed using aseptic procedures.
  • Ensure that no animal is used in more than one major operative procedure from which it is allowed to recover unless satisfactorily justified for scientific reasons by the principal investigator, in the IACUC protocol.

• With respect to any and all euthanasia procedures, the AV is authorized to:
  • Ensure that the method produces rapid unconsciousness and subsequent death without evidence of pain or distress, or utilizes anesthesia produced by an agent that causes painless loss of consciousness and subsequent death such as those described in the most current version of the AVMA Panel on euthanasia.

• With respect to the Animal Facility Disaster Plan,
  • Fulfill the role of an “official responder” within the IACUC Emergency Plan, and should participate in the response to a disaster.

IACUC Support through Office of Research Integrity (ORI)

Responsibilities
The responsibilities and support of the IACUC will be overseen by the Director of the Office of Research Integrity and shared with members of the animal facility staff, IACUC, Attending Veterinarian, and Chair of the IACUC. These include, but are not limited to:

• Participation in the development of IACUC calendars, agendas, meeting minutes, program and inspection reports, position statements and operating procedures, and institutional guidelines

• Facilitation, tracking and documentation of the IACUC animal research review and approval process

• Provide assistance in the conduct of program reviews and facility inspections

• Record keeping requirements associated with the animal welfare regulations and institutional requirements by active documentation and maintenance of IACUC reports, records, and activities

• Participation in the development, implementation and documentation of training programs for IACUC members, animal users and animal supervisory staff

• Participation in the development, implementation and documentation of Occupational Health, Safety Program
• Provide guidance and all necessary checks and balances to ensure the timely address of the IACUC's regulatory, voluntary and institutional obligations

IACUC Responsibilities
Other critical responsibilities delegated to the UNCG IACUC in its review and approval of proposed animal activities includes ensuring:

• Animal use is justified
• Animal species is appropriate
• Animal numbers are the minimum necessary to achieve statistical significance
• Non-animal alternatives have been considered
• Alternatives to potentially painful procedures have been considered
• A written description of the methods and sources used to determine that alternatives to painful procedures are not available is provided
• Research is not unnecessarily duplicative
• Humane endpoints are addressed

Alternatives and Investigator Responsibilities
Investigators are obligated to conduct a comprehensive review of the scientific literature prior to proposing an animal use activity. Literature searches are conducted to ascertain the most appropriate research model (e.g. non-animal or animal), the most appropriate species if an animal model is indicated, the minimum number of animals necessary to obtain reliable information, the available refinements to minimize study length, degree of invasiveness and pain and distress, and finally, to ensure that research will not unnecessarily duplicate previous research.

Alternatives to Animal Testing AltWeb or PubMed
The IACUC encourages investigators to conduct animal alternatives literature searches using available mechanisms. For example, the Alternatives to Animal Testing Web (AltWeb) Search Engine is designed to allow investigators to search selected sites on the Internet that contain information about alternatives or animal welfare. The AltWeb Site is found at URL http://altweb.jhsph.edu.

Guidelines of Animal Research

The “3Rs” of Animal Research
Animal alternatives are commonly referred to as the 3Rs of Russell and Burch: Replacement, Refinement and Reduction (Russell, W. M. S., Burch, R. L. 1959. The principles of humane experimental technique. Methuen & Co., Ltd., London.)

• Replacement is the use of non-animal technologies such as computer and mathematical models, or the use of in vitro techniques in place of whole-animal systems, or the modification of methods for use of a lower order or a less sentient animal species.
• Refinement is the minimization of pain and distress during animal research including the use of pain-relieving agents or the incorporation of refined techniques, which prevent or minimize pain and distress.
• Reduction is the use of the minimum number of animals necessary to obtain statistically significant results. Reduction of animal numbers may be achieved in a variety of ways including the use of more sensitive or combined endpoint assays.

A strong understanding of these concepts is necessary to perform successful animal alternatives literature searches.
The IACUC relies on the satisfactory completion of several sections in the IACUC application to evaluate animal use justification, animal alternatives and other related issues.

Resumes and/or statements of animal use experience may also be required by the IACUC for review and evaluation in order to secure full IACUC-approval of an animal use activity.

**Justification of Animal Use and Species Rationale**
The USDA Animal Welfare Regulations obligate investigators proposing animal research to provide “A rationale for involving animals and for the appropriateness of the species and numbers of animals to be used”. In the Animal Use Section of the IACUC Form, the investigator must justify the use of animals and the proposed animal species, and describe the relevance of the animal research to human or animal health and/or the advancement of knowledge including the specific characteristics that make the proposed species the best choice for the work.

**Animal Numbers**
In the Animal Use section of the IACUC application, the investigator provides approximate numbers of animals to be used in a study (i.e. number of animals per group, number of groups per study and total number of animals per year).

In addition, the investigator must identify the sources supporting the proposed numbers of animals (e.g. supporting historical data, published literature, statistical analysis, regulatory requirements, dictated by *in vitro* requirements, other specified sources).

**Animal Alternatives**
In the Pain/Distress section of the IACUC application, the investigator must answer to the availability of alternatives to painful and/or distressful or potentially painful and/or distressful procedures. This section obligates the investigator to seek out and consider, if available, alternative methods and systems that may **REPLACE** animal use with non-animal systems, non-whole animal systems or systems which use a lower order species; may **REDUCE** animal numbers by utilizing fewer animal numbers without compromise to the statistical significance of the data; and/or **REFINE** the research design by preventing or minimizing the degree and/or duration of pain or distress.

If alternatives are available, the investigator must explain and satisfactorily justify why available alternatives cannot be used (i.e. why the use of the alternative would compromise research objectives).

In addition, the investigator must identify the methods and sources used (e.g. literature databases), the date of the literature search, the period covered, and key words searched, to seek animal alternatives information including alternatives to painful or potentially painful procedures, distressful or potentially distressful procedures.

**Painful/Distressful or Potentially Painful/Distressful Procedures**
Anesthetic, analgesic, or tranquilizing agents should be administered for any procedure with the potential for causing more than minimal and/or transient pain or distress to the animal. If a potentially painful/distressful or painful/distressful procedure is proposed, the investigator is required to:

- Develop the procedure in consultation with the Attending Veterinarian
- If pain-relieving agents must be withheld, provide scientific justification for withholding them
- Provide assurance that the painful/distressful procedure will continue only for period of time necessary
- Clearly establish the steps to monitor for pain/distress and to respond to animals in pain/distress
Even in those programs that incorporate the use of pain relieving agents to prevent or minimize pain or distress, the availability of alternatives must be addressed for each procedure with a potential for causing greater than slight or momentary pain or distress (i.e. pain or distress greater than that caused by routine injections or venipuncture). That is, the use of pain relieving agents to prevent or minimize pain or distress does not rescind this responsibility.

**Non-Duplication**
No animal use activity should be performed without a thorough review of the literature to eliminate the possibility of unnecessary duplication of previously conducted research. The investigator identifies the literature databases searched to ensure that the proposed research does not constitute unnecessary-duplication In the Principal Investigator Assurance section of the IACUC application, and as required by the USDA regulations, the investigator assures that the proposed research is not unnecessarily duplicative.

**IACUC Review and Approval of Proposed Animal Use**
As an agent of the university, the IACUC is authorized to review and approve, require modification (in order to secure approval), or withhold approval of all proposed activities involving animals.

The Institutional Animal Care and Use Committee reviews and evaluates all research animal use activities conducted at the university at least every twelve months.

**Animal Use Activity Defined**
Animal use activities cover any and all activities involving animals including testing, teaching and research (e.g. animals used in specific research programs, sentinels in animal health surveillance programs, animals used for training personnel in both, animal care and animal use techniques, breeding programs, blood and tissue donors etc.).

These activities are not limited to those performed in-house but include all animal research programs without regard to where they are conducted, i.e. any collaborative or subcontracted animal research conducted at otherwise unaffiliated institutions which originate from the university and to which the university provides total or partial funding, or provides unique services/products/agents, or designates, directs or suggests the animal procedures to be followed, and from which the university has potential to derive benefit.

At institutions with an established IACUC and where animal research activities which originate in total or in part from the university, the university IACUC may choose to rely on the review and approval of the animal use activity by the non-affiliated IACUC. While dual IACUC review is not required by PHS Policy or the USDA Animal Welfare regulations, the UNCG IACUC retains its authority to assess the adequacy of IACUC review and approval of an animal activity by a non-affiliated institution. If the review and approval are deemed inadequate, the UNCG IACUC will not permit its initiation until the non-affiliated IACUC has reviewed the proposal and granted it full-approval.

**Purpose of IACUC Protocol Review and Approval Process**
The IACUC Protocol application review and approval process are the IACUC-established mechanisms to ensure that the IACUC fulfills its responsibilities in the review and approval of animal use activities prior to their initiation. This process permits the IACUC to evaluate proposed animal use activities and suggest significant changes to IACUC-approved activities to ensure that they will be conducted in keeping with all applicable federal laws, regulations and policy, the “Guide for the Care and Use of Laboratory Animals”
(the Guide, 8th edition), and all IACUC and institutional guidelines, unless satisfactory scientific justification for a departure is presented by the investigator and approved by the Committee.

No animal use activity or significant change to an IACUC-approved animal use activity can be initiated unless it has been reviewed and granted IACUC approval.

**Purpose of the IACUC Protocol**
The IACUC uses an IACUC Protocol completed by the Principal Investigator (PI) for the review and approval of all proposed animal use activities.

A completed IACUC Protocol provides committee members with critical information required to evaluate and ensure:

- Use of minimum numbers of animals and the appropriate species
- Appropriate pre- and post-procedural housing, husbandry and veterinary care
- Satisfactory evidence and assurance that the activity does not constitute unnecessary duplication
- Consideration of non-animal alternatives, and evidence that non-animal alternatives are not available or, if available, will not fully meet the research objectives
- Satisfactory measures to prevent or minimize pain and distress that are consistent with sound research design.
- Consideration of alternatives to painful procedures
- Written account of the methods and sources used to determine that alternatives to painful procedures are not available
- Potentially painful and distressful procedures are supported by satisfactory scientific justification and appropriate established measures to prevent and/or minimize pain and distress
- Use of appropriate anesthetics, analgesics and tranquilizers during painful and distressful procedures unless withholding pain relieving agents is scientifically justified and the procedures are permitted to continue only for the time period necessary
- Potentially painful or distressful procedures including those which utilize anesthetics, analgesics and tranquilizers to prevent, minimize or alleviate pain and distress are developed in consultation with the Attending Veterinarian or his/her designee
- If paralytic agents are used in conjunction with anesthesia, proper monitoring of the animal’s vital signs are performed to ensure an unconscious state including but not limited to the following:
  - Blood pressure
  - Heart rate
  - Respiratory rate and effort
  - Assessment of oxygenation (pulse oximetry, capnography, arterial blood, gas, mucous membrane coloration)
  - Assessment of the level of anesthesia (i.e. responsiveness to stimuli, changes in anesthetic regimen)
- Euthanasia at the end of the procedure or, if appropriate, during the procedure, of animals that would otherwise experience severe or chronic pain or distress that cannot be alleviated
- Aseptic technique for all survival surgeries
- Major surgical procedures on non-rodeum species are performed in dedicated facilities
• Multiple major survival surgeries, within the same protocol, is supported by satisfactory scientific justification (e.g. necessary and related components of a research activity) or evidence supporting their conduct in order to conserve scarce animal resources or for clinical reasons as determined by the Attending Veterinarian or his/her designee

• Appropriate pre-surgical and post-surgical care

• Continued animal participation in applicable enrichment and exercise programs during the conduct of the activity unless supported by scientific justification or upon the recommendation of the Attending Veterinarian to ensure animal well-being

• Appropriate methods of euthanasia, consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines on Euthanasia, unless a deviation is scientifically justified and complies with the PHS policy on humane care and use of laboratory animals clarification regarding use of carbon dioxide for euthanasia of small laboratory animals

• Appropriate animal housing and care which contributes to animal health and comfort

• Housing, feeding, and non-medical care activities directed by qualified individuals trained and experienced in the animal's species-specific needs

• Appropriately trained and qualified personnel are designated to participate in the activity

• Availability of a qualified veterinarian for the provision of medical care usually for field studies or off campus studies

• Implementation of appropriate safety precautions throughout the procedure for the protection of personnel and animals

**Scientific Merit Review (Departmental Review)**

Before an animal use application is submitted, PIs are encouraged to request scientific merit review (Departmental Review) and general acceptance review from their Department Reviewer before submission. The PI must complete the IACUC Application. PIs are strongly encouraged to request scientific merit review (Departmental Review) and general acceptance review from their Department Reviewer before submission. The PI must be a member of the UNC Greensboro faculty. This review is to include verification of funds to support the project if external funds will not be sought.

If a student desires to conduct animal research, he/she must identify a faculty member to take full responsibility as PI.

Each department can determine the basis for conducting the review but at a minimum, reviewers should consider a brief synopsis of the background, hypothesis tested, animal numbers and proposed data analysis. Reviewer comments should be forwarded to the PI as they may provide helpful suggestions for improving the experimental design. Please note that the departmental review is not intended to be an editorial review of the IACUC protocol, but any added feedback the departmental reviewer can provide the PI will aid in the overall review process. The review may include, but should not be limited to, the IACUC application, which focuses on animal welfare.

In addition, departmental review may also wish to evaluate the proposal for adequacy of the following areas (adapted from the NIH peer review process):

• Significance: does the project address an important problem in the field?

• Investigator: are the PI and other researchers capable of carrying out the project?
• Innovation: do the experiments challenge current scientific paradigms?

• Approach: are the overall strategy, methodologies, and analyses appropriate to accomplish the specific aims of the project?

• Environment: is the scientific environment adequate for successful completion of the work?

Upon acceptance, the Department Reviewer must notify the ORI that the Departmental Review has been completed.

IACUC Required Training

CITI Training

All individuals that will handle animals as part of a proposed IACUC Protocol are required to take CITI Training Modules “Working with the IACUC: Investigators, Staff and Students” and the CITI module that is specific for the species used. Also, if you are conducting studies that have the potential to cause “more than momentary pain and distress” in mice or rats, you must take the Minimizing Pain and Distress module. If conducting major surgery on non-rodent species you must take the aseptic surgery module.

For wildlife research, the PI and research team will need to complete the CITI module related to wildlife research.

UNCG Occupational Health Program

The University of North Carolina at Greensboro is committed to ensuring the health and safety of individuals working with animals in their professional activities, both on and off campus. The goal of the UNCG Occupational Health program is to prevent occupational injury and illness while working with animals by avoiding, controlling or eliminating hazards on campus and, to the extent possible, off campus. The emphasis of such a program is the prevention of illness and injury, but our program also includes provisions for early diagnosis and treatment when necessary.

There are two programs for preventing occupational injury and illness while working with animals at UNCG. One is for personnel hired by the Animal Facility and one is for individuals that work with animals within a research study. Animal Facility personnel include individuals who work in the Animal Facility on a full or part-time basis. Individuals who work with animals within research include faculty, staff, and students engaged in funded or unfunded research projects or teaching in a class or field setting. Personnel in the Animal Facility must follow guidelines established by the Animal Facility. Research staff working with animals must follow the guidelines contained in this document.

The Occupational Health program is supported by the Office of Research Integrity, the staff of the animal facility and the Attending Veterinarian. It requires effective interactions among researchers, the Animal Care and Use Committee (IACUC), the Attending Veterinarian, the Environmental Health and Safety Office, training materials (on-line), and a clearance form from the Student Health Services. The Occupational Health program has four (4) key points: Hazard Identification and Risk Assessment, Personnel Training, Personal Hygiene/Protection, and Medical Evaluations.
Hazard Identification and Risk Assessment

It is the responsibility of principal investigators (PI) and students approved to work on their protocols to work with animals to assess dangers associated with their work and to select safeguards appropriate to the risks. In some cases the IACUC may determine there is a need for an additional risk assessment to be conducted by UNCG Environmental Health and Safety. The Anna M. Gove Student Health Center will perform medical evaluations to ensure that the risks remain at acceptable levels.

Personnel Training

Individuals who work with animals should be given clearly defined procedural training for the risks they incur by working with animals. This training should include chemical safety; zoonosis (any infectious disease that may be transmitted from animals, both wild and domestic, to humans or from humans to animals); proper handling of waste materials; microbiological and physical hazards (including those related to radiation and allergies); unusual conditions or agents that might be part of experimental procedures (e.g., immunocompromised animals), personal hygiene, and other considerations (e.g. precautions to be taken if personnel are pregnant, ill, or have decreased immunocompetence) as appropriate to the risk imposed by their workplace/environment. The PI is responsible for providing this training. Any and all trainings must be reported the IACUC and ORI. If needed, he or she may draw upon input from the occupational health doctor at Student Health Services, the Attending Veterinarian, the Office of Research Integrity, and/or the UNCG Environmental Health and Safety. This training must provide appropriate instructions for conducting duties, an understanding of the hazards involved, and assurance that proficiency is attained in implementing the required safeguards. This training is in addition to the IACUC required Collaborative Institutional Training Initiative (CITI) modules.

Personal Hygiene and Protection

It is essential that all personnel maintain a high standard of personal cleanliness. Individuals who work with animals should wash their hands and change clothing as often as necessary to maintain good personal hygiene. They should wear clothing suitable for use in the Animal Facility, classroom laboratories, or field studies. Disposable gloves, masks, head covers, coats, coveralls, and shoe covers may be desirable in some circumstances. Laboratory coats worn in the Animal Facility should not be worn outside it. Likewise, clothing worn in field studies should be contained in a safe and sanitized manner.

Medical Evaluations

All individuals who have a potential risk from their work with animals are required to have a medical evaluation prior to initiating the work, referred to in this document as the initial medical evaluation. Thereafter, a follow-up evaluation is required annually, as long as the work with animals continues. All individuals that submit an IACUC protocol will be required to have a medical evaluation, unless the PI identifies particular individuals who will not have any risks associated with animal exposure.

Both the initial and the follow-up medical evaluations are conducted by the Anna M. Gove Student Health Center. After satisfactory completion of either evaluation, the Anna M. Gove Student Health Center will notify the ORI and the individual.

The first step of the initial medical evaluation, and frequently the only step required, is for the individual who will be working with animals to complete a medical questionnaire. In the questionnaire individuals disclose existing medical conditions, species to which they will be exposed, and other relevant personal
health information. This questionnaire may be taken in person or sent via interoffice mail to Anna M. Gove Student Health Center, located at 107 Gray Drive, Greensboro on the UNCG campus. Researchers may also fax completed questionnaires to 336-334-3299. The purpose of this evaluation is to provide early identification of conditions, if any, that may present an increased risk of adverse health effects that could result from working with animals. The questionnaire is evaluated by the Anna M. Gove Student Health Center for a nominal fee for UNCG faculty and staff. Students who are currently enrolled at UNCG will not be charged a fee. A fee will be charged to the appropriate department for students from another institution who are working at UNCG. Work with animals may begin unless Anna M. Gove Student Health Center identify that additional steps are necessary. Then work should be delayed until they are completed.

Based on the recommendation from Anna M. Gove Student Health Center, individuals may be asked to submit to a second step of the initial medical evaluation, a physical examination. The physical examination can be done by either the Anna M. Gove Student Health Center or the individual’s personal physician. *Please note that this additional step of the examination is outside of the standard clearance form requirements.* The expense for this examination will be paid by the individual or his employer.

Anna M. Gove Student Health Center does not accept any insurance. This examination may identify the need for vaccinations or immunizations. Once this step is completed satisfactorily, work with animals may begin.

**Renewal of Health Clearance**

All individuals who have been issued a medical clearance will be required to submit an annual follow-up medical questionnaire at the time their work is being renewed with a de novo review application. Any changes to the work with animals that has occurred since the last medical clearance must be reported. The medical questionnaire will be evaluated by the Anna M. Gove Student Health Center for a nominal fee for UNCG faculty and staff. Students who are currently enrolled at UNCG will not be charged a fee. The Anna M. Gove Student Health Center will give the results of this evaluation to the ORI and the individual. Personal medical information generated by any of these exams will be kept confidential. If a physical examination is necessary, this information will remain between the employee and the physician. The employee can contact the physician who performs the examination with any questions regarding the results.

**Use of Respirators**

Some individuals who work with animals may need to wear a respirator while they are working with them. They can self-identify or it can be determined as a result of the information supplied on the initial medical evaluation. If it is determined to be necessary for an individual to use a respirator when working with animals, the individual must complete the [OSHA Respirator Medical Evaluation Questionnaire](#). This questionnaire is required to be completed by any paid UNCG employee, including graduate students. This form must be evaluated by the Anna M. Gove Student Health Center prior to the use of a respirator.

Once the Student Health Center has evaluated the OSHA Respirator Medical Evaluation Questionnaire, EHS will conduct a fit test and respiratory protection training. The fit test will allow EHS staff to determine what type will fit best for each individual. After the fit test, EHS can provide the PI or respirator user with purchasing information. Only then can a respirator be used or purchased.
Principal Investigator Assurance
As part of completing the IACUC Protocol, the PI must sign a statement of assurance by which the investigator,

1. I certify that I am familiar with and assure compliance in this protocol with the legal standards of animal care and use established under the Federal and State laws and the policies on animal welfare of the National Institutes of Health and the University of North Carolina at Greensboro.
2. I assume responsibility for ensuring that all persons working with animals on this project are familiar with and are trained in relevant animal procedures and that they will comply with established laws and policies regarding animal care and use.
3. I certify that all individuals working with animals on this project will register with the University Occupational Health Clinic by completing and submitting the "Occupational Health Program Initial Health Screening" or the “Occupational Health Program Annual Screening for Continued Work with Animals” medical history questionnaire and I will follow the guidelines of the Animal Facility Manual as well as the Standard Operating Procedures of the UNCG Office of Research Integrity.
4. I certify the following: the research proposed herein is not unnecessarily duplicative of previously reported research; appropriate non-animal alternatives for this research do not exist; no alternatives to the potentially painful and/or distressful procedures conducted in this project exist. I have indicated methods used to make these determinations in the appropriate section of this animal use application.
5. I will secure IACUC approval before changing procedures or personnel associated with this study (including adding personnel).
6. I assure that I and personnel under my direct supervision will use the animals acquired for the activity described herein solely for said purpose. I also certify that if live animals are shared with other PIs or are used in any procedure other than those described in this application, I will provide the details in the form of a written amendment to the original application prior to their use.
7. I acknowledge that veterinary care will be administered to moribund animals or animals experiencing more than momentary or slight pain or distress. Animal Facility staff or veterinary staff will attempt to contact me regarding the care of treatment of a moribund animal, but will institute treatment or euthanasia, as needed, if I cannot be reached.
8. I assure that I will notify the IACUC and the attending veterinarian regarding any unexpected study results that adversely impact the animals, including any unanticipated pain or distress, morbidity or mortality.
9. I agree if at any time any member of the research team or their immediate family members have financial interest in, receive personal compensation from, or hold a position in an industry sponsoring this study or otherwise have a personal conflict of interest, the Potential Conflict of Interest in Research form must be attached to this application.
10. I assure the IACUC and the University of North Carolina at Greensboro that the general procedures involving animals described in my grant application have been described in the animal use application and submitted to the IACUC for review.
11. I assure that I have read the "Euthanasia" link, available on the ORI website understand how it applies to animals in this animal use application.
12. If I use any biological, chemical or radiological hazards in animals in Animal Facility I will contact the ORI for information as to how to proceed.
13. I will follow the recommendations originating from veterinary consultation with specific emphasis on procedures expected to cause pain or distress. Such procedures will be restricted to the minimum time necessary to meet the objectives of the research. If an animal experiences severe or chronic pain or distress that cannot be relieved, it will be euthanatized at the end of the procedure, or if appropriate, during the procedure. In the event of unanticipated pain or distress, a signed retrospective report, detailing the circumstances of the event and referencing the appropriate IACUC protocol number, will be submitted to the IACUC with in seven (7) days of the event.

**IACUC Initial Protocol Review**

There is only one acceptable method of IACUC Protocol review and approval. An IACUC Protocol that poses the potential for greater than transient and mild pain or distress will NOT be approved unless it receives approval from the Attending Veterinarian.

**Routing and Review process for New Protocols:**

1) It is strongly suggested that all new IACUC protocols have a scientific merit review (also called a departmental review) by a member of their department ahead of submission to the ORI. If there is no departmental representative, then one can be assigned by the IACUC Chair. If requested, ORI will route the application to departmental representative for a scientific merit review. The departmental reviewer may request changes from the PI. Those changes will be addressed and returned to the departmental reviewer who will approve the changes. The departmental reviewer must sign off on the changes before the PI can submit.

2) **All new** protocols will be reviewed by the full IACUC at regularly scheduled meetings. In order to get a new study reviewed at the next IACUC meeting, the study should be submitted to the ORI at least two (2) weeks of review to make sure all requested changes are made at least eight (8) working days ahead of the next scheduled IACUC meeting date.

3) Principal investigator submits IACUC application to the Office of Research Integrity (ORI). ORI/IACUC coordinator checks for current occupational health certification and current CITI training and species-specific CITI trainings.

4) All Individuals that will have handle animals as part of a proposed IACUC Protocol are required to take CITI Training Modules “Working with the IACUC: Investigators, Staff and Students” and the CITI module that is specific for the species used. Also, if you are conducting studies that have the potential to cause “more than momentary pain and distress” in mice or rats, you must take the Minimizing Pain and Distress module. If conducting major surgery on non-roden species you must take the aseptic surgery module.

5) Once a new study is placed on the meeting agenda, the IACUC Chair will assign two (2) members of the IACUC to act as Primary and Secondary reviewers. These reviewers will examine all aspects of the study and note any concerns they have with the protocol. At the IACUC meeting, the Primary reviewer will present the study to the committee. The Secondary will add any information he or she feels the Primary reviewer overlooked. These two reviewers will be assigned to the protocol for the life of the protocol, and will review any future amendments and annual renewals.
6) All committee members including the Attending Veterinarian, will be sent a complete copy of the protocol and any related supplemental documents for review prior to the meeting. Any IACUC member that has a conflict of interest will recuse themselves from the review of the protocol at the full board meeting. If the recused member’s absence affects quorum for a full board meeting, then the protocol will be rescheduled to be reviewed at the next meeting when quorum is present.

7) All members must be present (a quorum) and a formal vote taken to approve, withhold or require modifications to secure approval with minor clarifications. When the outcome is “require modifications to secure approval”; the quorum of the full committee present may unanimously agree to review the resubmitted protocol by the DMR process or request to see the amended version at the next full committee meeting. If any DMR reviewer requests FCR then the revised protocol will be resubmitted back to the full committee at the next convened meeting when a quorum is present.

8) Stipulations are communicated to the PI by the IACUC Chair based on the members’ feedback and these changes are returned to the

9) After the protocol is approved by the full committee review, it is sent to the Office of Research Integrity. This office sends an approval letter to the PI with copies to the Facility Operations Manager.

Criteria for Approval

a) Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design.

b) Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia, or anesthesia, unless the procedure is justified for scientific reasons in writing by the investigator.

c) Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized at the end of the procedure or, if appropriate, during the procedure.

d) The living conditions of animals will be appropriate for their species and contribute to their health and comfort. The housing, feeding, and nonmedical care of the animals will be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied.

e) Medical care for animals will be available and provided as necessary by a qualified veterinarian.

f) Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.

g) Methods of euthanasia used will be consistent with the current recommendations of the American Veterinary Medical Association (AVMA) Panel on Euthanasia, unless a deviation is justified for scientific reasons in writing by the investigator.

h) If the work will take in the field, then the appropriate required state and/or federal permits will need to be submitted by the time of approval.

Stipulations for Additional Information

To assist IACUC members in making their decision, members are asked to report requests for clarifications or additional information to the IACUC Chair. The IACUC Chair will communicate the nature of the request to the PI, in writing.

Investigator responses are reported back to the IACUC Chair or other designated IACUC member to the
IACUC member(s) for review and consideration. Upon completion of their review, and if they desire a full-committee review, IACUC members notify the IACUC Chair with their decision and the review will be
placed on the next meeting agenda. Any IACUC member's request for clarifications, additional information and additional review time are honored.

Failure to supply the IACUC Chair with the requested information with in the IACUC-specified time frame can lead to suspension of all research studies for the PI.

Approval Status

There are three possible categories of approval:

1. Approved (as written)
2. Approved pending modifications to secure approval
   Modifications are either incorporated into a revised IACUC Protocol, or described in the body of the IACUC Approval Memo or described and agreed to in a written memo from the PI and attached to the IACUC Protocol. The research cannot begin nor animals procured until approval is granted.
3. Approval withheld
   When the IACUC determines that a proposal has not adequately addressed all of the requirements of the PHS Policy and AWRs as applicable, the committee may withhold approval. This action may only be taken if the review is conducted using the full committee method of review.
   As indicated above, a higher institutional authority may not administratively overrule an IACUC decision to withhold approval of a proposal.

IACUC Approval Number

Each IACUC Protocol is assigned an IACUC Approval Number only after full approval has been granted. The first two numbers represent the last digits of the calendar year in which the protocol was approved. The second set of digits represents the sequential order in which the IACUC Protocol was received. For example, the 13th IACUC Protocol submitted in calendar year 2010 is assigned the number 10-013.

An IACUC Approval Number is required to place animal orders. The corresponding IACUC Approval Number is required on cage cards. For a room housing animals all belonging to the same research program, the IACUC Approval Number can be clearly displayed on the animal room door or inside the animal room rather than on individual cage cards.

Approval Notification

When the IACUC approves an animal research protocol, ORI staff sends the PI an approval letter indicating the dates of approval, and the IACUC protocol number with the Chair’s signature.

Approval Period

The IACUC approval to conduct a research program covers a period of three years. At a minimum, all animal research programs will be reviewed as a "de novo" review at the beginning of the fourth year of the protocol and as a new application.
For first time submissions and 3rd year submissions, the PI must submit a completed “IACUC Animal Use Application” (the “IACUC Protocol”) for de novo review.

**IACUC Protocol Expiration**

At the date of expiration, no further use of the animals may occur. In addition, “no costs for activities with live vertebrate animals may be charged to NIH if there is not a valid Animal Welfare Assurance and Institutional Animal Care and Use Committee (IACUC) approval”, if applicable.

Approximately 30, 60, and 90 days prior to the pending expiration of IACUC-approval to conduct a research program, the PI is notified in writing or is verbally advised to a new “IACUC Protocol after the completion of the protocol’s 3rd year of approval.

**IACUC Review and Approval of Minor, Significant, and Highly Significant Amendments**

IACUC approval of proposed animal activities or significant changes to previously approved animal activities is granted after full committee review (FCR) or designated member review (DMR). Additionally, institutions may establish and IACUCs may approve policies (e.g., guidance documents, standard operating procedures, drug formularies) for the conduct of animal activities.

**Personnel Amendments**

Most personnel amendments will be forwarded and approved by the IACUC Chair. In some cases, the ORI may review for the training for the personnel requesting approval to be added to a study and may approve independently of the IACUC. Subsequent addition of personnel to a current IACUC-approved IACUC Submission may be considered a minor or a significant modification that must be reviewed and approved by the IACUC through an amendment before new individuals can participate in the program. Individuals other than the PI who are deemed trained and qualified to perform their assigned responsibilities may be added administratively to the IACUC Protocol without additional approval by the IACUC. Written assurance from the principal investigator must be provided stating that new participants are qualified to conduct the indicated procedures and documented evidence of relevant and training and qualifications must be on file with the IACUC. In addition, the IACUC may exercise its right to require training or demonstrated proficiency before new personnel can participate in the activity.

New personnel or untrained personnel are permitted to engage following the approval of a protocol amendment in animal use activities as designated “trainees” and only under the strict supervision of individuals currently approved as trained and qualified. The Principal Investigator notifies the IACUC in writing via the Visitor form. This form, available on the ORI IACUC website includes the names of the assigned trainers, the planned animal use training activities and a copy of the trainee’s resume and/or other relevant background information. If any IACUC member objects to permitting the individual to enter the program as “trainee”, they are directed to contact the Principal Investigator and Director of the animal program and the individual will not be permitted to enter the training process until the matter is
discussed (and resolved) at a subsequent convened meeting of the IACUC. If no member expresses concern, the designated trainee is permitted to enter the program and their progress and proficiency is presented at a subsequent IACUC meeting. At that time, the IACUC will determine if additional training is needed or if the individual can be upgraded from “trainee” status to “Animal Handler” (without strict supervision) and approved for addition to the personnel sections of specified IACUC Form.”

Evaluation of Proposed Amendments

It is the IACUC’s responsibility, not the PI’s responsibility, to determine if a change is minor or significant in nature, and therefore does require IACUC review and approval prior to its initiation.

The IACUC has some discretion to use IACUC-reviewed and -approved policies to define what it considers a significant change, or to establish a mechanism for determining significance on a case-by-case basis in accordance with the PHS Policy IV.C.1.a.-g. It is the IACUC’s responsibility to clearly define and communicate its policy for determining significance to investigators.

In brief, significant changes include changes that have, or have the potential to have, a negative impact on animal welfare (see paragraph 1., below). In addition, some activities that may not have a direct impact on animal welfare are also considered to be significant (see paragraphs 2. and 3., below).

Amendments to currently approved protocols are submitted via the Amendment application form. The PI must notify the IACUC via the ORI Amendment process. Amendments will be handled by a Designated Member Review (DMR) process. When an amendment is submitted to ORI, the amendment will be forwarded by the IACUC Chair to the full committee by email to ask if any member requests that amendment go to the full committee. The committee will have three (3) days to make this request to the ORI. If no member requests full board review, then the IACUC chair and another member of her choosing will review the amendment alongside the Attending Veterinarian, if necessary. Any of these reviewers (Chair, AV, designated member) may also request the submission be reviewed by the Full Board Committee at any time. If all reviewers (Chair, Vet, Primary and Secondary) agree that the submission is acceptable as is, the ORI will approve the submission for the IACUC.

All amendments will be reported to the full committee at the next convened meeting. Highly significant changes to protocols may not be handled via an Amendment and may require submission of a new protocol. If any member requests the amendment go to the full committee, the amendment will be put on the agenda for the next scheduled meeting.

a. anesthesia, analgesia, sedation, or experimental substances;
b. euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals
c. duration, frequency, type, or number of procedures performed on an animal.

Evaluation of Significant Amendments

If the nature and/or extent of the proposed significant modification(s) change the original IACUC-approved program substantially, and at the discretion of the IACUC, the IACUC may require the investigator to submit a new IACUC form. The following changes fit in with these criteria:

• from nonsurvival to survival surgery;
• resulting in greater pain, distress, or degree of invasiveness;
• in housing and or use of animals in a location that is not part of the animal program overseen by the IACUC;
• in species;
• in study objectives;
• in Principal Investigator (PI); and
• that impact personnel safety

In support of the use of performance standards and professional judgment and to reduce regulatory burden, IACUC-reviewed and -approved policies (e.g., guidance documents, standard operating procedures, drug formularies) for the conduct of animal activities may be used for the administrative handling of some significant changes according to the following considerations:

The specific significant changes described below, may be handled administratively according to IACUC-reviewed and -approved policies in consultation with a veterinarian authorized by the IACUC. The veterinarian is not conducting DMR, but is serving as a subject matter expert to verify that compliance with the IACUC-reviewed and -approved policy is appropriate for the animals in this circumstance. Consultation with the veterinarian must be documented. The veterinarian may refer any request to the IACUC for review for any reason and must refer any request that does not meet the parameters of the IACUC-reviewed and -approved policies. This includes changes in:

d. anesthesia, analgesia, sedation, or experimental substances;
e. euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals (PDF - 1.4 MB); and
f. duration, frequency, type, or number of procedures performed on an animal.

Evaluation of Other Amendments

The specific significant changes described below, may be handled administratively according to IACUC-reviewed and -approved policies in consultation with a veterinarian authorized by the IACUC. Changes that may be handled administratively without IACUC-approved policies, consultations, or notifications include:

a. correction of typographical errors;
b. correction of grammar;
c. contact information updates; and
d. change in personnel, other than the PI. (There must be an administrative review to ensure that all such personnel are appropriately identified, adequately trained and qualified, enrolled in occupational health and safety programs, and meet other criteria as required by the IACUC.)

PLEASE NOTE: Investigators using fewer animals than approved does not require IACUC approval, notification, consultation, or administrative handling.

Failure to Obtain IACUC Approval of Significant Modifications

If a research protocol is found to be inconsistent with the IACUC approved program -that is, if significant modifications have been initiated without prior IACUC review and approval - the IACUC has the authority to suspend the research. The Institutional Official, in consultation with the IACUC, must report the suspension to the appropriate regulatory agencies.

De Novo Review

The purpose of the de novo review is:
- to inform the IACUC of the current status of the animal activity and the number of animals used
- to ensure the activity continues to be conducted in compliance with all applicable federal laws and regulations, voluntary guidelines and institutional requirements
- to determine whether or not advances in animal alternatives (replacement, refinement and reduction) dictate consideration of changes to the research design.

De Novo Process

The de novo review will be submitted a new application of the continuing work on an animal use protocol which has come to the end of its third year. The De Novo will be submitted to ORI, it will be forwarded to the full committee for review at the next convened IACUC meeting. Animal numbers will be verified by the Facility Operations Manager.

Official Request for IACUC Protocol Termination

At any time, a PI can request the official “termination” of an IACUC approved program. For approved animal use activities that will not proceed, the IACUC encourages the PI to request termination prior to or at annual renewal or prior to or 3rd year “de novo” review.

IACUC Guidelines: General Animal Use and Specific Animal Techniques

The IACUC reserves the right to establish guidelines and positions on the humane conduct of animal use methods common to the field of biomedical research as well as other animal use issues (e.g. blood collection routes and frequency, physical methods of euthanasia, physical restraint, conduct of surgery, identification of the moribund condition). These guidelines will be based on sound scientific evidence and professional judgment and will meet or exceed the federal laws, regulations and voluntary guidelines for these procedures.

IACUC Guidelines are subject to IACUC revision and modification as deemed necessary to ensure the continued humane use of research animals.

IACUC-Approval of Protocols Originating from Non-UNCG Institutions and/or Conducted at UNCG

No animal research activity can be initiated at UNCG until an “IACUC Application” has been reviewed and granted full-approval by the UNCG IACUC

Criteria for IACUC-approval of Protocols from non-UNCG Institutions

While “dual [IACUC] review” is not required by either the USDA or OLAW, if an animal use activity will be performed at UNCG (i.e. UNCG is the performance site), the UNCG IACUC requires its own review
and full approval before the activity is initiated. The non-UNCG IACUC’s approval alone is not sufficient for initiating an animal research activity at UNCG.

If an animal use protocol originates from a non-UNCG institution required by law to have an Institutional Animal Care and Use Committee or its equivalent, written evidence of approval from the non-UNCG institution may also be required before the UNCG IACUC will grant full-approval.

The UNCG IACUC may also require additional information from the non-UNCG institution regarding the overall objectives of the research program and other information necessary to fully evaluate the proposal and to ensure that UNCG will remain in compliance with all applicable animal research laws, regulations and policies as well as its own institutional policies (e.g. consideration of alternatives, nonduplication, etc.).

Criteria for IACUC-approval of Protocols from UNCG and Conducted at non-UNCG institutions

The UNCG IACUC does NOT require its own review and approval of an animal use activity if the activity will be conducted at a non-UNCG institution (the performance site) and if the performance site has an established IACUC.

However, and at a minimum, the UNCG IACUC will require evidence that the IACUC at the performance site has reviewed and approved the protocol. In addition, the UNCG IACUC may also require the UNCG IACUC Chair and/or UNCG (consulting) veterinarian review the performance site’s approved protocol.

Criteria for IACUC-approval of Protocols from UNCG and performed and non-UNCG institutions WITHOUT Established Review and Approval Mechanisms (e.g. non-PHS Assured Institutions)

If the performance site does not have an established mechanism for the review and approval of animal activities (i.e. no IACUC in place), the UNCG IACUC will require the Principal Investigator at UNCG or the Principal Investigator at the performance site to complete the UNCG “Application for Use of Animals in Research and Teaching” or “IACUC Form”. The UNCG IACUC must review and approve the application before work can be initiated at the performance site.

Criteria for IACUC-approval of Protocols conducted at UNCG animal facility from non-UNCG institutions

The UNCG IACUC will review and approve any research conducted by faculty of non-UNCG institutions. In addition, the non-UNCG institutions must also have an animal use protocol approved by that site’s IACUC prior to being submitted to UNCG’s IACUC for the use of the animal facility. A UNCG faculty member must be listed on that protocol as a Principal Investigator and must act as a representative for the non-UNCG institution’s faculty and research staff while work is being conducted on the UNCG campus and, with that, follow all required responsibilities and guidelines of the UNCG IACUC Standard Operating procedures as well as the rules of the animal facility while listed on the protocol.

The non-UNCG institution must also adhere to the terms of any legal contracts between UNCG and that site. Personnel from any institution other than UNCG that perform work at UNCG are required to comply with any researcher prerequisites (training, health clearance) that are required of UNCG personnel.
Sub-granting of PHS Moneys to non-UNCG Institutions

If UNCG has been awarded PHS funds in support of an animal use activity, and these moneys will be sub-granted in part or in their entirety to a non-UNCG performance site, UNCG must comply with the following *:

1. UNCG must notify the NIH Grants Management Official (GMO) of its intention to sub-grant moneys to another, unrelated institution for the purpose of conducting the funded animal research activity. Notification can take place by phone or letter. The GMO must ensure that the sub-granted institution was listed and approved as a performance site in the initial grant application.

2. If the sub-granted institution was not listed (and approved) in the initial grant application, the GMO must ensure that the activity has been granted IACUC approval and the GMO must contact OLAW to determine if the performance site has a current PHS Assurance on file.

3. If the performance site has a PHS Assurance and the activity has IACUC-approval, the GMO can grant the addition of the performance site to the grant.

4. If the performance site does not have a PHS Assurance, UNCG has two options:

   1. UNCG must notify OLAW to request an amendment to the UNCG Assurance to include the performance site. A total renegotiation of the Assurance is usually not necessary. If OLAW agrees to add the performance site to the UNCG Assurance, the UNCG IACUC is obligated to include the performance site as a satellite facility and review its program and facilities as it does the UNCG program and facilities. As a covered component, all aspects of the approved UNCG Assurance must be seamlessly applicable to the performance site or;

   2. The performance site must negotiate its own PHS Assurance with OLAW.

Once IACUC-approval has been confirmed and the performance site is PHS-Assured (either as a component of the UNCG Assurance or as an independently PHS-Assured entity), the GMO can grant the addition of the performance site to the grant.

Once permission is granted, the animal activity can be initiated.

When necessary, UNCG IACUC/ORI will also seek out direct guidance from the Grants Manager at the specific funding institution on the expectations and requirements for adding a performance site to an existing grant. While the grants policy covers all NIH institutes, there may also be some institute-specific procedures, such as an Institutional Assurance from NIH. As a consequence, consultation in advance of seeking permission from the GMO is advised.

Transfer of Animals

In order to help ensure the humane transfer and receipt of animals from UNCG, and prior to transportation of animals to outside institutions, intended recipients are requested to complete an animal transfer form. (Appendix: UNCG Animal Transfer Form)

The animal transfer form requests specific information about Transfer Destination, Acquisition Information, and Attending Veterinarian. It also includes an assurance statement that must be signed and dated:
Assurance: I hereby assure that provisions will be in place for the humane receipt and housing of animals at the time of their arrival. I assure that high quality animal care and use standards are established and observed at my institution, and meet all applicable animal welfare laws and regulations.

**Intra-campus Transfer of animals**

In order to assist in the documentation of animals on campus, researchers must complete an “Animal Transfer Form” when they wish to transfer animals from one protocol to another. This form is available from the Manager of the Animal Facility and must be submitted via ACAP (as an attachment to the most current approved submission) to the ORI and IACUC.

**Criteria for IACUC-approval of Programs which Terminate in the Transfer of Animals to otherwise Unaffiliated Institutions**

If an animal research activity terminates in the transfer of research animals to an otherwise unaffiliated institution, the UNCG IACUC may require the recipient facility to provide written assurance that high quality animal care and use standards are established and observed, and that the non-UNCG institution meets all applicable federal, state and local regulations at the recipient facility.

**Animal Procurement, Animal Usage and Related-Issues**

All research animals on UNCG protocol or in other areas outside the centralized animal facilities including investigator laboratories must be associated with a current Application for Use of Animals in Research and Teaching or the “IACUC Form” approval number.

**Criteria for Placing Animal Orders**

Animal orders can be placed ONLY if the corresponding IACUC Submission has been granted IACUC approval. The animal order must have a corresponding and current IACUC-approval number (assigned at the time of IACUC-approval).

The number of animals ordered must not exceed the number designated and/or approved for use in the IACUC Form. The total number of USDA-regulated animals may not exceed the total number of animals approved for use by the IACUC for the 1-, 2- and 3- year periods indicated on the approved IACUC Form. The total number of unregulated species may not exceed 5 – 25% (more than 25% will require a new protocol) the total approved for use by the IACUC for the 1-, 2- and 3- year periods.

**Animal Vendor Source**

Animals may be ordered only from vendor sources approved by the Attending Veterinarian. As a rule, animals are not accepted from non-commercial sources. However, if such an arrangement is needed, the non-commercial source (e.g. another research institution in support of collaborative projects or special strain unavailable from licensed animal vendors) will be required to provide a health status report supporting the appropriate health status before animals are shipped and accepted. The quarantine program is initiated upon arrival of animals for a specified period of time determined by the Animal Facility Manager.
Biologic Materials
Biologic materials that are potential sources of murine viruses (e.g. transplantable tumors, hybridomas, cell lines, other biologic materials) are evaluated prior to their introduction into animal research programs and handled in ways to prevent transmission to animal colonies.

Display of the IACUC-Approval Number
To ensure that animals housed at UNCG can be readily associated with their corresponding research program, the IACUC-approval number must be displayed on cage identification cards.

Criteria for Initiating Research on Received Animals
Animal orders cannot be placed and research cannot be initiated until the corresponding IACUC Submission has been granted full IACUC-approval. Only the Facility Operations Manager has the authority to place animal orders.

Tracking Animal Use, Animal Transfers, and Total Animal Numbers Used
The Facility Operations Manager will monitor and track the number of animals available in order to ensure that the total number of animal approved for use and designated in the IACUC Submission is not exceeded.

Exceeding Animal Numbers Approved for Use
Investigators who approach the total number of animals approved for use during the 1-, 2- and 3-year periods (indicated in the approved IACUC Form) and who expect to exceed this number must submit to the IACUC a written justification for additional animals as well as a revised estimate of the total number of animals to be used during the 1-, 2- and 3-year periods. Only upon IACUC-approval can additional animal (up to 25% (more than 25% will require a new protocol) of initial number approved by IACUC) orders be placed.

Retention of Research Animals under Expired IACUC-Approval Numbers
If animals remain in the animal facility under expired IACUC-approved programs that will not be renewed, the Facility Operations Manager will make every effort to reassign these animals to current IACUC-approved programs. All internal transfers will be documented, tracked and accounted for in animal usage records by the principal investigator. Those animals for which research programs cannot be identified will be euthanized prior to the expiration of funded projects.

Transfer of Animals to other IACUC-Approved Programs
The IACUC maintains that it is acceptable under certain circumstances to make internal transfers of animals to other IACUC-approved research programs. In particular, internal transfers of animals are encouraged if the animals cannot be used in their own designated IACUC-approved program.

Criteria for Internal Transfers
Internal transfers will be permitted only if the following criteria are met:

- transfers are made only to current IACUC-approved programs
- transfers are be documented including the date of transfer and the corresponding IACUC-approval numbers (transferred from, transferred to)
- transfers are made only to those programs that have not yet met and will not exceed (upon receipt of the transferred animals) the total number of animals approved for use
- transfers are tracked and accounted for in animal usage records
when transferring USDA regulated species that have had a major surgery investigators should follow guidance at

Animal Usage Record Keeping Requirements
It is necessary to maintain accurate and current animal use records. Animal use records include the
documentation of the acquisition of animals (including their receipt through commercial or non-
commercial vendors, through transfers from other in-house research programs and through in-house
breeding programs), documentation of their use as designated by an IACUC-approval number including the
associated pain category assignment, and documentation of animal disposition.

If animals are acquired for research purposes and are not entered into the program, but are euthanized or
transferred outside of UNCG without research use, these animal numbers must be accurately accounted for
as well.

Animal Usage Record Keeping - Responsible Parties
The principal investigator for each IACUC-approved program is responsible for maintaining accurate
animal use records, which are verified by the Animal Facility staff. This responsibility also includes
reporting animal usage for each IACUC-approved program to the IACUC on an annual basis and reporting
annual animal use if and when required by regulatory agencies (e.g. OLAW, USDA).

Failure to consistently maintain accurate records could lead to issues of protocol non-compliance and be
cause for IACUC review and/or sanctions

Animal Usage Records
Animal usage records will include the following:

- Total number of animals used during the 1-, 2- and 3-year approval periods, including
  animals euthanized prior to weaning.
- Total number of animals used in painful or distressful procedures with or without the
  use of pain relieving agents
- Justification for withholding pain relieving agents
- A brief description of the research protocol if pain-relief was withheld

UNCG’s Lab Animal Resources Protocol (LARP)

UNCG has established a Lab Animal Resources Protocol (LARP) to provide a mechanism for holding
animals not on a study or not currently assigned to UNCG protocols.

All animals maintained by the University of North Carolina at Greensboro must be covered by an active,
approved IACUC protocol. The IACUC has the responsibility to ensure all animal use activity meets
federal law, Public Health Service policy, and AAALAC accreditation expectations.

1. Situations which may result in the use of this protocol might include:
   a. Animals to be used for training purposes
   a. Animals ordered without an approved protocol (non-compliance situation)
   b. Animals originating from inactive (or terminated) protocols.
c. Animals on a protocol under investigation for potential issues of noncompliance where the welfare or well-being of the animals is in question.

d. Investigators without an approved UNCG protocol having animals that may require immediate housing at UNCG (new faculty).

e. Investigators that are leaving UNCG and do not have the necessary approvals for transfer to the new institution.

Requests to place animals on the LARP will be generated by the Facility Operations Manager, PI, the IACUC, the ORI Director, or the AV (designee). An investigator requesting the use of the LARP must complete the “Lab Animal Resources Protocol Request Form” and submit to the Facility Operations Manager.

**Transfer Required Due to Termination of Approved Protocol**

IACUC- and ORI-authorized transfers from expiring protocols will be generated through currently produced monthly reports: Protocol Expiration Memo and New Numbers for Expiring Protocols. These reports will be generated and sent to Animal Facilities within two (2) business days after the IACUC Full Committee meeting. These reports are the authorizing source documents for Animal Facilities staff to transfer animals to the LARP.

**Transfer Required Due to Non-Compliant / Adverse Event**

The IACUC Chair, the ORI Director, or the Attending Veterinarian are authorized to initiate the transfer of animals from an active protocol to the LARP. These actions will be reported to the IACUC at the next regularly scheduled meeting.

**Transfer due to abandonment**

The PI of an approved research protocol may elect to transfer animals to the LARP. Once the transfer has been accepted by the Facility Operations Manager, these animals are considered “Abandoned by Researcher” and may be transferred to other protocols in line with the SOPs of UNCG and as the Facility Operations Manager sees fit. This transfer may be acceptable in the following situations:

a. Extra animals were inadvertently shipped from the Procurement center. If they are not needed for the approved protocol, Animal Facilities may allow transfer of the surplus into the LARP.

b. Non-experimental animals alive at the cessation of a protocol may be allowed by the Facility Operations Manager to be transferred.

Animal Facilities will transfer animals within three (3) business days of receipt of transfer request from the PI or monthly reports from IACUC and ORI.

**Management of Animals on the LARP**

The following may be done with animals on this protocol:

a. Breeding performed to maintain viability of specific lines may occur under this protocol. Expansion colony breeding is not authorized. Animal Facilities will perform all procedures necessary to maintain colony viability.

b. Feeding, sanitation, and environmental enrichment will be provided according to the approved protocol.

c. Animal Facilities may transfer animals from the LARP to other IACUC approved studies, provided such animals are abandoned by researcher.
d. When ordering new animals, PIs will be notified by the Facility Operations Manager of available, relevant animals currently on the LARP.

Appropriate transfer forms must be completed, and semiannual transfer list documenting all transfers to and from the LARP in the most current period must be submitted to the ORI. Also, when animals are transferred to this protocol, the Facility Operations Manager will notify any PI that may have a need for these available animals. When applicable, a PI may make a request to the Facility Operations Manager to transfer animals off of the LARP to an approved protocol.

These animals may then be used to practice approved procedures or for actual use in the protocol and all request to use animals on this protocol must be approved via an amendment to the ORI and IACUC. Any animal acquired from the LARP will count toward the PI’s number of approved animals. No animals being held temporarily under an investigation of noncompliance (i.e. “in holding”) can be used for any procedure until the investigation is complete and the holding status on the animals has changed.

Animal Facilities must be notified of any pre-existing conditions of note prior to transfer of animals onto the LARP (for PI-initiated actions); and will coordinate with the PI concerning any special conditions when the transfer request is initiated by the IACUC or ORI. Examples include but are not limited to:

a. Existing surgical implants.
b. Zoonotic disease.
c. Special dietary needs.
d. Past surgical history.
e. Viral vectors.
f. Poor fecundity.

Fees
Per diem, procedure, or the fees for support of the animals on any protocol in holding for a PI will be charged to the investigator (or department) while their animals are “in holding”. Animal Facilities may place a surcharge for animals on a holding protocol. The Facility Operations Manager may waive this surcharge as appropriate.

NOTE: Federal grant funds may NOT be used for support of any animals in a holding protocol status due to non-compliance or failure to obtain IACUC approval for a 3 year replacement protocol.
NOTE: New faculty transfers to UNCG may use federal funds for support of animals on a holding protocol, until such time that a protocol is approved.

A copy of the form to request transfer to the holding protocol by principal investigators is located on the ORI website.

Veterinary Medical Program
The University of North Carolina at Greensboro UNCG Attending Veterinarian is responsible for developing and implementing the Veterinary Care Program. The Attending Veterinarian for UNCG has expertise in the areas of laboratory animal medicine and science and direct animal care and use program authority and responsibility for activities involving animals. The Attending Veterinarian is also the appointed Doctor of Veterinary Medicine on the UNCG IACUC.

Based on UNCG’s programmatic goals and relatively small size of the animal program, the services of the Attending Veterinarian are provided on a consultative basis. Under this arrangement, other qualified and
authorized individuals on the Attending Veterinarian’s behalf conduct certain components of the Veterinary Care Program such as daily monitoring of animal health and behavior. The criteria for selection of Attending Veterinarian designees includes, at a minimum, training and demonstrated ability to conduct the designated activities. Together, the Attending Veterinarian and these delegated individuals develop, implement and re-evaluate on a continuing basis those mechanisms necessary to ensure the continued well-being of research animals maintained at UNCG.

These mechanisms include a schedule of direct and frequent communication to ensure that timely and accurate information is conveyed to the Attending Veterinarian regarding identified animal health, behavior, and well-being deviations or concerns. They also include the provision of back-up veterinary support from other qualified and authorized individuals in the absence of the Attending Veterinarian.

In addition, an "emergency" notification plan has been established in the event of an animal health problem necessitating direct and/or immediate veterinary attention or guidance. In the event of a medical emergency necessitating direct and/or immediate veterinary attention or guidance, an Emergency Contact list is posted in the animal facility, which lists contact information for key animal facility personnel and the Attending Veterinarian.

**Overview of Animal Care and Use Facility Personnel Training**

Individuals hired into the institution to work in the Animal Facility in any animal care and use activities often possess prior specialized training and experience and/or certification in the field of animal care and/or use. They may also maintain national membership and/or certification in the American Association of Laboratory Animal Science (AALAS), AALAS Certification Registry, an organization active in public education in the importance of humane animal research and agricultural animal food production.

UNCG animal care and use personnel may also be appointed to the IACUC as non-voting members. In this capacity, they work very closely with the committee by overseeing the majority of the administrative functions. As IACUC members, these individuals attend IACUC meetings and act as sources of information to the IACUC in the review of animal use proposals and the conduct of program reviews and facility inspections. By virtue of their IACUC appointments and IACUC responsibilities, they receive the same initial and continuing education as IACUC members including the verbal updates and hard copy materials that are intended to train and educate committee members with regard to the humane care and use of animals and the current animal welfare laws and regulations.

The IACUC may also participate in training new animal care and use employees, who are not appointed to the IACUC in issues related to IACUC activities and animal care and use responsibilities. These individuals are encouraged to attend IACUC meetings and inspections or program reviews.

Other instructional mechanisms for continued training and education of animal care and use personal may include proficiency evaluations, individual (one-on-one) instruction provided by the Attending Veterinarian or other qualified and experienced persons, the provision of established guidelines, regulations and other self-instructional materials and institutional and/or IACUC handbooks and materials containing basic general information regarding animal care and use issues and occupational health.

**Procedural Training Program for Animal Users**

The Animal Facility’s Operations Manager is qualified to provide training and resources for working with animals within research and within the UNCG Animal Facility.
The Facility Operations Manager will provide group training sessions focusing on new techniques or areas of interest communicated by research staff on a regular basis (semiannually), depending on the needs of the research and the techniques being used, as well as formally-requested as-needed training on specific techniques approved for the protocol. Animal handling training will also be provided as part of the new research animal facility orientation. An email will be sent out to notify all research teams of upcoming available and group training opportunities.

Investigators may make a request to the Facility Operations Manager for additional training. If available, arrangements will be made for training requested. This may also include webinars, off-site training, and/or bringing in a consultant/trainer if necessary.

**Preventive Medicine**

**Quarantine, Stabilization, and Separation**

**Receiving and Initial Evaluation Procedures**

Upon receipt, all animals are checked for order specifications (e.g. species/strain, sex, age, weight, health status, number) to ensure that the shipment received is as ordered. During removal from their shipping cartons and placement into their cages, newly received animals are examined for injury, signs of dehydration, heat exhaustion, illness, abnormal behavior, etc.

In consultation with the Attending Veterinarian and depending on the nature of the problem and/or the potential risk to other colony animals, newly received animals with suspected medical problems may be treated and retained or euthanized.

**Quarantine and Isolation Facilities and Procedures for Purpose Bred Animals**

The Quarantine/Isolation area is used when so indicated. Animals are housed in microisolators on shelving units. The Quarantine room is made up of four cubicles, each having its own air supply and exhaust. The Quarantine room airflow is negative to the animal facility to prevent the potential for contamination. The general Animal Facility housing areas consists of four animal holding rooms. Each room has its own air supply and exhaust. Animals are housed in microisolators on ventilated racks.

A sentinel program has been established. Sentinel animals are evaluated every 3-6 months to establish the health status of the animal colony.

**Periods for Physiologic, Psychological, and Nutritional Acclimation**

With the possible exception of animals designated for acute non-survival studies, newly received animals by the Animal Facility are closely observed during a minimum 7 - 14 day acclimation period for physiologic, psychological, and nutritional stabilization. The length of time depends on the type and duration of animal transportation and the intended use of the animals. The personnel of the Animal Facility, in consultation with the Attending Veterinarian, and depending on the nature of the problem and/or the potential risk to other colony animals, animals with suspected medical problems during the acclimation period might be treated and retained or euthanized.

Animals designated for acute non-survival studies (e.g. tissue collection, diagnostic purposes/vendor screen) may be used prior to completion of the acclimation period.
Program for Separation of Animals by Species, Source, and Health Status
Animals are housed in rooms with animals of the same species only. Animals from the same shipment are housed individually or in groups in microisolators designated animal rooms. Since only animals with comparable health status are acquired and only from approved reputable vendors, animals from different sources may be housed in the same animal room.

Surveillance, Diagnosis, Treatment, and Control of Disease Program

Daily Observation of Animals and Responsible Personnel
Animal Facility personnel conduct daily checks of animals. If needed, and based on professional judgment and in consultation with the Attending Veterinarian, more frequent observations of animals are conducted as in the cases of post-operative recovery, anticipated delivery of pups, post-partum health checks, pup well-being, etc. Additionally the Principal Investigator can request more frequent observations of their animals by contacting the Facility Operations Manager.

Individuals responsible for conducting animal care checks are trained to recognize signs of illness, injury, and/or abnormal behavior.

Emergency Notification
An Emergency Contact list is posted in the animal facility, which lists contact information for key Animal Facility personnel and the Attending Veterinarian.

Medical Records - Maintenance Procedures
Animal Facility personnel are responsible for maintaining all animal health and medical records on file in the Facility Operations Manager’s office. These reports include:

- Vendor health screen reports that accompany all animal shipments
- Diagnostic reports generated from the quarterly sentinel program
- Results of other diagnostic evaluations which may be conducted in the event of a disease investigation or suspected illness warranting diagnostic evaluation
- Weekly "Colony Population, Animal Health and Facility Environment" Reports
- Medical records generated in the event of a sick or injured animal, including date and nature of illness or injury, on-going accounts of actions taken (e.g. administration of medical treatment) and the description of the animal's progress. (Medical records may also include information about experimental procedures.)
- Records of animal deaths

Sentinel Program - Quarterly Health Monitoring:
The Sentinel Program is a primary means for ensuring the continued health quality of research animals maintained in the animal colony at the facility. On a quarterly basis or more often if needed, sentinels from the animal colony are submitted for a comprehensive diagnostic and health evaluation screen to determine the health of the research animal colony. The sentinel program is conducted as approved by the UNCG IACUC. The housing of sentinel animals, in equivalent macro- and micro-environments, as well as their direct exposure to fomite-contaminated bedding from these other, non-sentinel animals, enable monitoring the research animal colony for exposure to common murine pathogens.
Typically, one to two sentinels are housed per cage, one cage per side of rack, and positioned on the lowest shelf of an animal rack housing other boxes of research animals. Cages are changed once a week. To ensure direct contact with fomites to increase the chances of pathogen transmission, small amounts of soiled bedding from every cage of other research rodents housed on the same rack are introduced into the sentinel cages in-between cage changes.

The design of the sentinel program may be modified as deemed necessary to meet the needs of the program and to ensure high quality monitoring of the health status of the research animals. The sentinel program is reviewed and approved by the IACUC on an annual continuing review and a triennial de novo review basis. After 3 months within the facility, sentinels are transported to a reputable animal diagnostic laboratory for either a "comprehensive" evaluation or diagnostic testing.

The "comprehensive" battery includes:

- **Pre-Necropsy Examination**: Hair Coat/Skin, Skeletal Palpation, Nasal Discharge, Ocular Discharge, Diarrhea, Hydration, Body Fat, Ears
- **Gross Necropsy Pathology**: Respiratory System, Digestive System, Musculoskeletal System, Urinary System, Genital System, Thymus, Spleen, Lymph Nodes, Adrenal Gland, Thyroid, Middle Ear, Eye
- **Histopathologic Pathology** (on representative tissue samples if evidence of lesions or disease): Lung, Cecum, Small Intestine, Liver, Colon
- **Parasitology**: Ecto-parasites (pelt examination), Endo-parasites (fetal-floatation, cellophane tape test)
- **Mouse Serology**: Mouse Hepatitis Virus, REO3, Minute Virus of Mice, Lymphocytic Choriomeningitis Virus, Ectromelia Virus, MCMV, Polyoma, Sendai Virus, Pneumonia Virus of Mice, EDIM, GDVII, K-Virus, MPUL, MAV, HANT, ECUN, MTLV, CARB, MPV NS1 and MPV VP2
- **Rat Serology**: Sendai, PVM, SDAV, KRV, H-1, REO, MPUL, RPV, TMEV, LCMV, MAV, HTN, ECUN, CARB

In addition, all sentinels are tested for Helicobacter (H. species, H. hepaticus, H. bilis).

**Disease Investigations**

In the event of a suspected illness, and in consultation with the Attending Veterinarian, representative animals and/or their tissues/products are submitted to reputable diagnostic facilities for evaluation.

**Diagnostic Reports**

Diagnostic reports are submitted to the Attending Veterinarian or authorized designee for review, evaluation and action plan development. Diagnostic reports are maintained in the animal colony medical health records.

**Diagnostic laboratory facilities, equipment and commercial services**

UNCG relies exclusively on reputable commercial sources for animal health support services. UNCG submits animals, animal tissues/products and/or cell lines to reputable contract research animal diagnostic facilities. There is no in-house support for diagnostic services including serology, necropsy, pathology, and radiology.
Annual Diagnostic Frequency

The number of sentinels submitted for diagnostic services and animal health evaluation per year varies based on the health status of the colony, average daily census, and other factors.

Study Records

The Principal Investigator and corresponding IACUC-approved animal use personnel are responsible for maintaining animal records associated with an animal use activity. These records include but are not limited to an on-going account of animal procedures performed, the nature of any animal illness or injury and corresponding actions, the Controlled Drugs Log-Book (if applicable), etc.

Failure to consistently maintain accurate records could lead to issues of protocol non-compliance and be cause for IACUC review and/or sanctions.

Post –Approval Monitoring Program (PAM)

According to the Guide for the Care and Use of Laboratory Animals (8th edition), the Institutional Animal Care and Use Committee (IACUC) is charged with the responsibility to oversee and evaluate the University's animal program, procedures, and facilities to ensure that they are consistent with the recommendations in the Guide, the regulations of the Animal Welfare Act, and the Public Health Service Policy of Humane Care and Use of Laboratory Animals.

The goal of the post approval monitoring process at UNCG is to review active protocols to ensure research is being conducted in accordance with what is written and approved by the IACUC, and to enhance the education of the researchers who are entering the facility and working with animals.

The protocols will be selected randomly or as a result of a request by the IACUC, veterinary staff, or animal care personnel. The laboratory will visited by the IACUC Chair, Facility Operations Manager, and another IACUC- member and/or the Attending Veterinarian. Procedures on the selected protocol are observed and any drift away from the protocol is noted. The investigator then has the opportunity to correct any deviations by improving techniques or by submitting an amendment to the protocol.

The visit is as informal as possible and is an opportunity for the investigators to request any help they may need. Findings are reported at the next IACUC meeting. The report of the visit and any follow up visits are filed in the investigators IACUC protocol file. The laboratories receive a brief follow up visit after the first to document that any deficiencies highlighted in the first visit have been rectified.

The UNCG IACUC has historically performed post approval monitoring on a regular basis, based on the eyes and ears of the research staff, and the Animal Facility, and through the required semiannual program and facility inspections required by our assurance with PHS policy. In addition, the IACUC requires de novo reviews of all IACUC protocols, which is a time for animal numbers to be updated and verified as well as an opportunity for the PI to submit any modifications or interim findings as a report to the IACUC.

IACUC Procedures for the Investigation of Animal Care and Use Concerns

As an agent of the university, the IACUC has the authority and the responsibility to review, and if warranted, investigate all animal welfare concerns. In keeping with this charge, the IACUC has developed and established reporting procedures whereby laboratory and research facility employees as well as other employees and members of the public can voice animal welfare concerns or alleged violations to federal, state or institutional animal welfare regulations or IACUC policies to a group with the responsibility and authority to make appropriate changes (the IACUC).
The IACUC will address all animal welfare concerns raised by employees and from the public, including those concerns not specifically directed to the IACUC.

**Procedures for the Review and Reporting of Animal Welfare Concerns**

The procedures for voicing animal welfare concerns should be available to all personnel along with the university’s *Policy on Animal Care and Use* and in the Animal Facility manual that is distributed to all individuals that use the facility. Concerns may be addressed by submitting the concern on-line using the comments and concerns section of the Office of Research Integrity website.

**Employee Voiced Animal Welfare Concerns**

If any employee of the university wants to voice an animal welfare concern or an alleged animal welfare violation that individual is directed to contact the IACUC Chair, Director of the Office of Research Integrity, Attending Veterinarian, or animal facility staff who will in turn bring the concern to the attention of the full-committee.

**Public Voiced Animal Welfare Concerns**

In the event university administrative personnel receive a concern from the public (via phone or by written communication); they will direct the call to the attention of the Director of the Office of Research Integrity (ORI), IACUC Chair, or Attending Veterinarian.

Alternatively, if a concern is received, the administrative personnel may document the date and time the concern was received, obtain details about the concern, establish whether or not the caller wants to remain anonymous, obtain a mutually acceptable method for contacting the caller if a review of the IACUC responses and actions is desired, and assure the caller that the complaint will be forwarded to the IACUC for review.

In this latter case, and if confidentiality is requested, the personnel will forward the details of the complaint to the ORI Director or IACUC Chair without identifying the caller.

If the complaint involves sick or injured animals, the Facility Operations Manager and Attending Veterinarian personnel will be immediately notified.

**Animal Welfare Concerns and Guaranteed Anonymity**

Regardless of the origin of the concern, all individuals voicing concerns are absolutely assured anonymity if confidentiality is requested. No university employee or IACUC member shall be discriminated against or be subject to any reprisal for reporting suspected violations of any regulation or standards or animal welfare concerns. However, before the IACUC can make a reasonable evaluation of the concern and investigate the concern (if warranted), these individuals must be willing to provide a specified minimum amount of information.

**Personnel Training in the Handling, Notification and Documentation of Public Animal Welfare Concerns**

Training is provided to appropriate personnel in the IACUC-established procedures for handling animal welfare concerns from the public and bringing these concerns to the immediate attention of the IACUC.

In addition, personnel will use an “Animal Welfare Response Form” for documenting and handling the receipt of public animal welfare. This form prompts personnel to request and document the required
information and to notify appropriate individuals, if and when, an animal welfare concern from the public
is received. Copies of the form are maintained in a readily accessible location for use by trained
administrative personnel.

Review, Investigation and Documentation of Animal Welfare Concerns

The IACUC will review, and if deemed necessary, investigate and resolve the concern. The Vice Provost
for Research will be invited to the meeting whom may choose to invite a representative from the
Institutional Public Relation Office. The nature of the concern and the steps taken to review, and if
warranted, investigate, and resolve the concern will be documented in the IACUC meeting minutes. If
appropriate, the IACUC Chair will appoint a subcommittee to investigate alleged violations, notify proper
personnel and forward final reports of investigations to the full-committee. If follow-up was requested, the
IACUC Chair will implement necessary steps to ensure that the individual lodging the complaint or
concern is contacted and briefed on the IACUC actions.

The IACUC documentation of the review and investigation will be finalized within reasonable time frame
upon receipt of the complaint if possible. The documentation will include:

1. Date and time(s) the complaint was received (by the administrative personnel and/or IACUC
member).
2. Nature of the complaint.
3. Names of persons involved with the review and investigation.
4. Results of the review and investigation.
5. Conclusions.
6. Appropriate corrective actions.
7. Actions taken to inform the individual lodging the complaint of the IACUC actions, if requested.

This documentation will be forwarded to the Institutional Official for review and maintained for at least 3
years from the date of the report. If corrective action includes a suspension in animal activities or a serious
deviation or deficiency, the Institutional Official in consultation with the IACUC will report the incident to
the appropriate regulatory agencies.

ORI Policy on Investigation of Animal Use Concern and/or Potential Issues of
Noncompliance

In the normal course of administration, the PI is often asked to provide additional information to the
IACUC, IACUC Chair, or ORI for clarity or additional information. Researchers are expected to provide
this information in a timely manner.

When requests are made for information involving potential non-compliance, these requests will include
specific dates when the responses from the PI are due.

Once the PI is made aware of an investigation on an animal use protocol that may have jeopardized the
health and well-being of the animal, the PI should cease from any further work with animals until further
notice from the Chair or the IACUC.

The nature of the information required will vary depending on the circumstances, but often involves:
1) Interviewing complainants (if known), any persons against whom allegations were directed, and any pertinent program officials;
2) Observing the animals and their housing and experimental environment;
3) Reviewing any pertinent records (e.g., animal health records, protocol, and other documents).

If the PI does not respond within the specified time, the IACUC Chair may elect to label the lack of response non-compliance and/or take appropriate actions including but not limited to:

- “Pausing” the research, temporarily limiting PI interaction with research animals to basic husbandry
- Notifying the PI’s department head of the delay
- Notifying the ORI of the PI’s delay
- Notifying the Facility Operations Manager

A PI may request additional time if there are exceptional circumstances (e.g., the PI is out of the country), but these requests must be submitted before the due date and are subject to approval by the IACUC Chair.

If the IACUC determines that further investigation is required, the Chair, an individual appointed by the Chair, or the subcommittee appointed by the Chair, will conduct the investigation and report back to the IACUC. Members of the investigating subcommittee will be chosen to avoid actual or perceived conflicts of interest. The matter then will go to the full board of the IACUC for further review.

Emergency meetings may be necessary in these cases to ensure prompt consideration of concerns.

Continuing noncompliance encompasses multiple infractions by the same investigator or their research team. These infractions could be serious in nature or when independently evaluated could be categorized as non-serious. However, the infractions have happened on multiple occasions may be considered serious and reportable.

**Consequences of Noncompliance with IACUC Protocol, Policies, Procedures, or Decisions**

The IACUC shall review all reports from the investigation or initial report (in cases where further investigation was not required) and any information provided by the PI before reaching a decision. After evaluating these materials, the IACUC may request additional information and/or take action with respect to the investigation, including but not limited to the following:

- Dismissal of the complaint/concern;
- Requirement of submission and approval of a protocol amendment, or placement of specific additional conditions or stipulations on the protocol
- Imposition of specific remedial education and training for the PI and/or other personnel listed under the protocol
- Monitoring research, testing, or training that involves animals
- Temporary revocation of privileges to provide animal care or to conduct research, testing, or training that involves animals, pending compliance with specific, IACUC-mandated conditions
- Issuing letters of reprimand
- Restricting research practices, such as limiting the PI to conduct studies with certain procedures, or conduct research under supervision
- Suspension of approval for one or more of the PI’s studies and establishment of conditions for reinstatement
- Termination of approval for one or more of the PI’s studies
- Permanent revocation of privileges to provide animal care or to conduct research, testing, or training that involves animals
- Recommending to the Institutional Official that institutional (e.g., reassignment, suspension or termination of employment) sanctions be imposed.

The IACUC will notify the PI in writing of any action taken by the IACUC and the reasons for that action. In addition, the IACUC will notify, as it deems appropriate:

- Other investigators involved in the animal care and use activities at issue
- The PI’s department head (and any additional department heads where the PI holds multiple professional appointments)
- Any additional departments involved in the research
- The Institutional Official (who will contact any additional institutional authorities) and other pertinent program officials as required (such as appropriate supervisory and management staff, the public affairs office, the compliance office, the office of the general counsel)
- Any funding, regulatory or accreditation agencies, as required.

The PI may elect to respond in writing to the final report to the Chair of the IACUC if he/she would like to appeal the IACUC decision or present further information related to the incident.

**Suspension of Protocol**

As indicated above, the IACUC is empowered to suspend a protocol if it finds violations of the PHS Policy, The Guide, Assurance, or Animal Welfare Regulations. Suspension may occur only after review of the matter at a convened meeting of a quorum of the IACUC, and with a vote for suspension from a majority of the quorum present. In addition, the PI may (and in appropriate cases will be encouraged to) agree to voluntarily suspend his/her protocol pending review by the IACUC. 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 OLA and any federal agency funding that activity. At the time of suspension of a protocol, the IACUC will vote on terms for reactivation of the protocol. The IACUC may vote for the IACUC Chair to be empowered to reactivate the protocol at his/her discretion or it can vote that the Committee itself must approve reactivation. Protocols will be reactivated only after violations have been corrected.

**Reporting Suspension of On-Going Animal Activities**

As an agent of the university, the UNCG IACUC is authorized to suspend any and all animal activities due to noncompliance, report suspensions to the Institutional Official, and through the Institutional Official, notify OLA if a regulated species is involved and any other required regulatory agency including corresponding federal funding agencies. The IACUC is authorized to suspend any and all animal activities that are not in compliance with applicable animal welfare laws and regulations or university policies including, but is not limited to, the PHS Policy and UNCG PHS Assurance, the Animal Welfare Act and USDA Animal Welfare Regulations and Standards (if applicable), the Guide for the Care and Use of Laboratory Animals, the UNCG’s Animal Care and Use Policy, and UNCG IACUC policies.

Non-Compliance is defined as
1) Activity that endangers the health and well-being of animals
2) Violations of the AWA that are grossly inconsistent with PHS Policy or are serious deviations from the provisions of the Guide
3) Serious deviation from accepted practices

Non-serious issues of noncompliance do not need to be reported to OLAW, but do need to be documented and managed by the IACUC. Examples of non-serious issues of noncompliance can be found in the attached document entitled “Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals” page 5 (Examples of situations not normally required to be reported).

Serious issues of noncompliance must be reported to OLAW. Examples of serious noncompliance can be found in the appendices (1) of this document entitled “Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals” page 56 (Examples of reportable situations)

The IACUC will file a report to OLAW in the event of:

- A serious deviation that is or may be a threat to the health or safety of the animals or continuing noncompliance with PHS Policy
- A serious deviation from the Guide for the Care and Use of Laboratory Animals
- An IACUC suspension of an animal protocol

In order to ensure prompt reporting of the noncompliance or suspension to the appropriate regulatory agency(ies), the Institutional Official, in consultation with the IACUC, will

- Verbally notify the appropriate regulatory agency(ies), then follow up with a written report from the IACUC, signed by the Institutional Official, and delivered to: Office of Laboratory Animal Welfare, National Institutes of Health, 6705 Rockledge Drive, Rockledge I, Suite 360 MSC 7982, Bethesda, MD 20892-7982 (use zip code 20817 for delivery of express or overnight mail)

Notification will include full explanation of the reportable event and an IACUC-approved plan and schedule for corrective action.

**Semi-Annual Facility Inspection**

As an agent of the university, the IACUC is authorized to inspect and evaluate all animal facilities and animal study areas or satellite facilities at least once every six months.

The IACUC must conduct a Semi-Annual Program Evaluation of the Institutional Animal Care and Use Program. This Program Evaluation consists of two components:

1. A Facility Inspection component
2. A Program Review component

Both components must be conducted at least semi-annually and the corresponding reports of these evaluations must be written and submitted to the Institutional Official at least semi-annually.
The IACUC inspects and evaluates all animal facilities and animal study areas (and satellite facilities, if applicable) at least once every six months. Inspection teams include at least two voting members of the IACUC.

**Standards for Facility Inspection**

The IACUC utilizes the following standards for program review and evaluation (if applicable):

2. *The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, NIH, Amended 2003*
3. *The UNCG Animal Welfare Assurance (PHS)*
5. *2013 AVMA Guidelines on Euthanasia, American Veterinary Medical Association*
7. *State and Local Research Animal Welfare Laws and Regulations*
8. *The UNCG Policy on Animal Care and Use*
9. *Occupational Health and Safety in the Care and Use of Research Animals, National Academy Press, 1997*
10. *The UNCG Program of Occupational and Safety for Animal Care and Use Personnel*

The IACUC inspects all animal facilities, animal study areas (and satellite facilities, if applicable) and surgery areas at least once every six months.

**Required Areas of Inspection**

Animal facilities include all of the areas within both animal facilities including buildings, rooms, areas, enclosures, vehicles, holding areas, animal care support areas (e.g. anterooms, cage wash facilities, feed/bedding storage areas, implement storage areas, etc.), animal use support areas (e.g. procedure rooms, surgeon and patient preparation areas, surgery and recovery areas, euthanasia and necropsy areas, pharmacy, etc.) and personnel preparation areas (e.g. change facilities, locker areas, showers/rest rooms, etc.).

Surgery areas include all areas within or outside of the central or core animal facilities where any form of surgery is performed including non-survival or survival surgery, minor or major surgery, and regardless of whether or not the animal is USDA-regulated or non-regulated, and regardless of the time period held.

*The IACUC remains responsible for all animal activities and the areas where they are conducted even if they do not meet the criteria of “animal facilities”, “animal study areas or satellite facilities” or “surgery areas”. For these areas, the IACUC can inspect on a less frequent basis than semi-annually and/or designate at least one trained and qualified individuals to conduct inspections on the IACUC’s behalf as long as the IACUC remains responsible for the recommendations and report to the Institutional Official.*
**Inspection Participants**

While every IACUC member is not *required* to participate in the facility inspection, no member can be denied participation. All voting IACUC members must be given the opportunity to participate.

For areas that involve non-regulated species, the IACUC may designate at least one trained and qualified individual to conduct inspections on the IACUC’s behalf as long as the IACUC remains responsible for the recommendations and report to the Institutional Official.

In addition, consultants may be invited to participate in facility inspections but cannot vote unless they are official appointed voting members of the IACUC.

Regardless of its approach, the IACUC remains responsible for the recommendations and report to the Institutional Official.

**Facility Inspection Preparation**

Materials relevant to the Semi-annual Facility Inspection, including the most recent facility inspection report, are provided to inspection team(s) prior to the inspection.

**Semiannual Facility Inspection Checklist**

To facilitate the inspection, the IACUC uses a Semiannual Facility Checklist. Inspection teams will take notes during the inspection to assist in preparation of the final report. If possible, identified deficiencies will be addressed at the time of the inspection with those responsible for direct management or oversight to ensure the accuracy of the team's perception of the “deficiency” or “deviation”.

Including:

- Introduction and Instructions for Checklist
  

- Facility Inspection: Animal Housing & Support Areas
  

- Facility Inspection: Cagemash
  

- Facility Inspection: Aseptic Surgery
  
  URL [http://grants.nih.gov/grants/olaw/sampledoc/check2c.htm](http://grants.nih.gov/grants/olaw/sampledoc/check2c.htm)

- Facility Inspection: Procedure Areas, Non-Survival Surgeries, Laboratories, Rodent Surgeries
  

- Facility Inspection Checklist: Additional Comments

**Inspection Findings**

Results of the animal facility inspection are presented for review and discussion at a convened meeting of a quorum of the IACUC at which time the IACUC develops its recommendations to the IO.

**Record Keeping and Reports**
According to the University of North Carolina at Greensboro records retention schedule the ORI will send a copy of all IACUC minutes, reports, and Animal Welfare Assurance to the IO semiannually. All IACUC related documents noted above and including the actual IACUC protocols will be destroyed by the ORI three years following the closure of the research as mandated by the Office of Laboratory Animal Welfare.

**IACUC Semiannual Reports to Institutional Official**

As an agent of the university, the IACUC is authorized to prepare reports of its evaluations at least every six (6) months and submit them to the Institutional Official.

By law, the IACUC is responsible for meeting specific record keeping requirements which are handled by the ORI including

- Timely preparation and submission of reports to the Institutional Official and/or appropriate federal authorities
- Maintenance of records relating to the institutional animal care and use program for at least the duration of the activity plus an additional three years
- Release of records for purpose of inspection (and copying for removal from the university in the event of an alleged violation requiring further investigation) upon request of authorized representatives of OLAW or other PHS office, and/or USDAAPHIS, at reasonable times and in a reasonable manner

The Semiannual Report consists of a program review component and a facility inspection component. Together, these two activities comprise the Semiannual Report.

The IACUC prepares and submits a report of the Institutional Animal Care and Use Program Review, reviewed, approved and signed by a quorum of the IACUC to the Institutional Official. Reports must be submitted at least every 6 months.

The program review report includes:

1. Date of the program review
2. Addressed to the Institutional Official
3. Names and IACUC title of members in attendance at the convened program review
4. Names and IACUC title of members not in attendance at the convened program review
5. Confirmation that a quorum of the committee was present during the program review
6. A list of the standards used for program review (check list)
7. A summary of the program review
8. A detailed account of any identified programmatic deficiencies and an explanation for each
9. A clear distinction between minor and significant* programmatic departures or deficiencies
10. A reasonable, specific action plan and time table for the correction of significant and minor programmatic departures or deficiencies
11. Recommendations for revision or modification of the current program, facilities, or personnel training
12. All minority views (if none, so state)
13. Signatures of a quorum of the voting IACUC members and corresponding dates signed
A significant departure or deficiency is defined as any departure/deficiency, which is or may be a threat to the health, safety or welfare of an animal.

**Failure to Correct Programmatic Deficiencies or Departures within the IACUC-Established Time Table**
Any significant deficiency that is not corrected within the established timetable will be brought to the attention of the Institutional Official and documented in a written report.

The Institutional Official, in consultation with the IACUC, will promptly report the uncorrected deficiency, or any serious or continuing noncompliance with the PHS Policy, the Animal Welfare Act, USDA Animal Welfare Regulations or serious deviation from the provisions of the ILAR Guide including a full explanation of the circumstances and actions taken, to OLAW, if applicable, and any other regulatory agency including corresponding federal funding agencies as required.

During the notification period, the IACUC will prioritize efforts to investigate, develop and document a definitive corrective plan and a schedule for implementation and make every attempt to resolve the problem.

**Semiannual Facility Inspection Report**
The Semiannual Program Evaluation consists of a program review component and a facility inspection component. Together, these two activities comprise the Semiannual Program Evaluation.

The IACUC prepares and submits an inspection report, reviewed, approved and signed by a quorum of the IACUC, to the Institutional Official. Reports must be submitted at least every 6 months.

The facility inspection report includes:

1. date(s) of the inspection
2. addressed to the Institutional Official
3. names of IACUC inspection team members
4. names and titles of consultants to the inspection team
5. names of IACUC members in attendance at the convened inspection review
6. names of IACUC members not in attendance at the convened inspection review
7. confirmation that a quorum of the committee was present during the convened inspection review
8. a list of the standards used for inspection (check list)
9. a list of the areas inspected including study rooms and areas outside the central animal facility
10. a summary of the inspection results including a description of the nature and extent of the university’s adherence to the standards
11. a detailed account of any identified facility departures or deficiencies and an explanation for each
12. a clear distinction between minor and significant facility departures or deficiencies
13. a reasonable, specific action plan and time table for the correction of significant and minor facility departures or deficiencies
14. recommendations for changes or improvements to the facility or facility operations
15. all minority views (if none, so state)
16. signatures of a quorum of the voting IACUC members and corresponding dates signed

Items #5, 6, and 7 may be documented in the inspection report itself, the corresponding meeting minutes and/or in an attached cover memo.
9 A significant departure or deficiency is defined as any departure/deficiency which is or may be a threat to the health, safety or welfare of an animal.

Report of Failure to Correct Facility Deficiencies or Departures within the IACUC-Established Time Table

Any significant deficiency that is not corrected within the established timetable will be brought to the attention of the Institutional Official and documented in a written report.

The Institutional Official, in consultation with the IACUC, will promptly report the uncorrected deficiency, or any serious or continuing noncompliance with the PHS Policy, the Animal Welfare Act, USDA Animal Welfare Regulations or serious deviation from the provisions of the ILAR Guide including a full explanation of the circumstances and actions taken, to OLAW, if applicable, and any other regulatory agency as required.

During the notification period, the IACUC will prioritize efforts to investigate, develop and document a definitive corrective plan and a schedule for implementation and make every attempt to resolve the problem.

Animal Facility Visitor Policy

All University animal facilities are open upon request to the IACUC, Office of Research Integrity, inspection agents from the Office of Laboratory Animal Welfare, and other federal agencies as required by law.

Access to animal facilities by other visitors is restricted and monitored to protect the health and safety of both the visitors and research animals and to avoid disruption of research activities. To achieve this goal all visitors will be apprised of the occupational health risks and program. Clearance to enter the facilities must be obtained through both the ORI and the Animal Facility Manager.

The PI will complete all required forms and send them to the ORI. Once ORI has verified all trainings are completed and either an Occupational Health Clearance or a waiver form is presented to the ORI, ORI will forward the form on to the Animal Facility Manager. Additional requirements and documentation, including picture identification, may be required by the Animal Facility Manager prior to entrance in any animal facility.

1. It is preferred that visitors complete all necessary paperwork prior to their arrival. However, it is understood that this is not always possible and will work with individuals in time frames shorter than two weeks.

2. All non-institutional or federal visitors will need to complete both the “Agreement for non-employees” and “Animal Exposure Questionnaire.

3. Visitors that will have direct contact with animals will need to enroll in the Occupational Health Program or sign the appropriate waiver.

4. During visit(s), every effort must be made to avoid disturbing laboratory animals and settings. To avoid personal injury, visitors must follow all posted facility rules and refrain from unauthorized contact with animals.

5. Use of cameras or sound recording devices is not permitted in any animal facility unless approval is obtained from Animal Facility Manager and the PI of the animal room prior to the visit.
6. Persons receiving permission to visit animal facilities agree to observe all rules and conditions established for the visit. Permission to visit campus animal facilities may be revoked at any time by the Animal Facility Manager, PI whose animal room is being visited, or a representative of the campus administration.
Appendix 1
Some visitors at UNCG observe or participate in research activities involving animals. Exposure to research animals can include risk to visitors and to research animals. For example, persons with suppressed immune systems are vulnerable to illness from some animals. On the other hand, some diseases like M. tuberculosis can be managed medically in humans, but is deadly for some animals.

*Please note* This signed and approved form will serve as the record of your visit to the Animal Facility on the dates listed below. This form will be kept on file in both the Office of Research Integrity (ORI) and the Animal Facility. Additional requirements and documentation, including picture identification, *may* be required by the Animal Facility Manager prior to entrance in any animal facility.

All visitors need to complete the Animal Exposure Questionnaire and the Visitor Agreement and submit to the ORI.

**Things to consider at least TWO WEEKS BEFORE your visit:**

1a. Will the visitor be in the facility but not in any animal rooms?
   - Yes
     - Proceed to question 2
   - No
     - No further action is needed

1b. Will the visitor be in the animal facility working with animals or tissue?
   - Yes
     - Proceed to question 2
   - No
     - No further action is needed

2. Will the visitor be at UNCG for more than 3 days?
   - Yes
     - Complete the Occupational Health Prescreening form and send directly to the Anna Grove Student Health Center
     - The sponsor will need to add the visitor to their IACUC protocol(s) by submitting an Amendment - Personnel Only Form to the ORI.
   - No
     - Although the visitor is here for only a short period, animal research-related medical and training requirements still apply (item 1.a or 1.b above). The visitor should be escorted at all times by the UNCG sponsor, or designee. It is recommended that the UNCG sponsor retain a copy of the Visitor Agreement in department files.

3. What are animal related training, safety and medical requirements?
The linked Animal Contact Table and Occupational Health Table list requirements and is provided for information purposes. For actual requirements, use the contacts above. Requirements depend on species, level of exposure to animals, and the type of activities that will performed.
Animal Exposure Questionnaire

Sponsor Name: ___________________________ Sponsor Department: ___________________________

Visitor Name: ___________________________ Date: ___________________________

The following information is essential for assessing the physical/health hazards for this individual so that appropriate safety training and Occupational Health requirements may be applied.

A. Length of Visit (Period of exposure to Animals) Check one.

☐ 3 days or fewer

☐ More than 3 days

B. Level of Animal Contact (Mark all that apply)

<table>
<thead>
<tr>
<th>Type of Contact</th>
<th>Tissue only</th>
<th>Live animal</th>
<th>Direct or within 10 feet</th>
<th>Greater than 10 feet</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cold Blooded (e.g., amphibians, reptiles, fish)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Rabbits or Rodents</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Other - name:</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Other - name:</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Other - name:</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>
C. Prior Training. Briefly describe the type of training

Example. At Great Eastern University, I completed the following CITI courses:

- Two Basic courses
- Post-Procedure Care of Mice and Rats in Research: Reducing Pain and Distress
- Working with Mice in Research Settings

Please complete and return to ori@uncg.edu

For further information, please contact:

Institutional Animal Care and Use Committee at ori@uncg.edu
**Agreement for Non-Employees**

(Includes, but is not limited to: Volunteers, Visiting Professionals, Visiting Students)

**University of North Carolina at Greensboro**

*Please complete and return this form to Office of Research Integrity, MHRA 2718, ori@uncg.edu*

<table>
<thead>
<tr>
<th>Name of Non-Employee (please print)</th>
<th>Name of School (if student)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department</td>
<td>On-Site Supervisor/Sponsor (please print)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Begin Date</th>
<th>*End Date</th>
</tr>
</thead>
</table>

*End Date must be specified prior to signing this Agreement. At End Date, access to UNCG systems and parking (If applicable) will be terminated. Extension of End Date must be approved by Office of Research Integrity. If person leaves prior to End Date, department must contact Office of Research Integrity.

**Reason for visit, including duties and responsibilities:**

[Blank space]

Non-employee understands and agrees that this is of a voluntary nature from which he/she will benefit only by receiving academic credit and/or on-the-job training or experience. Non-employee understands he/she is not an employee of University of North Carolina at Greensboro or any of its affiliates. Non-employee will have no right to typical benefits of employment, such as: minimum wage, retirement, sick leave, paid vacation, holiday pay, workman’s compensation or any other compensation.

Department understands that this assignment should not extend beyond six months. Extension of this agreement must be approved through the Office of Research Integrity.

<table>
<thead>
<tr>
<th>Signed by: On-Site Supervisor/Sponsor</th>
<th>Signed by: Non-employee visitor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department</td>
<td></td>
</tr>
<tr>
<td>Extension</td>
<td></td>
</tr>
</tbody>
</table>

Address

City, State, Zip

Phone
<table>
<thead>
<tr>
<th>Visitor Name:</th>
<th></th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sponsor Name:</td>
<td></td>
<td>Dept:</td>
</tr>
</tbody>
</table>

**Primary Work Environment Assessment (choose one)**

- [ ] Clinical Function
- [ ] Administrative/Academic Function
- [ ] Laboratory Function
- [ ] Other
- [ ] Animal Resources Program

**Hazard Exposure Assessment (check all that apply)**

### ANIMAL HAZARDS

- [ ] Cold blooded (amphibians, reptiles, fish)
- [ ] Rodents or rabbits
- [ ] Other animals
- [ ] Other animal TISSUE

### ERGONOMIC STRESSORS

- [ ] PC Workstation1: Spends 2-4 hours a day on computer
- [ ] PC Workstation2: Spend 4+ hours a day on computer
- [ ] Repetitive motion: May perform repetitive motions
- [ ] Heavy Lifting: Routinely lifting 25lb or more

### RADIATION HAZARDS

- [ ] Lasers: May use lasers, class 3a, 3b, 4
- [ ] Research Contact: Radioactive materials in a laboratory
- [ ] Equipment: Contact/use of gamma knife, x-

### BIOLOGICAL HAZARDS

- [ ] Biological Materials: May be exposed to select agents, toxins, Vaccinia virus, or other hazardous materials
- [ ] Human Blood and Body Fluid: Contact with human blood/body fluids/tissue/cells.
- [ ] Laboratory: In a research setting
- [ ] Clinical: In a clinical setting
- [ ] Patient Contact: May be exposed to human patients
- [ ] Administrative Exposure: Brief contact only, less than 5 minutes at a time

**HAZARDOUS CHEMICAL and/or MATERIAL CONTACT**

- [ ] Clinical Contact: with hazardous chemicals/drug/materials
- [ ] Research Contact: with hazardous chemical/drug/materials
- [ ] Formaldehyde: May be exposed to formaldehyde
- [ ] Glutaraldehyde: May be exposed to glutaraldehyde
- [ ] Controlled Substances: Will handle controlled substances Schedule I-V & NC VI
<table>
<thead>
<tr>
<th>Anesthetic Gasses</th>
<th>May be exposed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cryogenic materials</td>
<td>May be exposed to liquid nitrogen, etc</td>
</tr>
<tr>
<td>MRI</td>
<td>May work with or around MRI</td>
</tr>
<tr>
<td>Respirator use</td>
<td>May need a respirator for chemical contaminants or transmissible disease protection</td>
</tr>
</tbody>
</table>

**OTHER/MISCELLANEOUS**

Sponsor Signature: _______________________________
UNCG Waiver of Liability
for
Visitors** Exposed to Laboratory Animals, Animal Tissue, and/or who have
Access to Areas Where Animals are Housed or Used

Identification (PRINT OR TYPE)
Last Name __________________________  First __________________________  Gender (M/F)
Email ________________________________  Phone ( ) __________________________

In Case of Emergency (Optional)
Notify Name ______________________________
Relationship ___________________________  Phone ( ) __________________________

Risk of Infection or Illness

Please be informed that infectious (e.g. zoonotic) diseases represent a known risk to individuals exposed to laboratory animals (e.g. housed or used). General concerns are tetanus, rabies, allergies, and bacterial infections. For the most part this will typically include rodent-related disease.

Typically rodent colonies maintained by commercial suppliers and used in laboratories today are closely monitored for infectious diseases, thus minimizing the likelihood that laboratory workers will be exposed to infectious animals. All persons working with these species should be immunized against tetanus. Proper handling and restraint procedures will minimize the risk of animal bites and transmission of disease.

1. **Lymphocytic Choriomeningitis Virus** is a rodent virus found in the nervous tissue of infected animals. Hamsters and wild rodents are the major animal reservoirs of the virus, which is shed in urine and saliva. In people, the virus causes an acute flu-like illness and occasionally death. While most commercial vendors monitor their animals for the presence of this virus, care must be taken when handling wild rodents and rodents from sources that do not perform routine surveillance. Potentially infected materials, such as blood, bedding and transplantable tissues, should be handled with care.

2. **Allergies:** Rodents are commonly identified as a cause of allergies in people. Dander, serum, urine, and saliva are just some of the materials that can induce an allergic reaction. Allergic responses generally are seen immediately after handling an animal, but may not appear for several hours after exposure. Sneezing, tearing, and red, swollen eyes are typical responses; however, a rash, wheal, hives, or other type of skin inflammation also may be seen. It is thought that use of personal protective equipment (PPE) reduces exposure to animal allergens. Personnel with known or suspected allergies to animals should report their condition to their supervisor and Medical Center Employee Health Services.

3. **Other Infections:** Wild rodents are a common source of zoonotic infections in people. These animals may be sources of leptospirosis, bubonic plague, salmonellosis, and other bacterial and viral diseases, including Hantavirus Pulmonary Syndrome. Unless serologic surveillance of the
animals indicates otherwise, special quarantine procedures should be used whenever handling or caring for wild rodents or animals of unknown health status.

I recognize that exposure to animals and their tissue may expose me, and, if I am pregnant or planning to become pregnant, my fetus, to unknown disease. In consideration of being allowed to serve as a volunteer, I hereby assume the risks inherent in the activities engaged in by me in connection with my volunteer work for UNCG, and I agree to indemnify and hold harmless UNCG, the State of North Carolina and their employees and agents from all liability, loss, damage, costs, expenses, and claims, brought or asserted either by me or by others as the result of activities engaged in by me in connection with my volunteer work for UNCG, even to the extent that such liability, loss, damage, costs, expenses, and claims result, in whole or in part, from the negligence of UNCG, its agents or employees.

My signature below indicates that I have received and reviewed a copy of this document and have read and understand the risks posed by entering animal research areas, and/or handling animals or animal or human tissue.

Signature__________________________________________ Date________________________

PLEASE RETURN COMPLETED FORM TO: The Office of Research Integrity at ori@uncg.edu

**Individuals who are not UNCG faculty, staff or students and who will have at least transient contact with animals or animal or human tissue for a period of time not to exceed 3 days.**
APPENDIX 2

Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals

Notice Number: NOT-OD-05-034

Key Dates

Release Date: February, 24, 2005

Issued by

Office of Laboratory Animal Welfare (OLAW), Office of Extramural Research (http://grants.nih.gov/grants/olaw/olaw.htm)

This Notice provides guidance to Public Health Service (PHS) awardee institutions and Institutional Animal Care and Use Committees (IACUCs) on the prompt reporting requirements of the PHS Policy on Humane Care and Use of Laboratory Animals (Policy) (http://grants.nih.gov/grants/olaw/references/phspol.htm). This guidance is intended to assist IACUCs and Institutional Officials in determining what, when, and how situations should be reported under IV.F.3 of the Policy, and to promote greater uniformity in reporting. This Notice supersedes the January 12, 1994 Dear Colleague letter from the former Division of Animal Welfare, Office for Protection from Research Risks (now the Office of Laboratory Animal Welfare, or OLAW).

Background

PHS Policy, IV.F.3, requires that:

“The IACUC, through the Institutional Official, shall promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:

a) Any serious or continuing noncompliance with this Policy;

b) Any serious deviation from the provisions of the Guide [for the Care and Use of Laboratory Animals] ; or

c) Any suspension of an activity by the IACUC.

IACUC suspensions of activities are cited at IV.C.6 and 7 of the Policy, and require a convened meeting of a quorum of the IACUC and the vote of a majority of the quorum present. The Institutional Official must review the reasons for suspension in consultation with the IACUC, take appropriate corrective action and report that action with full explanation to OLAW.

All institutions with Animal Welfare Assurances are required to comply with the provisions of IV.F.3. The Institutional Official signing the Assurance, in concert with the IACUC, is responsible for this reporting.
Reporting promptly to OLAW under IV.F.3 serves dual purposes. Foremost, it ensures that institutions deliberately address and correct situations that affect animal welfare, PHS-supported research, and compliance with the Policy. In addition, it enables OLAW to monitor the institution's animal care and use program oversight under the Policy, evaluate allegations of noncompliance, and assess the effectiveness of PHS policies and procedures.

The underlying foundation of the PHS Policy is one of institutional self-evaluation, self-monitoring and self-reporting. Public Law 99-158 (http://grants.nih.gov/grants/olaw/references/hrea1985.htm) requires that institutions be provided a reasonable opportunity to take corrective action before a grant or contract is suspended or terminated, and it is OLAW's role to assess whether the corrective actions reported by institutions under IV.F.3 are adequate. OLAW will assist the reporting institution in developing definitive corrective plans and schedules if necessary. Compliance actions affecting an award are rare because institutions are usually able to address incidents successfully and take appropriate actions to prevent recurrence.

**Guidance on Prompt Reporting**

A comprehensive list of definitive examples of reportable situations is impractical. Therefore, the examples below do not cover all instances but demonstrate the threshold at which OLAW expects to receive a report. Institutions should use rational judgment in determining what situations meet the provisions of IV.F.3 and fall within the scope of the examples below, and consult with OLAW if in doubt. OLAW welcomes inquiries and discussion and will provide guidance with regard to specific situations. Situations that meet the provisions of IV.F.3 and are identified by external entities such as the United States Department of Agriculture or the Association for Assessment and Accreditation of Laboratory Animal Care International, or by individuals outside the IACUC or outside the institution, are not exempt from reporting under IV.F.3.

Examples of reportable situations:

* Conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanical failures, resulting in actual harm or death to animals;

* conduct of animal-related activities without appropriate IACUC review and approval;

* Failure to adhere to IACUC-approved protocols;

* Implementation of any significant change to IACUC-approved protocols without prior IACUC approval as required by IV.B.7.;

* Conduct of animal-related activities beyond the expiration date established by the IACUC (note that a complete review under IV.C is required at least once every three years);

* conduct of official IACUC business requiring a quorum (full Committee review of an activity in accord with IV.C.2 or suspension in accord with IV.C.6) in the absence of a quorum;

* conduct of official IACUC business during a period of time that the Committee is improperly constituted;

* Failure to correct deficiencies identified during the semiannual evaluation in a timely manner;
* Chronic failure to provide space for animals in accordance with recommendations of the Guide unless the IACUC has approved a protocol-specific deviation from the Guide based on written scientific justification;

* Participation in animal-related activities by individuals who have not been determined by the IACUC to be appropriately qualified and trained as required by IV.C.1.f;

* Failure to monitor animals post-procedurally as necessary to ensure well-being (e.g., during recovery from anesthesia or during recuperation from invasive or debilitating procedures);

* Failure to maintain appropriate animal-related records (e.g., identification, medical, husbandry);

* Failure to ensure death of animals after euthanasia procedures (e.g., failed euthanasia with CO2);

* Failure of animal care and use personnel to carry out veterinary orders (e.g., treatments); or

* IACUC suspension or other institutional intervention that results in the temporary or permanent interruption of an activity due to noncompliance with the Policy, Animal Welfare Act, the Guide, or the institution's Animal Welfare Assurance.

OLAW recognizes that there may be levels of morbidity and mortality in virtually any animal-related activity, including those associated with the care and use of animals in research, testing, and teaching that are not the result of violations of either the Policy or the Guide. OLAW offers the following examples of situations which may not meet the threshold for reporting, based on consideration of the circumstances by the IACUC.

Examples of situations not normally required to be reported:

* Death of animals that have reached the end of their natural life spans;

* Death or failures of neonates to thrive when husbandry and veterinary medical oversight of dams and litters was appropriate;

* Animal death or illness from spontaneous disease when appropriate quarantine, preventive medical, surveillance, diagnostic, and therapeutic procedures were in place and followed;

* Animal death or injuries related to manipulations that fall within parameters described in the IACUC-approved protocol; or

* Infrequent incidents of drowning or near-drowning of rodents in cages when it is determined that the cause was water valves jammed with bedding (frequent problems of this nature, however, must be reported promptly along with corrective plans and schedules).

**Time Frame for Reporting**

Institutions should notify OLAW of matters falling under IV.F.3 promptly, i.e., without delay. Since IV.F.3 requires a full explanation of circumstances and actions taken and the time required to fully investigate and devise corrective actions may be lengthy, OLAW recommends that an authorized institutional representative provide a preliminary report to OLAW as soon as possible and follow-up with a thorough report once action has been taken. Preliminary reports may be in the
form of a fax, email, or phone call. Reports should be submitted as situations occur, and not collected and submitted in groups or with the annual report to OLAW.

**Information to Be Reported**

Include as many of the following items of information as possible in the initial contact with OLAW. A follow-up report may address anything not known at the time of the initial report and should summarize the institution's corrective action. If a long term plan is necessary, describe the plan and include a reasonable schedule. This information will allow OLAW to assess the circumstances and actions taken to correct and prevent recurrence of the situation.

Information to be included:

* Animal Welfare Assurance number (http://grants.nih.gov/grants/olaw/assurance/300index.htm);

* Relevant grant or contract number(s) if the situation is related to an activity directly supported by PHS;

* a full description of any potential or actual affect on PHS-supported activities if the situation is not directly supported by the PHS but is in a functional, programmatic, or physical area that could affect PHS-supported activities (e.g., inadequate program of veterinary care, training of technical/husbandry staff, or occupational health; inadequate sanitation due to malfunctioning cage washer; room temperature extremes due to HVAC failures);

* full explanation of the situation, including what happened, when and where, the species of animal(s) involved, and the category of individuals involved (e.g., principal or co-principal investigator, technician, animal caretaker, student, veterinarian, etc.);

* Description of actions taken by the institution to address the situation; and

* Description of short- or long-term corrective plans and implementation schedule(s).

**Preliminary and final reports should be made to:**

Axel V. Wolff, M.S., D.V.M., Director  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
Rockledge 1, Suite 360, MSC 7982  
6705 Rockledge Drive  
Bethesda, MD 20892-7982  
Phone: 301-594-2061  
FAX: 301-402-2803  
E-mail: wolffa@od.nih.gov

**Inquiries**

For questions or further information, contact:

Eileen Morgan  
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982
Phone: 301-435-0931/FAX: 301-402-2803
E-mail:

Should include the February 2013 updates: