



Making Cancer History®

JOHN S. DUNN CENTER FOR RADIOLOGICAL SCIENCES INVESTIGATOR/RESEARCHER GUIDELINES

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POLICY DEFINITIONS

Purpose

The purpose of this policy is twofold: 1) to ensure that institutional assets are properly safe guarded in accordance with existing federal and state regulations as well as institutional guidelines and policies, and 2) to facilitate best stewardship of the resources of the center.

Scope

The Center provides facilities, equipment, and personnel to aid Investigators in their research pursuits. However, there are certain requirements, expectations, and guidelines to which the researcher must adhere to when utilizing Center resources.

Policy Statement

The mission of the Center is to improve the management of the cancer patient through development and teaching of imaging-guided minimally invasive techniques for treatment and diagnosis. These facilities allow faculty to take clinical problems, translate them into research models and develop solutions, which are then reintroduced into the clinic

Communication and Adaptability

The two most important expectations and requirements of investigators utilizing Center resources are maintaining open communication and allowing some degree flexibility with scheduling and timing.

It is imperative that investigators communicate frequently, clearly, honestly, and openly with both the laboratory manager and appropriate laboratory personnel, and that they seek input from these team members. It is essential that all laboratory personnel know ahead of time the goal and rationale of a project as well as a sufficiently detailed plan to accomplish it. The Dunn Center staff make extensive efforts to be as accommodating as possible but there may be times and/or situations when requests are unable to be handled. Frequent communication will help to minimize the potential for misunderstandings and problems conducting research.

It is also crucial that investigators demonstrate flexibility. They must be able to work in situations involving uncertainty, shifting priorities, and rapid change, and they must be able to deal constructively with challenging situations.

COMPLIANCE AND SAFETY MEASURES

Individuals utilizing Center resources are required to comply with all institutional, accrediting agency, state, and federal policies, guidelines and laws governing the use of animals in research, testing, and teaching as outlined at: <http://inside.mdanderson.org/departments/eresearch/>

Please note that IACUC, IBC, Radiation Safety and MTA's are now accessed through eResearch. To obtain access to eResearch, the PI and all users must complete an OneAccess Request at <https://oneaccess.mdanderson.org>

Institutional Care and Use Committee (IACUC)

The IACUC is responsible for overseeing and evaluating the institution's animal care and use program, facilities, and procedures involving animals. As part of these responsibilities, the IACUC reviews all animal protocols used for research, testing or education purposes to ensure the humane care and use of animals. IACUC meetings occur on the third Tuesday of each month.

IACUC Training: Prior to performing any procedures on animals, investigators must complete all of the IACUC training modules required for protocols on which they are listed as an animal manipulator.

Animal Care and Use Form (ACUF)

- All ante- and post-mortem procedures performed on animals must be described in an Animal Care and Use Form (ACUF) and approved by the IACUC.
- Animal protocols are submitted through the electronic Animal Care and Use Form (Click-IACUC in eResearch) system. The protocol submission deadline is the 25th of each month.
- The laboratory manager is available to assist PIs in filling out, submitting and modifying their protocols. However, the PI must provide a detailed description of all procedures. Interventional Radiology PIs should list the laboratory manager and appropriate lab personnel as the contact persons on their protocol (ACUF).
- All investigators must have or be listed on an active ACUF protocol before they can be granted card-key access to the area in which the Center facilities are located.

Institutional Biosafety Committee (IBC)

The IBC reviews research involving biological and hazardous agents, compounds, materials and the use of transgenic animals to ensure institutional compliance and safety in research conduct. IBC meetings occur on the second Tuesday of each month.

Institutional Biosafety Committee Protocols:

- All biological and hazardous agents, compounds, materials and transgenic animals to be used must be described in an IBC protocol/registration form and approved by the IBC.
- All investigators utilizing any of the above listed items must have an active IBC protocol/registration in advance of use. Any items requiring IBC approval must also be described in your IACUC protocol.
- IBC protocol/registrations are submitted through the electronic Institutional Biosafety Committee system in eResearch. The submission deadline is the last Tuesday of each month.
- The laboratory manager is available to assist PIs in filling out, submitting and modifying their IBC protocol/registrations. However, the PI must provide a detailed description of all biological and hazardous agents, compounds, materials and transgenic animals to be used as well as the

procedures in which they will be used. Interventional Radiology PIs should list the laboratory manager and appropriate lab personnel as the contact persons on their protocol (IBC).

- Use of any of the above listed items will result in the need for special housing and safety training for handling the agents and animals in which they will be used. It is the responsibility of the PI to discuss the proposed use of all biological and hazardous agents, compounds, materials and transgenic animals with the laboratory manager, laboratory personnel, and Veterinary Medicine personnel in advance of use.
- Investigators or their designee are responsible for any clean-up/decontamination that use of the above listed items may require.

Institutional Radiation Safety Committee

The Radiation Safety Committee functions to provide compliance with State regulations, addresses safety concerns regarding the use of radioactive materials, and regulates the use of all radioactive material and ionizing radiation-producing equipment in all areas of the institution. The Radiation Safety Committee establishes policy relating to the acquisition, use, storage, and disposal of radioactive material. Authorization requests to use specific isotopes are reviewed and approved by this committee before they may be purchased. The RSC may modify, suspend or revoke an authorization at any time should they believe the user is violating the conditions of the authorization or the institution's license, or is handling radioactive materials in an unsafe manner. RSC meetings routinely occur on the third Friday of every other month or at other times as deemed by the RSC Chairman.

- The use of any radioactive isotope in animals must be reviewed and approved by the RSC. All Investigators utilizing radioactive isotopes/agents must have or have a Co-investigator with RSC approval in advance of use. Forms: Application for Approval of Non-Human Use of Radioisotopes and Radioisotope Use in Animals can be found on the RSC website or done electronically through eResearch.
- Radioactive isotope/agent to be used in animals must also be described in your IACUC protocol.
- Laboratory manager is available to assist PIs in filling out, submitting and modifying their RSC forms. However, the PI must provide a detailed description of the isotopes/agents to be used as well as the procedures in which they will be used.
- Use of any radioactive isotope will result in the need for special handling/housing and safety precautions for your animals. It is the responsibility of the PI to discuss these specialized needs with the laboratory manager, laboratory personnel, and Veterinary Medicine personnel in advance of use.
- Investigators or their designee are responsible for clean-up/decontamination and required wipe tests following use of radioisotopes in the Center facilities.

Safety

<http://inside.mdanderson.org/departments/facilities/emergency-safety/index.html>

- Individuals are expected to learn and comply with all laboratory safety guidelines.
- Investigators are required to complete all appropriate laboratory safety training courses (e.g., IBC and Radiation Safety) prior to initiation their research protocol.
- Everyone working with or around radiation (e.g., fluoroscopic C-arms, CT, isotopes) within the Center must have and wear a Radiation Monitoring Badge.

SCHEDULING

With the growth of the Dunn Laboratory program and expanded capabilities that the combine imaging system provides scheduling has become critically important.

- All procedures/uses of Dunn Laboratory Angio Suites must be scheduled in advance with both the laboratory manager and lab personnel. This is to ensure all necessary veterinary scheduling/paperwork are in place and that the space/time slot you are requesting is available.
- We will do our best to accommodate your needs but Investigators and their personnel are not allowed to take either space or time slot for use without scheduling in advance with both the laboratory manager and lab personnel.
- If the time you would like to schedule your study is already booked, we will offer alternative times/space accommodations. Please Note: Investigators from the Section of Interventional Radiology are normally given priority for scheduling of the Center facilities, equipment and personnel.
- All procedures scheduled should be placed on the Dunn Lab calendar and any changes to that schedule must be communicated in advance. Please note: Depending on work already scheduled, we may not be able to accommodate last minute scheduling changes.
- Investigators are responsible for discussing animal and consumable supply needs with laboratory manager in advance of scheduling procedures. This is required so that the animals and necessary supplies are on hand for the performance of scheduled procedures. At least 2-3 weeks is required to obtain and condition animals prior to their use in projects, while the time to obtain supplies varies dependent on the item(s) needed.
- Investigators are responsible for discussing the need for special services (e.g., blood work, tumor preparation, immunohistochemistry) with the both the laboratory manager and Dunn Lab personnel in advance of scheduling procedures. This is required to determine if the required services are available and to discuss the needs with the appropriate veterinary laboratories.

Cancellation/No Show Policy

- While we are flexible in our scheduling, we do require that investigators and/or their personnel notify us when the scheduled must be changed.
- Ideally, notification of cancellation or changes in schedule should be given at least 24 hours in advance of scheduled procedures. However, we are well aware that this may not always be possible (emergencies happen, tumors don't grow, etc.).
- Investigators will not be penalized when these issues occur if the lab manager and lab personnel are advised by 7 am on the day procedures are scheduled.
- This policy also applies to Investigators and there personnel who schedule procedures in the lab then fail 1) to show up, 2) to communicate with the lab, and 3) do not respond to either phone calls or emails regarding there scheduled procedures.
- The investigator/investigator personnel will received a warning following each of the first three violations of this policy. These warnings will be issued to the investigator by the lab manager via email.
- After the third warning, all subsequent violations of this policy by the investigator/investigator personnel will result in the investigator being charge a cancellation/no show fee.

DOCUMENTATION

Record Keeping

- Each Investigator is expected to maintain detailed and accurate records of their studies. Center personnel maintain records of animals and procedures; however, those records may not contain information that is critical to study.
- Investigators utilizing the Center's fluoroscopic C-arm imaging systems are responsible for archiving all images crucial to their research. These systems are capable of storing a limited number of images and automatically delete the oldest images as new images are acquired. Therefore, if vital images are not archived in some way (e.g., on a flash drive) following a procedure, they may be lost.

Tissue Processing

- Investigators or their designee are expected to cut in tissue for histopathology and record the information on histology log sheets that are provided by the Center. The original should remain with the paraffin blocks, the PI/Investigator should keep a copy, and a copy should be left with Center personnel.
- If the Investigator prefers to have a Veterinary Pathologist perform necropsies and/or cut in tissues for histopathology, the Investigator is expected to meet with the pathologist prior to study initiation to discuss what tissues are required, fill out and submit the required Pathology Request Form, and attend the first necropsy to make sure the correct tissues are collected and photographed. Please keep in mind that this is a service provided by the Department of Veterinary Medicine and Surgery, and charges will apply.

Discoveries (Intellectual Property)

<http://inside.mdanderson.org/departments/technology-discovery/index.html>

- Investigators are required to disclose inventions that are made using institutional time or resources or inventions that are related to their work at the institution.
- An Invention Disclosure Report (IDR) provides the pathway to disclose a new invention to the Office of Technology Commercialization. This brief report provides a description of the invention and will provide the basis to start a patent application following evaluation. New IDRs are evaluated for scientific utility, patentability and the market potential.
- For the inventor in The University of Texas MD Anderson Cancer Center, the payback is the most generous of universities in the United States. After recovery of patenting costs, 50% of royalties gained from licenses flow back to the inventor personally, and another 25% is returned to the inventor's department for his/her research. The remaining 25% goes to MD Anderson to continue patenting and licensing activities.

Publications/Presentations

- Investigators utilizing Center facilities and/or personnel assistance are expected to acknowledge the support of the John S. Dunn Research Foundation in all related publications and presentations using the following citation: "Research supported in part by a grant from the John S. Dunn Research Foundation."
- Investigators utilizing animals are expected to acknowledge the institution's Core Grant support in all publications and presentations using the following citation: "This research is supported in part by the National Institutes of Health through MD Anderson's Cancer Center Support Grant CA016672."

CENTER CHARGE SCHEDULE

It is the Investigators responsibility to insure that adequate funding is available prior to the initiation of a project. Investigators are encouraged to contact the Center for cost estimates when preparing grant budgets. Please contact the laboratory manager for cost estimates/budgets, to insure that the appropriate authorizations are on file or if you have any questions.

- No work will commence until a signed and valid authorization to invoice
- Investigators from the section of Interventional Radiology and MDACC will receive a monthly invoice and the charges will be paid via an IDT from the cost center on file.
- Investigators from external Academic Institutions or Industry will receive a per service invoice unless otherwise specified. Invoice payments will be expected within 30 day of receipt.
- Failure to pay invoices in a timely manner will result in the suspension of your project.
- Updated fees rates will be provide and are subject to change.
- In addition to the fee schedule provide, Investigators will be billed for any Center supplies that are utilized. A list of utilized supplies will be provided upon request.

ADDITIONAL RESOURCES

Department of Veterinary Medicine and Surgery

Information on the facilities and services provided by the Department of Veterinary Medicine and Surgery can be found on their website along with a schedule of charges and necessary request and authorization forms.

<http://inside.mdanderson.org/departments/dvms/index.html>

Additionally, Investigators and their personnel can access information (number of animals remaining on the protocol, purchases and delivery of animals, invoices, etc.) through eSirius. The laboratory manager will request that you be added as a principle investigator to the eSirius system and will require a list of all personnel who should be part of your lab group.

<http://d1pwlesiriuspr.mdanderson.edu/eSirius3g/>