UNIVERSITY OF ILLINOIS HOSPITAL AND CLINICS
MANAGEMENT POLICY AND PROCEDURE

NO.: IC 5.00
APPROVAL DATE: June 2, 2017
EFFECTIVE DATE: June 19, 2017

SUBJECT: Non-Human Research Subjects in the Hospital and Clinics

OBJECTIVE

To protect patients and staff from biological hazards while supporting research initiatives for medical advancement by studying non-human research subjects in the hospital and clinics.

DEFINITIONS

For the purpose of this policy, the following definitions apply:

Non-human refers to any animal species.

POLICY

Hospital equipment can be used only when the technology cannot be accommodated by the Biological Research Laboratory (BRL). The use of alternative veterinary facility, equipment, and instrument options other than those of the Hospital must have been exhausted before undertaking the procedure within the University of Illinois Hospital and Clinics. A request to use hospital resources must be completed and approved prior to any service. Patient care rooms where invasive procedures are performed (e.g. Operating Room, Cardiac Catheterization Laboratory) are not used to provide any services to non-human subjects.

Prior to transportation of a non-human research subject to the hospital, the research protocols must have obtained all required approvals. Approvals include review by the Animal Care Committee, Infection Control, the Hospital Director (i.e. radiology administrative director), and Chief Operating Officer. Protocols must meet the highest possible scientific and ethical standards. Protocols for non-human research that involve infectious agents will not be permitted to use the same facilities as human patients. In addition, the BRL veterinarian will ensure that non-human research subjects do not have infections that can be transmitted to humans. Introduction of non-human research subjects cannot interfere with, by any means, the routine care patients seek at the hospital. For example, if an urgent patient study is needed, the non-human study must be postponed or aborted if it has already begun to ensure that no non-human subjects are in the same clinical space as patients at any time. All studies conducted on non-human research subjects should occur outside established departmental operating hours (i.e., off-hours). Non-human subjects are not permitted in patient care areas when patients are present. Hours permitted for human research subjects are less restricted, please confirm with the department for specific hours for either type of research study.

UNIVERSITY OF ILLINOIS HOSPITAL AND CLINICS
MANAGEMENT POLICY AND PROCEDURE

PROCEDURE

A. **Researcher/principal investigator seeks approval/permission**:
   1. The researcher/principal investigator should follow LD 2.05 Use of Hospital Resources for Research and Other Sponsored Studies.
      a) The researcher/principal investigator submits the following documents to Infection Control and the Area Director: see **Addendum #1- Checklist and Signature Page.**
         - All research staff involved in protocols using UIH facilities will have documented education of this policy and documents from Appendix A. See **Addendum #2- Documentation of Research Staff Education.**

B. **Once approval/permission has been granted:**
   1. Non-human research subjects will only be allowed in pre-approved areas of the University of Illinois Hospital and Clinics. A screen of the non-human research subjects must occur by the BRL veterinarian to assure that they do not have diseases that are transmittable to humans before being transported to the hospital environment.
   2. BRL staff/ BRL trained research staff is to provide the transportation and staff for the entire procedure. If BRL staff is unavailable a hospital staff member needs to accompany the research team.
   3. The anesthetized non-human research subjects are to be transported from the Biological Research Laboratories through the hospital tunnel system, or any other route approved by both BRL and the hospital, in a box or container covered to prevent inspection of the non-human subject by non-BRL staff and/or guests. The container must have a solid bottom and sides to prevent subject's body fluid from being released into the environment. The non-human subject may not be transported in any corridor in which patients are present.
   4. A BRL veterinarian, veterinary technician and/or research BRL technician trained by the BRL veterinary staff must accompany the non-human research subject to the appropriate hospital location.
   5. When in the University of Illinois Hospital and Clinics, non-human research subjects must be transported in service elevators whenever possible. If alternative elevators must be used a hospital staff member or BRL/trained staff member must travel in advance of the non-human subject and attendant to ensure the pathway of travel has no patient or visitor contact
   6. There may be no mixing of human patients and non-human research subjects, even in a thoroughfare.
   7. BRL and research personnel must be compliant with the hospital Infection Control policies. This includes the wearing and use of appropriate personal protective equipment (PPE) when handling non-human research subjects (e.g., gloves, lab coats, aprons, face shields, shoe covers, etc.), and demonstrating appropriate hand hygiene practices
      a) BRL staff and research staff are required to complete annual training in infection control and demonstrate competency. (See **Addendum #1- Checklist and Signature Page).**
   8. Guidelines for Infection Control must be strictly followed. These include but are not limited to:
      a) Standard Precautions will be observed at all times.

b) Appropriate hand hygiene will be used at all times.
c) Safe work practices

9. Equipment that comes in contact with the mucous membranes of human patients) will not be shared with non-human research subjects. In this situation, equipment used on non-human subjects will be dedicated for this purpose. Cleaning, maintenance, and storage of the equipment will be the responsibility of the BRL staff and will occur at a facility separate from the hospital. Such equipment will not be cleaned, repaired, or stored with equipment to be used on humans. Materials and equipment for such repair and cleaning will be dedicated for this purpose and will not be used for the cleaning or repair of equipment for use on humans.
10. Invasive procedures or instrumentation, with the exception of placement of a peripheral IV, or intramuscular or intraperitoneal injection, should not be performed on non-human subjects in the University of Illinois Hospital and Clinics. In addition, IV access, if needed, will be placed prior to transport to the Hospital, and only done in the Hospital, if adjustment or replacement is needed. Whenever, possible the non-human subject will be removed to a non-patient care area to have IV access re-established.
11. Equipment that cannot be easily cleaned and disinfected (e.g., soft or leather restraints) will be dedicated for non-human research subjects.
12. Used non-human subject supplies may not be stored with patient care supplies. BRL staff and research team will bring on the transportation cart a sharps container and appropriate material to collect waste, and linen to return to the BRL.
13. Any contact between the non-human research subject or the self-contained box containing the non-human research subject and the treatment table and/or equipment must be cleaned/disinfected by BRL/BRL trained research staff with a hospital approved disinfectant at the end of the procedure.
14. Prior to study initiation, consultation with environmental services about appropriate disinfectants and contact time will be obtained.
15. After non-human study is complete, BRL trained research staff will disinfect hospital equipment used, any contaminated surfaces, along with high touch surfaces, such as light switches, door handles and countertops, using a hospital approved disinfectant and follow contact times listed on the label.
16. Environmental services will be notified that the study is complete and will clean the area prior to patient care exams.
17. The non-human subject and the research team must vacate the patient care area 70 minutes prior to patient care studies. This time is needed to allow sufficient air exchanges to clean the air and help remove airborne dander, microorganisms and allergens after non-human research subjects have been in patient care areas and prior to subsequent treatment or testing of human subjects (e.g. The recommended clearance time to remove 99.9 % of airborne contamination from x-ray treatment rooms is 70 minutes.)
18. Patient care of humans always takes precedence over non-human research. If hospital equipment is needed for patient care during off-hours, scheduled non-human research procedures must be canceled or aborted if already initiated, to accommodate patient needs.
19. Failure to comply with hospital Infection Control Policy 5.00 may result in loss of access to hospital equipment and resources.

UNIVERSITY OF ILLINOIS HOSPITAL AND CLINICS
MANAGEMENT POLICY AND PROCEDURE

References:

Rutala, W. et al. Healthcare Infection Control Practices Advisory Committee (HICPAC) Centers for Disease Control (2008). Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. Retrieved from https://www.cdc.gov/hicpac/Disinfection_Sterilization/acknowledg.html

Murthy, R, et al. SHEA Expert Guidance - Animals in Healthcare Facilities: Recommendations to Minimize Potential Risk. ICHE Vol 36(5): May 2015, pp 495-516.

Hospital Management Policy and Procedure
LD 2.05 Use of Hospital Resources for Research and Other Sponsored Studies.

Hospital Infection Control Policies

Addenda

Addendum #1- Checklist and Signature Page to be Submitted for Approval of Non-Human Subjects in the Hospital

Addendum #2- Documentation of Research Staff Education

Rescission Date

May 2014
Formerly IC 6.00 renumbered September 2016
November 2009
August 2007
September 2004
June 2001

Policy Owner - Medical Director Infection Control

UNIVERSITY OF ILLINOIS HOSPITAL AND CLINICS
MANAGEMENT POLICY AND PROCEDURE

Addendum #1. Checklist and Signature Page to be Submitted for Approval of Non-Human Subjects in the Hospital

Date	Initials	Documents
		a. Copy of protocol and associated authorizations (i.e. Animal Care Committee).
		b. Outline of testing procedure to be executed in the UI Hospital
		c. Documentation why non-human research facilities cannot accommodate the study.
		d. Documentation of education of BRL staff and researchers on Infection Control Policy 5.00 Non-Human Research Subjects in the UI Hospital.
		e. Documentation of education by LMS or in person education on Infection Control Policy and Procedures including the following: 1. Safe work Practices 2. Hand Hygiene Practices – patient/animal zone 3. Respiratory etiquette 4. Standard precautions including Personal protective equipment (PPE) 5. Cleaning and disinfection
		f. Documentation of Health Clearance for BRL and research staff to work at UIH. Immunity to Measles, Mumps, Rubella, Varicella and prove annual compliance with Flu Vaccination and TB screening. Reference: IC 4.01, 4.04, HR 1.12.
		g. Plan for transport within the UI Hospital
		h. List of requested UI Hospital equipment to be used
		i. Names of Hospital and BRL staff supervising the research team
		j. Hospital approved disinfectants to be used with consultation on environmental services.
		k. Proposed dates and times
		l. Approval via Policy LD 2.05 Use of Hospital Resources for Research and Other Sponsored Studies..

Principal Investigator

Printed Name	Signature	Date

Biological Research Laboratory

Printed Name	Signature	Date

Infection Control

Printed Name	Signature	Date

Hospital Dept. Director

Printed Name	Signature	Date

Chief Operating Officer

Printed Name	Signature	Date

UNIVERSITY OF ILLINOIS HOSPITAL AND CLINICS
MANAGEMENT POLICY AND PROCEDURE

Addendum #2: Documentation of Research Staff Education

Date	Initials	Items
		a. Outline of testing procedure to be executed in the UI Hospital
		b. Documentation of education of BRL staff and researchers by LMS or in person education on Infection Control Policy 5.00 Non-Human Research Subjects in the UI Hospital.
		c. Documentation of education by LMS or in person education on Infection Control Policy and Procedures including the following: 1. Safe work Practices 2. Hand Hygiene Practices – patient/animal zone 3. Respiratory etiquette 4. Standard precautions including Personal protective equipment (PPE) 5. Cleaning and disinfection
		d. Plan for transport within the UI Hospital
		e. Names of Hospital and BRL staff supervising the research team
		f. Hospital approved disinfectants to be used with consultation on environmental services.
		g. Proposed dates and times for use of UIH facilities

	Printed Name	Signature	Date
Research Staff (Staff will accompany animal in Hospital)			
Principal Investigator			
Biological Research Laboratory			
Infection Control			
Hospital Dept. Director			
Chief Operating Officer			