Regional Health POLICIES PROCEDURES STANDARDS GUIDELINES		
TITLE:	Animal Studies in Mixed Use Imaging Facilities	**NUMBER:**
CATEGORY:	Research	**PAGE:** of
DEPARTMENT SERVICE/PROGRAM:	Diagnostic Imaging	**POLICY** ρ **PROCEDURE** ρ **GUIDELINE** ρ **STANDARD** ρ
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OBJECTIVE:

Thunder Bay Regional Health Sciences Centre, through the Thunder Bay Regional Research Institute, is engaged in developing and translating research ideas that will motivate advances in the way that we use imaging modalities to diagnose and treat disease. To be successful in the translation of research ideas in to clinical practice, TBRHSC will be host to both pre-clinical and translational research projects that involve animal subjects. Leading research organizations have demonstrated that using imaging equipment for both animal and human subjects is a safe practice if precautions for safe use are fully defined and implemented with rigor.

POLICY:

Thunder Bay Regional Health Sciences Centre, with guidance of Infection Control and the Biosafety Committee, will implement infection control measures to prevent the potential transmission of zoonotic pathogens from animals to humans, when animal research is conducted in mixed-use patient care areas. Infection control measures will be designed to prevent potential exposures either through direct contact with an animal or its bodily secretions, indirect contact with potentially infectious material on equipment and/or supplies, or through environmental exposure via uncontained aerosols and/or airborne organisms.

1. **Animal Housing and Animal Procedure Rooms**

1.1 Research animals will be housed in a designated space separate from any patient care area

1.2 Animal housing and animal procedure rooms are to be located in a separate designated space, which meet the CCAC guidelines and OMAFA requirements, and are approved for the purpose intended.

1.2 Research laboratories where animals or animal tissues/parts will be used must have proper air filtration and ventilation parameters and include but are not limited to the following:

- The heating ventilation and air conditioning (HVAC) system must be independent and separate from other supply/exhaust fans and ducts. (i.e. 100% fresh air and 100% exhausted air directly outside). Exhausted air should be high efficiency particulate air (HEPA) filtered for certain types of research[1]
- The exhaust ducts are to be exhausted directly outside and placed at least 60 ft (18

[1] This would be particularly for avian influenza or TB research, and animals such as: sheep, primates and felines. References are Health Canada Guidelines and Canadian Food Inspection Agency. (NB – this type of research is not being conducted at this time).

m) from any air intake grills; if the location of the exhaust duct is close to ground level, the duct must be located away from pedestrian traffic.

- Rooms conducting animal research/manipulation must be under negative pressure relative to the corridors.

2. Mixed Use Facilities

2.1 Wherever feasible, animal research will be conducted in space dedicated to animal studies only. Where excessive cost precludes duplication of equipment and facilities (e.g. suites equipped with MRI or CT scanners), mixed use may be considered, recognizing the priorities of patient care and patient safety.
2.2 Diagnostic Imaging Suites, where no "interventional" procedures beyond the insertion of IV lines are performed, may be used for studies on clinical patients as well as animal research subjects. Mixed use may be considered in these suites only where conditions facilitate compliance with mixed use policy as below.
2.3 Animal procedures in mixed used facilities will be conducted outside scheduled patient care hours.

3. Animals

3.1 Animals deemed to be of significant risk for harboring pathogens dangerous to humans (i.e. primates, sheep, felines) will not be used as research subjects at this time, and therefore, this policy does reflect any needs or precautions specific to those species.
3.2 All procedures involving animals must be approved by and be performed in accordance with the policies of the Lakehead University's Animal Care Committee.
3.3 Animals will be obtained from a healthy, reputable source as defined by the Animal Care Committee (ACC); where possible, those certified as pathogen-free will be selected. Animal health will be verified at the Lakehead University's animal facility located at 290 Munro St. prior to use as research subjects in mixed use studies.
3.4 Animals infected with microbiological agents (e.g. bacteria, viruses), with an approved ACC research protocol that are to be used in mixed-use facilities, will also require approval from the Biosafety Committee, as well as Infection Control.

4. Transportation & Disposal

4.1 Transport of animals to and from the Munro St. Research Facility will be done by a trained person, and will follow an approved ACC transport protocol.
4.2 Transport routes that avoid patients or the public will be designated within the TBRHSC for animal research subjects.
4.3 Animals must always be contained in an enclosed HEPA-filtered cart which completely contains any fluids or air-borne particles, and or via an equivalent transport protocol as approved by the ACC. Transport carts will be cleaned before and after use, will be inspected regularly, and will have a secure door to ensure containment.
4.4 Transport to a mixed use room will only commence when the imaging suite is confirmed to be free of patients and has been prepared for animal arrival. If a public elevator must be used in transit, that elevator will be locked out of service to the public prior to animal transportation and will remain so until transit is completed. Elevators used for transport of sterile supplies will not be used.
4.5 Euthanized animals will be will be placed in paper bags and returned to the Munro St. Research Facility for disposal. All biohazardous waste (including disposable utensils, plastic and absorbent coverings, and fluids) resulting from the research will be segregated from human waste and will be either returned to the Munro St. Research Facility or to the Research Lab (room 3110) for disposal.
4.6 Needle disposal, scalpel blades, suture needles, and other sharps waste will be placed in a puncture resistant, labeled, stabilized needle box during transportation. Disposal of sharps will be separated from sharps used in humans. These will also be either

returned to the Munro St. Research Facility or to the Research Lab (room 3110) for disposal.

4.7 All instruments used on animals must be either returned to the Munro St. Research Facility or to the Research Lab (room 3110) for reprocessing (cleaning, disinfection and sterilization).

4.8 Disposal of biohazardous waste when returned to the Research Lab (room 3110) will be done after autoclaving. At the Munro St. Research Facility it will be disposed in the designated containers at the Waste Room from Lakehead University Animal Care Facility.

5. Animal Management

5.1 Prior to use, animals must be cleaned, and (as needed for any procedures) shaved, intubated, and anesthetized in an approved animal procedure room. In addition, any surgical procedures involving significant exposure to fluids (including cutdowns and like procedures) will be performed in an animal procedure room.

5.2 While in a mixed use facility, imaging and minimally invasive device manipulation on animals will be performed as quickly as possible under conditions which maintain containment of all animal fluids within disposable / removable liners.

5.3 All areas where the animal is handled within mixed use facility will comply with the design requirements for the facility given above (including transfer rooms, etc).

PROCEDURE:

Suite Preparation, Animal Care within Suite, and Post-Procedure Clean-up

1. Imaging Suite Preparation

i. Animals are only brought to the imaging suite after all patient studies are completed. All disposables used for prior human imaging must be discarded and the suite cleaned prior to animal arrival.

ii. All loose clinical equipment (coils, injectors, disposable supplies, etc) must be removed from the imaging suites or draped prior to the arrival of the animal.

iii. The table-top upon which the animal will be placed will be covered with absorbent pads. All other equipment that remains in the mixed use imaging room will be covered with plastic sheets or disposable absorbent sheets.

iv. Any radiofrequency (RF) coils to be used with animals will be covered in plastic before the study and cleaned with sterile wipes afterward following the manufacturers recommendations. Infection Control should be provided with details on coil cleaning from manufacturer.

v. Direction of air flow and number of air exchanges must be regularly monitored (i.e. monthly) and any deviations from standard must be reported to Infection Control. It is the responsibility of the Infection Control to ensure air flow and quality is monitored through Environmental Services. The Researcher will also ensure monthly checks are documented and forwarded to the TBRRI Facilities Coordinator; these records will be kept on file for a one year rolling period.

2. Animal Preparation within the Animal Procedure Room

i. All invasive animal procedures must be performed in an animal procedure room prior to transport to the imaging suite. Invasive procedures include, but are not limited to, any insertion or manipulation of a device (including IV's, intubations, prosthesis, catheters, etc.) and any incision.

3. Animal Care within the Imaging Suite

i. Upon arrival in the imaging suite, the animal will be transferred to the prepared table-top and secured with (animal-only) straps.

ii. Animal monitoring will be performed with animal-dedicated equipment (no components

coming into physical contact with humans will be shared with animals).

iii. Anesthesia will be maintained with animal dedicated equipment, including the anesthesia machine and ventilator.

iv. Investigators will use dedicated oxygen gas cylinders and will not connect to the wall oxygen sources used for clinical studies; due to the projectile hazard of these tanks, they must be vertically secured outside of the magnet room.

v. All studies will be conducted under sterile conditions to prevent complications such as fever or infection in the animal.

vi. All implements used in animal studies will be segregated to prevent inadvertent use in humans.

vii. At the conclusion of the imaging study, the animal will either be prepared for return to the animal care facility (chronic study) or euthanized (acute study) and placed in a plastic bag.

viii. Following the imaging procedure, the animal may be held for a short-time, as determined and recommended by the ACC, in the animal procedure room to prevent undue stress on the animal. Animals will be required to be held in a contained HEPA filtered rack for the duration of their stay. For protocols involving this resting period, Infection Control and the Biosafety Committee will be apprised.

4. Post-Procedure Clean-up

i. The Researcher must document the preparation and clean-up completion in a comprehensive, signed, checklist. These are to be kept on file with the TBRRI Facilities Coordinator for one year and may be requested by Infection Control and or the Biosafety Committee for review.

ii. The Researcher must remove all items used during the animal imaging procedure, including disposal items, medications, and equipment.

iii. All animal instruments, equipment (such as recorders, respirators, anesthesia machine, and gas tanks), and medicine, will be removed from the mixed use room upon completion of the study.

iv. Plastic covering, absorbent pads, sharps, and other disposal items used with animals must collected and returned to Munro St. or to the Research Lab (room 3110) for disposal following the imaging procedure.

v. The Researcher and/or designated staff will carry out the initial decontamination of all contact surfaces within the procedure room, using a product suitable for animal decontamination, while also not harmful to humans, and approved by Housekeeping and Infection Control.

vi. All equipment, horizontal and vertical surfaces must be cleaned and disinfected after each animal case.

vii. Designated TBHRSC Staff will complete a terminal cleaning of the area where the procedure was done with an accelerated hydrogen peroxide disinfectant, or other equivalent product.

viii. After the terminal cleaning, the procedure room will be left vacant for a minimum of 60 minutes prior to any human use to allow for adequate air exchanges.

ix. The loose clinical equipment previously removed from the imaging suite will be returned at the start of clinical studies the following day after documented terminal cleaning.

x. If instruments designated for human patients is mistakenly used on animals, and the items can not be appropriately sterilized, then the item will no longer be permitted for use with human patients.

REFERENCES:

1. Brigham and Women's Hospital, *Brigham and Women's Hospital Advanced MRI Center Research Policy* (in particular the chapter "Animal Research")
2. CDC Guidelines on Animal Research
3. NIH Policy Manual, the section on animal research titled "Animal Care and Use in the

Intramural Program”

4. UCSF, *UCSF XMR Facility: Policy for the Use of Animals.*
5. SRI – “Animal Studies in Mixed Use Imaging Facilities” – Policy (*the TBRHSC policy was closely based on this policy*)
6. CCAC Guidelines
7. OMAFA – Animals for Research Act
8. Health Canada Guidelines and Canadian Food Inspection Agency