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1.0 PURPOSE

- 1.1 State the requirements (and relevant forms) required by the DHMRI’s Institutional Animal Care and Use Committee (IACUC) to be completed before access to the animal housing facility is granted or before work with live vertebrate animals in research may be performed.

2.0 SCOPE


- 2.1 This SOP applies to any researcher who intends to perform animal research at or in collaboration with DHMRI’s Center for Laboratory Animal Sciences (CLAS) facility.

3.0 RESPONSIBILITIES


- 3.1 All prospective animal research investigators and animals study personnel are responsible for ensuring this SOP is followed.
- 3.2 Quality Systems is responsible for:
- 3.2.1 Accuracy of assigned document numbers, DCO numbers and relevant meta data against the master logs before document approval.
 - 3.2.2 Effective document release, storage and retention.
 - 3.2.3 Biennial Review.

4.0 PROCEDURE


- 4.1 Online CITI Training – applies to ALL study personnel
- 4.1.1 The DHMRI IACUC requires completion of the following CITI Program modules:
 - 4.1.1.1 “Working with the IACUC” (Investigators, Staff and Students, Basic Course)
 - 4.1.1.2 “Reducing Pain and Distress in Laboratory Mice and Rats” (If working with these species.)
 - 4.1.1.3 Species-specific elective modules (e.g., “I work with Mice/Rats/Non-Human Primates”, etc.)
 - 4.1.2 To complete this process, go to: <https://www.citiprogram.org>
 - 4.1.3 Once completed, contact the CLAS Program Administrator for documentation of required modules.
 - 4.1.4 If you have completed comparable training through another institution within the past three (3) years, provide completion records to the CLAS Program Administrator (see Appendix for contact information).

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- 4.1.5 Note: Documentation of previous training or additional training may be requested by the IACUC.
- 4.2 Personnel Qualification to Perform Animal Research Form (FM-0027) – applies to ALL study personnel
- 4.2.1 The Personnel Qualification (PQ) Form documents the level of experience of the applicant and will be used by the Principal Investigator, the Attending Veterinarian, CLAS personnel and/or the IACUC to determine training needs and ensure they are addressed PRIOR to animal research being initiated.
- 4.2.2 The PQ Form must be completed by all study directors, research technicians, postdoctoral fellows, students and/or visiting scientists PRIOR to starting any research or entering CLAS to assist with animal research. If an investigator wishes to add personnel to a previously approved protocol, they must submit a protocol amendment (FM-0025) and await approval before the person can begin working under that protocol. The PQ Form for new personnel must also be submitted during this approval process.
- 4.2.3 The completed, signed PQ form should be scanned and emailed to the CLAS Program Administrator for review (see Appendix for contact information). This document may be completed on your computer.
- 4.3 Occupational Health Program Participation – applies to ALL study personnel
- 4.3.1 Each person named in the protocol application or working with animals must complete a Basic Health History Form (FM-0026).
- 4.3.2 The information provided on the form should be completed electronically. A PDF version of the form can be accessed on the DHMRI website within the NCRC Members Portal.
- 4.3.3 Each person should keep a copy of their signed completed Basic Health History Form for their records. The completed form may be emailed to the Occupational Health Program Administrator (see Appendix for contact information).
- 4.3.4 Note: if you have not had a tetanus shot within the last ten (10) years, you will need to get that vaccine updated.
- 4.4 Tuberculosis (TB) Screening
- 4.4.1 All lab and/or study personnel whose work would require coming into the CLAS facility must undergo TB screening PRIOR to entering the CLAS.
- 4.4.2 The TB screening (skin) test is available through the Carolinas Healthcare System (CHS) Occupational Medicine Office at no cost to you or your staff.

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- 4.4.2.1 Email the DHMRI Procurement Manager to request an authorization form and include your name, title, contact information and lab affiliation. You will be notified when your signed authorization form is ready to pick up. You will need to present the signed authorization form to the nurses at the CHS at the time of your skin test. Make a copy of your TB screening results and email to the CLAS Program Administrator (see Appendix for contact information).
- 4.4.2.2 Note: No appointments are necessary at CHS. Contact CHS to coordinate both your initial and follow up skin tests. The follow-up visit must be 72 hours after the initial test so keep this timing in mind when you schedule your appointments.
- 4.4.3 Frequency of Screening
 - 4.4.3.1 Persons working directly with Nonhuman Primates: every six (6) months
 - 4.4.3.2 For other researchers, contract staff and/or maintenance personnel who do not work directly with NHPs: every year (annually)\
- 4.5 Tetanus Vaccination
 - 4.5.1 All lab and/or study personnel whose work would require coming into the CLAS facility must provide documentation of a tetanus vaccination within the last 10 years to the CLAS Program Administrator.
- 4.6 CLAS Orientation/Training – applies to all lab and/or study personnel whose work would require coming to the animal housing facility
 - 4.6.1 Contact the CLAS Program Administrator to schedule and complete the Introduction to the Center for Laboratory Animal Sciences (CLAS) Training
 - 4.6.2 CLAS Orientation/Training must be completed prior to animal research being initiated
- 4.7 DHMRI IACUC Forms – for all animal use protocol submissions
 - 4.7.1 All proposals for animal research to be performed at DHMRI must be submitted on the DHMRI IACUC-approved forms. These forms are available on the DHMRI website within the NCRC Members Portal.
 - 4.7.2 Animal research cannot begin until the protocol is approved by the IACUC.
 - 4.7.3 Protocols are approved for three years. On or before the first and second anniversary, an Annual Renewal Form (FM-0024) must be submitted. The protocol expires after three years – if the research is to continue, a new protocol must be submitted to, and approved by, the IACUC.

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4.7.4 Any changes to an approved protocol require that a Protocol Amendment Form (FM-0025) be submitted and approved by the IACUC, before changed procedures are performed.

4.8 Review of the Animal Use Protocol

4.8.1 All research personnel must read each approved animal use protocol on which they are/will be listed and clearly understand all procedures in which they will be involved.

4.9 Attending Veterinarian (AV) Consultation – as required by the Animal Welfare Act

4.9.1 The Animal Welfare Act (§2.31(d)(iv (B))) requires consultation with the Attending Veterinarian prior to protocol submission to the IACUC. The Attending Veterinarian will provide advice regarding proposed animal use, numbers of animals to be used, and procedures, particularly if considering research falling under pain/distress categories C, D, and E. The CLAS Attending Veterinarian’s contact information can be found in the Appendix of this document.

4.10 Animal Ordering and Transfer

4.10.1 Animals may not be ordered without an approved protocol.

4.10.1.1 Animals may be ordered using the Animal Order Form.

4.10.1.2 Animals may be transferred from another protocol using the Animal Transfer Form.

5.0 REFERENCES AND RELATED DOCUMENTS

5.1 FM-0015, IACUC Protocol Form

5.2 FM-0040, IACUC Protocol Appendix 1: Breeding

5.3 FM-0016, IACUC Protocol Appendix 2: Antibody Production

5.4 FM-0017, IACUC Protocol Appendix 3: Test Substances

5.5 FM-0018, IACUC Protocol Appendix 4: Ante mortem Specimen Collection

5.6 FM-0019, IACUC Protocol Appendix 5: Surgery

5.7 FM-0020, IACUC Protocol Appendix 6: Special Husbandry and Procedures


5.8 FM-0021, IACUC Protocol Appendix 7: Additional Information

5.9 FM-0022, Animal Order Form

5.10 FM-0023, Animal Transfer Request Form

5.11 FM-0024, Annual Renewal Form

5.12 FM-0025, IACUC Protocol Amendment Form

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5.13 FM-0026, Basic Health History Form

5.14 FM-0027, Personnel Qualification to Perform Animal Research Form


6.0 DEFINITIONS

Term	Description
CHS	Carolinas Healthcare System
DHMRI	David H. Murdock Research Institute
NHP	Non-Human Primate
IACUC	Institutional Animal Care and Use Committee
NCRC	North Carolina Research Campus
CLAS	Center for Laboratory Animals Services
AV	Attending Veterinarian

7.0 APPENDICES

7.1 Contact Information

Title	Name	Address	Telephone	Email/Website
CLAS Program Administrator	Daniel Peralta	150 Research Campus Dr. Kannapolis, NC 28081	(704) 250-2671	dperalta@dhmri.org
IACUC DHMRI		150 Research Campus Dr. Kannapolis, NC 28081	(704) 250-2600	iacuc@dhmri.org
IACUC DHMRI		150 Research Campus Dr. Kannapolis, NC 28081	(704) 250-2600	iacuc@dhmri.org
Occupational Health Program Administrator	Daniel Hurley, MS CIH	500 Laureate Way Kannapolis, NC 28081	(704) 250-5056	djhurley@northcarolina.edu
DHMRI Procurement Manager	Stacie Thompson	150 Research Campus Dr. Kannapolis, NC 28081	(704) 250-2618	sthompson@dhmri.org
Carolinas Healthcare System (CHS)	Occupational Medicine Office	NorthEast Gateway Court, Suite 201, Concord, NC 28025	(704) 403-9000	http://www.carolinashealthcare.org/occupational-medicine-services

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7.2 IACUC Protocol Checklist Overview

- Online CITI Training
- Personnel Qualification to Perform Animal Research Form (FM-0027)
- Basic Health History Form (FM-0026)
- Tuberculosis (TB) Screening
- Tetanus Vaccine
- CLAS Orientation/Training
- DHMRI IACUC Forms (see Section 5.0)
- Review of the Animal Use Protocol
- Attending Veterinarian (AV) Consultation
- Animal Ordering and Transfer (as needed)

REVISION HISTORY		
Superseded Revisions	DCO Number	Effective Date
R1.0	13-200	30MAY2014
Current Revision:	R1.1	
Section Number	Description of Changes	Justification of Changes
7.1	Contact information updated	Contact information updated