

November 27, 2018

Guide to Research at UTGSM

Version 3.0



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Introduction

Mission Statement

To support and advance meaningful discovery at UTMC.

Vision

To enhance patient care through collaborative research that promotes sustainable, transformative healthcare at UTMC.

The University of Tennessee Graduate School of Medicine (UTGSM) is part of the University of Tennessee Health Science Center (UTHSC) School of Medicine (often referred to as “Memphis”). The Dean of the GSM reports to The Chancellor of UTHSC and many of our reporting lines go through UTHSC, including; the Institutional Review Board (IRB), contracts, grants, human resources, budgets, and more.

We are also affiliated with the University of Tennessee Medical Center (UTMC), “the medical center” and we often, when doing systems or patient-related research, use its databases, facilities, personnel and patient information. To perform this type of research, there are often additional permissions required from UTMC to satisfy criteria established by UTMC.

We contract with The University of Tennessee, Knoxville (UTK) for some services such as radiation safety, biosafety, chemical safety programs and the Institutional Animal Care and Use Committee (IACUC) and must abide by the regulations established by these compliance groups.

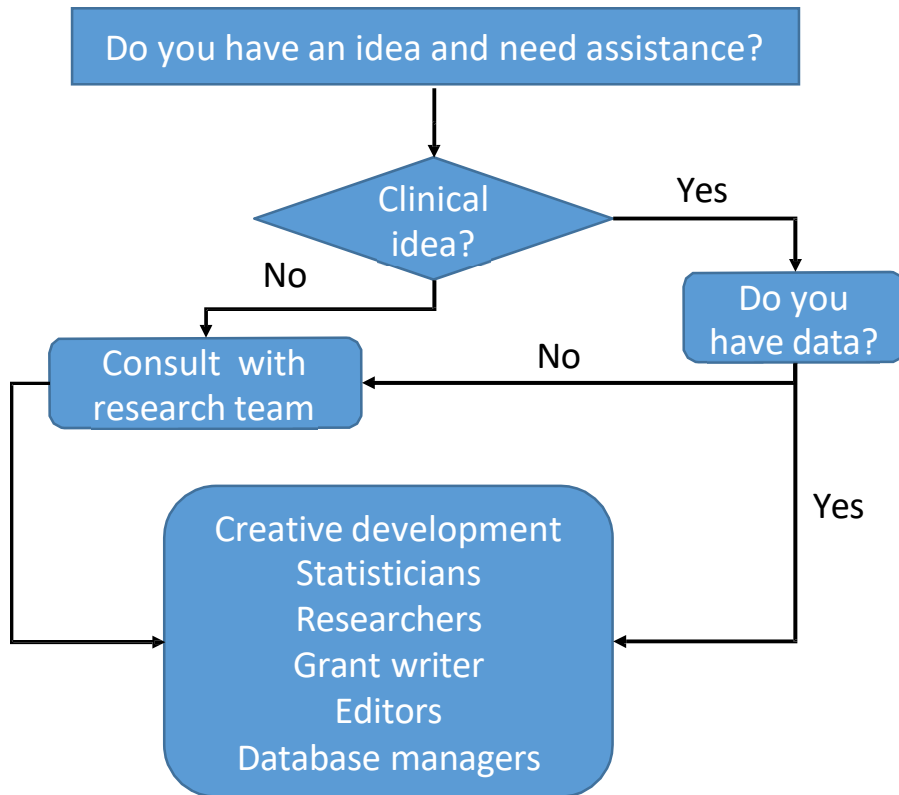
Finally, we collaborate with many organizations locally, regionally and nationally and, therefore, have to adopt, when necessary and appropriate, the rules of those institutions also. Given this complexity, it can often be daunting to effectively navigate the research waters. This guide provides information and assistance for this journey. It is intended to be a primary resource as you move along the research path at our institution.

The Guide is intended to be a living document. We expect people, offices, rules and other things to change over time. Therefore, if you find a needed change as a result of your personal journey, or there are other topics that you would like to include, please let us know by calling or emailing Kristen Vandergriff at 865-305-9749; klvandergriff@utmck.edu.

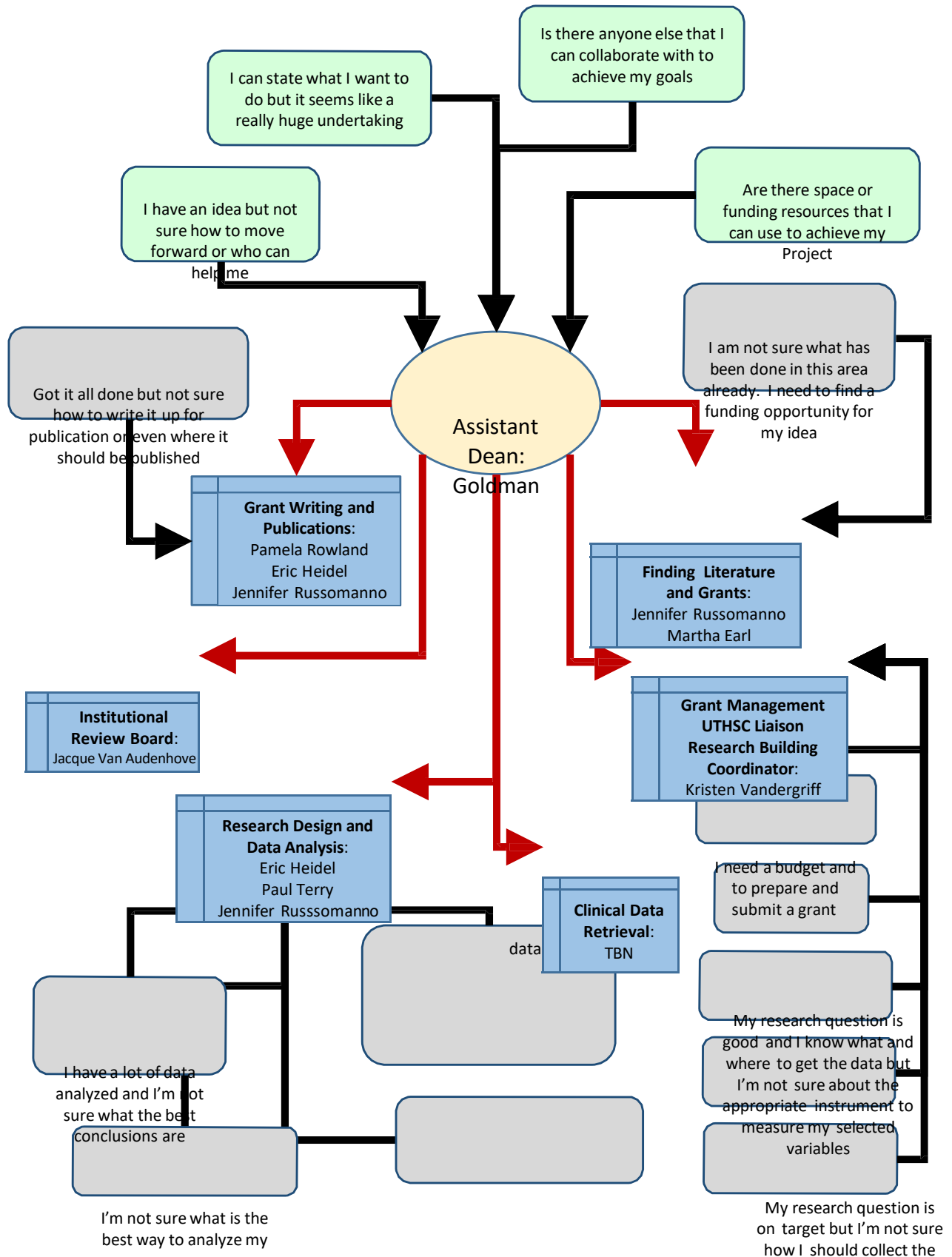
Clinical and Translational Research Office (GSM): Where do I start on my research project?

- Clinical Research Team: 865 305-9290
- The Clinical Research Team is designed to facilitate:
 - Finding a clinical or basic science research grant – “How do I get funding for my project?”
 - Doing a literature search – “What has been done on this subject before?”
 - Formulate the research question - “What is my hypothesis?”
 - Designing research projects - “What is the best way to look at this question?”
 - Finding collaborators - “I need input from other researchers to do this research”.
 - Finding resources to perform the project – “I need student help, other people, and resources to do this research”.
 - Editing, formatting, submitting, creating budgets for grants – “This is my first time putting together a grant or I am not sure how to get this one together”.
 - Editing research manuscripts for publication – “My writing skills could be honed for this paper”.

The Clinical Research Team, made up of the members below, is available to help you start a research project at UPMC and help from the very beginning to completion of the project and publication. One call will activate the team and convene the resources to enable the researcher to carry out a successful project.



The Clinical Research Team



data so its meaningful
and defensible

I need help to work
with Evisions -
Cayuse

I have a contract,
MTA, or CDA that I need
help processing

I need assistance with
compliance issues

I need assistance with
research facilities

Assistant Dean for Research:

- Mitchell Goldman, MD

Graduate School of Medicine, 3rd floor, 865 305 9290

mgoldman@utmck.edu

The Assistant Dean for Research oversees all aspects of the research conducted under the aegis of the UTGSM. The role of the Assistant Dean is to facilitate effective research and research training opportunities at the institution. The Assistant Dean is often the starting point for new research ideas and collaborations and a resource for navigating the systems to initiate and sustain research endeavors. The Assistant Dean has primary contacts with the research offices at UTHSC and UTK and is also responsible for making decisions regarding research-related resources, equipment, IRB issues, IACUC issues and other things that arise during the research effort. The Assistant Dean reports to the Dean of the GSM.

Pre-Award Grant Office and Research Coordinator:

- Kristen Vandergriff, MS

Research Building, 2nd floor, Rm 211, 865 305 9749

klvandergriff@utmck.edu

The Research Center at the Graduate School of Medicine (GSM) serves 9 departments with clinical faculty, basic science faculty, medical residents, student researchers, and 15+ members of laboratory staff who all submit their research through this office. The Research Coordinator, Kristen Vandergriff, directs and coordinates the day-to-day functioning of the research operations at the GSM. Kristen is responsible for implementing policy and procedures in accordance with federal granting agencies and monitoring compliance within the research arena. Kristen functions as the chief administrative and programmatic support for the Research Center; provides consultation on grant preparation; assistance and dissemination of the information regarding grant policies and procedures, as well as, UT Health Science Center (UTHSC) research policies.

She assists and helps direct principal investigators (PI's) through the grant application process by ensuring that all grant applications meet the requirements for error-free submission. Kristen oversees all compliance efforts within GSM. In addition, she manages and assists student and resident volunteers in the Research Center, as well as maintains up to date versions of position description questionnaires (PDQ's) for laboratory technicians and serves as a hiring manager for all new laboratory positions. Kristen is responsible for training for grant application procedures and can assist with training for researchers with the Office of Biosafety, Radiation Safety, and Environmental Health and Safety.

Institutional Review Board:

- Jacque Van Audenhove

Graduate School of Medicine, 3rd floor, Rm U76, 865 305 9781

JVanAudenhove@utmck.edu

Jacque Van Audenhove

is Director of the GSM IRB (IRB) and a source of information prior to and during preparation of IRB applications. Before initiating a new research study, it is advisable to contact Jacque to discuss what IRB requirements are needed to conduct the study in an appropriate and ethical fashion.

Coordination with Jacque(or Cynthia "Cindy" Langley, IRB Regulatory Specialist) will ensure that the IRB application process is efficient and appropriate. The function of the IRB office is

to provide administrative support and regulatory guidance to IRB members, faculty, residents, fellows and members of the research team.

Jacque is responsible for maintaining the Federal Wide Assurance (FWA) and keeping the IRB Registration current with the Office of Human Research Protections.

As an Alternate member of the IRB, Jacque reviews and approves Exempt applications, and reviews and acknowledges Case Reports, Not Human Subjects, and QI applications. She facilitates IRB Authorization Agreements between the GSM and other institutions. She manages the day-to-day operation of the IRB office. She works directly with investigators on the submission of research applications in iMedRIS. She develops and updates SOPs and is responsible for the direct training of staff, IRB members, and investigators regarding applicable laws and regulations, including HIPAA regulations, for the protection of human subjects.

Post-Award Grant Budget Office:

- Deb Strahler

GSM Building, 3rd floor GSM Business Office, 865 305 6192

dstrahler@utmck.edu

Deb Strahler is director of the business office at the GSM and assists with establishing accounts for research project, grants, and contracts. Deb can assist with all aspects of post award finances including preparing budget sheets for review by the PI and working with UTHSC and the granting agencies. She is responsible for invoicing sponsors and ensuring appropriate payment, when necessary. She will work closely with the PI to monitor grant and contract-associated funding.

Experimental Design and Biostatistics:

- Eric Heidel, PhD

Graduate School of Medicine, GSM 3rd floor, 865 305 3474

rheidel@utmck.edu

Dr. Eric Heidel is the biostatistician at the UTGSM. Dr. Heidel has been providing research and statistical consultation to residents, fellows, faculty, staff, and physicians for over 10 years at the UTGSM. He helps researchers with writing valid research questions, choosing the correct research design, running sample size calculations, measuring for variables, building and maintaining research databases, conducting statistical analyses, generating epidemiological and diagnostic testing measures, creating and testing survey instruments, running psychometric analyses, and publishing abstracts and manuscripts. Dr. Heidel is a critical component of the research process and should be consulted early in the project design and then throughout the process. Consultation, related to all these tasks, be scheduled via email at rheidel@utmck.edu or by contacting Brenda Chaves in the Dean's Office at (865) 305-9290.

Epidemiology:

- Paul Terry, PhD

Department of Medicine, GSM 2nd floor, 865-305-3781

pterry@utmck.edu

Dr. Paul Terry is an epidemiologist at UT GSM. Dr. Terry has been involved in the design and conduct of case-control, cohort, cross-sectional, randomized clinical trials, and methodological studies of various chronic disease outcomes. These studies have evaluated associations between the risk of disease or survival and a variety of factors including nutrition, lifestyle, body weight, physical activity, and energy balance, hormones, genetics, environmental exposures, substance abuse, and others. Dr. Terry is available for consultation related to research idea development, study design and conduct, presentations, publications, and grant applications. Appointments with Dr. Terry can be made through email (pterry@utmck.edu) or by calling Brenda Chaves in the Dean's office at (865) 305-9290.

Grant applications and editing:

- Jennifer Russomanno, MPH

Graduate School of Medicine, GSM 3rd floor, 865-305-9190

russomanno@utmck.edu

Jennifer Russomanno is a continuing education coordinator at GSM. Additionally, she is a current doctoral student in the UTK Department of Public Health. Jennifer specializes in qualitative research methods and study design. Jennifer has experience writing high-quality research proposals and grant proposals. She can assist principal investigators conducting qualitative research studies by ensuring study design, methods, and implementation are sound and well-founded. She can also assist researchers with locating grant funding opportunities, creating research proposals, analyzing qualitative data results, and assist with editing research manuscripts and posters.

- Martha Earl, MSLS, AHIP

Preston Medical Library, Health information Center, 865 305 9525

mearl@utmck.edu

Martha Earl received her Master of Science in Library and Information Science from the University of Tennessee and is a Distinguished member of the Academy of Health Information Professionals. Martha teaches a myriad number of classes for health professionals, students, consumers, and other librarians; and is involved in grant-funded outreach to consumers and health professionals. Martha serves on the IRB and the AAPTC. She also serves on the Medical Library Association Task Force on Revising the Research Imperative, including revision of research competencies. She is a member of the Nursing Research Council and participates as a member of the Nursing Research Think Tank.

Martha can assist with all aspects of information science, including literature searches and publication requirements. One of five library faculty at UT GSM, Martha can assist the researcher in refining the research question, searching the scholarly literature in a variety of databases, including PubMed, Scopus, Cochrane, Web of Knowledge, and digital repositories. She is also familiar with searching other electronic and print research sources and can provide referral to other librarian systematic review and content experts and sources of grant information when needed. Martha is well informed of other aspects of publications process such as advising the researcher on the target publications for the scope of their research and providing journal assessment data such as the h-factor or the impact factors of journals. Librarians can also assist researchers with bibliographic

management of their citations using Endnote and other bibliographic tools and direct researchers to scholarly impact and networking resources.

Grant and manuscript presentation and editing:

-

Hanover Research

In order to provide high-quality cost-effective resources to the UTHSC research community, the Office of Research thru the Office of Research Development is welcoming Hanover Research to UTHSC as our new grant consulting service provider.

More information on how to use this resource provided free of charge by the Office of Research can be found on the Office of Research Development's website. If you have any questions, please contact Lisa Youngentob, Director of the Office of Research Development, at lyoungen@uthsc.edu or (901) 448-1277

Quality Improvement/Performance Improvement (UTMC)

- Heather Creason, RN, BSN, MS, CPHQ, CCM

UTMC 4 Crossover, 865-305-6634

HCreason@utmck.edu

- Amy White, MBA, CSSBB, CQA

UTMC 4 Crossover, 865-305-8673

ADwhite@utmck.edu

Heather is proficient in all aspects of clinical database use and is familiar with all the systems housing clinical data at UTMC. She is available to help identify sources of data to address the clinical questions.

Amy is manager of performance improvement at UTMC. She is available to assist with the performance-improvement processes and is highly proficient on the Premier database which is our "quality" software system at UTMC.

Animal Facility:

- Ronnie Roberts, Director

Research Building, Basement, 865 305 9451

rroberts@utmck.edu

Ronnie is Director of the Animal Facility at the GSM, which is located in the basement of the research building. Ronnie is responsible for the maintenance of the facility and ensuring the health and well-being of the animals housed therein. Ronnie can assist with animal purchases – which can only be done after an Institutional Animal Care and Use Committee (IACUC)-approved protocol for animal use has been obtained. Ronnie also performs daily husbandry for the animals and can assist

with all aspects of animal housing, use of the small animal surgery suite and other issues related to the GSM animal facility.

Institutional Animal Care and Use Committee (IACUC) representatives

- Tom Masi, PhD.

Research Building, 3rd floor, Rm 302, 865 305 9472

tmasi@utmck.edu

- Eric Heidel, PhD.

Graduate School of Medicine, GSM 3rd floor, 865 305 3474

rheidel@utmck.edu

Drs. Heidel and Masi are currently serving terms on the UTK IACUC. In this role, they are able to advise on all aspects of the IACUC application process including guidance on completing the IACUC application and an explanation of the review process. Dr. Masi's expertise is in the preparation of IACUC applications that involve small animals (mice and rats). Dr. Heidel, has expertise in biostatistics and can assist with the statistical approaches to animal use and in particular statistical determination of animal numbers used in the protocol. All IACUC protocols require justification (generally using statistical methods) for the number of animals requested in the protocol. Additional assistance and guidance on the preparation of animal protocols can also be sought from the Attending Veterinarian at UTK, the Office of Laboratory Animal Care (OLAC), and the IACUC coordinator, Elizabeth "Betsy" Bailey (see contact information below).

Offices and Contacts (UTK):

UTK IACUC Coordinator

Elizabeth "Betsy" Bailey
336 Ellington Plant Science
2431 Joe Johnson Drive
Knoxville, TN 37996-4564
ebailey@utk.edu
Office: 865 974 3631
Cell: 865 566 6521
Fax: 865 974-5587

UTK Attending Veterinarian and Office of Lab Animal Care (OLAC)

Lori S. Cole, DVM
Interim Director,
Director of Animal Compliance,
The University of Tennessee, Knoxville
Institutional Animal Care & Use Committee
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UTK Biosafety Office

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Fax: 865 974 5587
<http://biosafety.utk.edu>

UTK Radiation Safety Office

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Laser Safety Officer,
Radiation Safety Department
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Fax: 865 974 0094

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Tony Rallings
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tralling@uthsc.edu

The Institute for Research, Innovation, Synergy and Health Equity
<http://irise.uthsc.edu>

Office of Scientific Writing
<http://www.uthsc.edu/research/scientific-writing/index.php>

Compliance

Submission of a Request to the Institutional Review Board (IRB):

The University of Tennessee Health Sciences Center (UTHSC) including the UT Graduate School of Medicine (UTGSM) has provided a guarantee Federal Wide Assurance (FWA) to the Office for Human Research Protection (OHRP) in the Department of Health and Human Services (HHS) that it will follow procedures which will assure the protection of all human subjects participating in research projects. The guarantee applies to all human subjects research conducted by anyone on premises owned, or leased by the UTGSM, and to research conducted anywhere by faculty, students, staff or others acting as representatives of the University:

<http://gsm.utmck.edu/irb/main.cfm>

In order to comply with this assurance, the UTGSM has established an institutional committee competent to review research projects that involve human subjects. Under the provisions of the HHS Regulations for Protection of Human Subjects (45 CFR 46) and similar FDA Regulations (21 CFR 50 and 56), this committee has been designated as the Institutional Review Board (IRB) and consists of representatives from the UTGSM, UHS and surrounding community.

The primary function of the IRB is to assist the investigator in the protection of the rights and welfare of human subjects. It is necessary for others who are independent of the research to share the responsibility for determining the standards for ethical conduct of research involving human subjects. Investigators however, carry primary responsibility for assuring that research protocols are planned, and conducted in an ethical manner and consistent with standards established by the IRB.

Before a human subjects research project can be initiated, it must first be reviewed and approved by the IRB and then conducted in full compliance with Federal Regulations. There can be no exceptions to this requirement, since violations may result in serious repercussions for the institution and the investigator.

The information provided is to assist UTGSM investigators in the preparation and submission of research proposals for review by the IRB, and to provide guidance during the conduct of human subject research. The guidelines, which serve as the official governance document for human subject research at the UTGSM reflect both the recommendations of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (The Belmont Report) and the Federal Regulations (45 CFR 46, 21 CFR 50 and 56) which regulate human subject research.

All research involving human subjects must undergo IRB review and approval prior to initiation of the research. The type of IRB review performed depends on the classification of the research as a) full Board review, b) expedited review, or c) exempt review. It is important to note that investigators may request a specific classification of review; however, the final decision is determined by the Board. If investigators are unsure of the method to follow, they are encouraged to discuss their proposed protocol with the IRB Chair or IRB staff, early in the process and thus, facilitate their preparation and the eventual review.

Nothing in the IRB guidelines and/or the Federal Regulations governing human subject research is intended to limit the authority of a physician or other health care provider from providing

emergency medical care to the extent the individual is permitted to do under applicable Federal, State, or local law.

Organization

The UTGSM in Knoxville is part of the UTHSC in Memphis. The Chair of the UTGSM IRB reports to the Assistant Dean of Research of the GSM. The UTGSM IRB is an autonomous board, but is a part of the overall compliance program of the UTHSC.

Affiliation(s)

The University of Tennessee Medical Center in Knoxville, an independent not-for-profit organization operated by UHS, has designated in its federal-wide assurance, the UTGSM IRB as an IRB of record, for review of research conducted by its physicians, staff or agents. In recognition of this affiliation, representatives from UHS are appointed to serve on the UTGSM IRB.

Submission of a Request to the Institutional Review Board (IRB)

iMedRIS is the online study submission and tracking system used by GSM Institutional Review Board (IRB), UTK IRB, UTK Intuitional Biosafety Committee (IBC) and UTHSC IRB and IBC.

Access to iMedRIS is through your UT Net ID (different from your hospital ID). If you don't have a NetID contact the IRB to be sponsored for one.

When do you need to submit to the IRB?

If a study meets the federal definition of human subjects' research, then the study must be submitted to the IRB for review, see <https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html#c1>

Types of IRB Reviews

- Not Human Subjects - Submitted by Residents, Fellows and any Trainee who will present findings at conferences and need an IRB number for travel requests
- Case Reports – Submitted by Residents, Fellows and any Trainee who will present findings at conferences and need an IRB number for travel requests
- Quality Improvement (QI) vs. Research – Submitted by Residents, Fellows and any Trainee who will present findings at conferences and need an IRB number for travel requests
- Exemptions – Exempt from Expedited or Full Board Review
- Expedited Reviews – Minimal risk to subjects
- Full Board Reviews – Greater than minimal risk to subjects

HIPAA Considerations

See SOP # IRB 009 HIPAA Authorization for the Use of PHI in Research and SOP # IRB 10 Use of PHI without Subject Authorization at: <http://gsm.utmck.edu/irb/sop.cfm>

What forms need to be used:

- Not Human Subjects – Go to <http://gsm.utmck.edu/irb/forms.cfm#training>
- Case Reports – Go to <http://gsm.utmck.edu/irb/forms.cfm#training>

- Quality Improvement (QI) – Go to <http://gsm.utmck.edu/irb/forms.cfm#training>
- Exempt, Expedited and Full Board forms – These forms are found within the IRB application in iMedIRS at: <https://ris01.uthsc.edu>
- Collaboration forms - These forms are found on the IRB Website at <http://gsm.utmck.edu/irb/forms.cfm>.

Application flow diagram

Flowchart for IRB Submissions

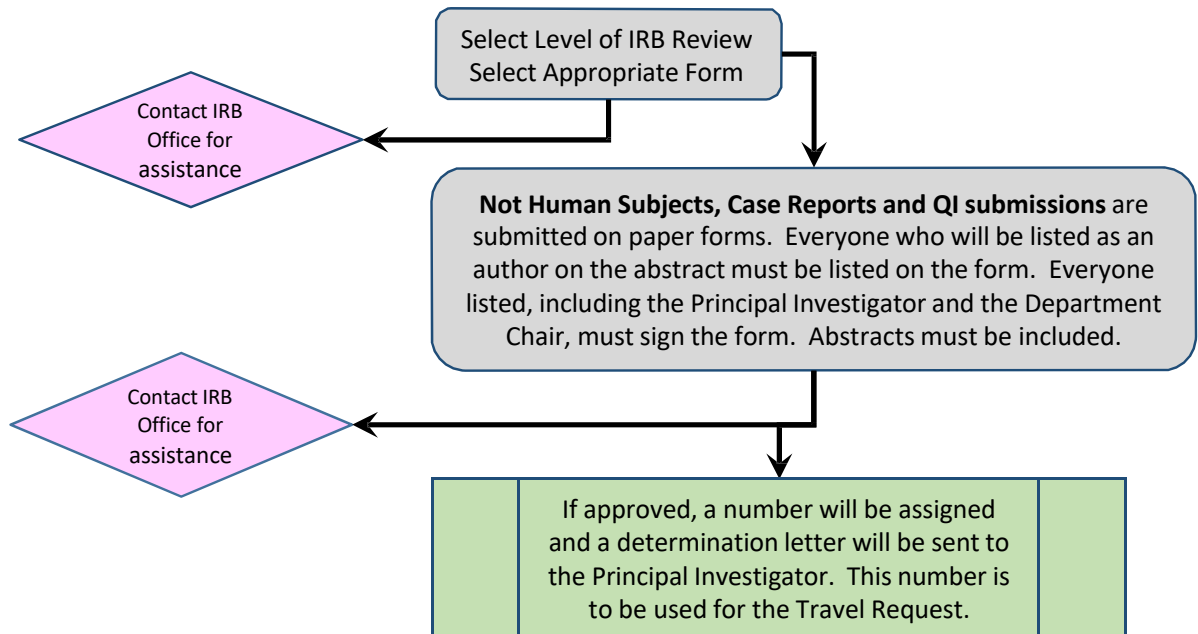
Actions completed by the PI



Actions completed by IRB staff



Actions completed by IRB Chair, Chair's Designee or Full Board



Submission of Animal Use Protocol (IACUC):

The Institutional Animal Care and Use Committee (IACUC) is a federally mandated committee, qualified through the experience and expertise of its members that oversees its institution's animal program, facilities, and procedures. It provides a framework for compliance with federal policies, guidelines and principles related to the use of animals in research, teaching and testing. The accredited program used by GSM researchers is the University of Tennessee Knoxville Area (UTK) <http://iacuc.utk.edu/>.

The US Department of Agriculture (USDA) and Public Health Service (PHS) require institutions using animals to appoint an IACUC and charge it with specific responsibilities.

To ensure compliance with all federal, state, and UTK regulations, policies and standards that are in place to protect animal welfare, IACUC members review all requests to use vertebrate animals. It also conducts inspections of all areas where animals are housed and used, and reviews the institutional program for animal use.

The UTK policies for animal care and use encompass regulations of:

- The Animal Welfare Act as amended (Public Law 99-198 – The Improved Standard for Laboratory Animals Act).
- The Guide for the Care and Use of Laboratory Animals (8th Ed.).
- The Guide for the Care and Use of Agricultural Animals in Research and Teaching.

The UTK IACUC is accredited by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC-i).

Guidelines and tips for completing the IACUC protocol

An IACUC protocol serves as a record of the precise and inclusive procedures that will be performed when using animals for research. **DEVIATION FROM THE PROCEDURES INCLUDED IN THE IACUC PROTOCOL – EVEN IF DEEMED “STANDRD OF CARE” – CONSTITUTE A NON-COMPLIANCE EVENT, UNLESS PRIOR APPROVAL HAS BEEN OBTAINED FROM THE ATTENDING VETERINARIAN OR A PROTOCOL AMENDMENT HAS BEEN APPROVED.** The following is a brief list of guidelines for preparing an animal use protocol:

- Describe briefly, but in detail and in lay terms, the work to be performed and stress the potential impact/benefit that the study will have on human or animal disease.
- Provide a detailed description of the methods and techniques that will involve live animals.
- To provide some experimental leeway and remain compliant, use terms such as “no more than”, “volumes less than”, “approximately”, etc. Additionally, where possible, provide alternatives to allow compliant flexibility e.g. with needle gauges and routes of administration (e.g., “drug will be delivered either intravenously or by intraperitoneal injection”). This approach will allow you to make “compliant” choices should unexpected circumstances arise during the study.
- When necessary, ensure that you are aware of alternatives to painful or distressful procedures, and be ready to scientifically justify your choices.

- Be prepared wherever possible to use pharmaceutical grade (in-date) materials in your study.
- The number of animals requested should be scientifically and, whenever possible, statistically justified. In general, pilot studies utilize ~ 3 animals. Statistical justification of animal number can be performed in consultation with Eric Heidel (rheidel@utmck.edu).
- If you need to perform procedures not outlined in the original protocol (e.g., you need to change drug type, injection timing, number of animals, etc.) the PI MUST submit a protocol amendment to the IACUC committee. The new procedure can only be performed once approval of that amendment is received from the IACUC.
- If the animal study is supported by an NIH grant, the “Research Design” and “Vertebrate Animal” sections of that grant should be submitted with the protocol.
- The IACUC has generated a series of “Standard Operating Practices” (available on the UTK IACUC website) that describe accepted methods for many standard procedures and techniques. The SOP’s provide accepted guidelines that can be referenced in your protocol.
- Be cognizant that all procedures performed should introduce the minimum amount of pain and distress to the subject. Always suggest methods to monitor pain and distress and ways to minimize them.
- Always consult with the IACUC chair, a member of the office of laboratory care (OLAC), or the GSM IACUC representatives if you require assistance with any aspect of the protocol or require training for procedures that you are not familiar with.

Submission of a Biosafety Protocol (IBC):

The primary objective of the UT Biosafety Program is to ensure a safe working environment for faculty, staff and students - <http://biosafety.utk.edu/>

In pursuit of this goal, the IBC office ensures that laboratory facilities and operations conform to the regulatory requirements as set by the Institutional Biosafety Committee (IBC) of the University of Tennessee, the state of Tennessee and federal agencies such as the National Institutes of Health (NIH) and the Occupational Safety and Health Administration (OSHA).

To mitigate the inherent risks associated with the laboratory setting, the IBC seeks to build a culture of safe work practices at the university. To do so, it provides a variety of educational opportunities to those involved in the investigation of biological activities in the form of classroom and online training sessions as well as informational modules found at <http://biosafety.utk.edu/>.

The IBC office also seeks to facilitate collaborative outreach between investigators at the University of Tennessee and the larger academic community. To this end, the IBC provides support and training for all areas of shipping and permitting for the import and export of biological materials.

Finally, the IBC office provides a route to properly dispose of both biologically hazardous and regulated medical wastes through our contracted disposal servicer.

Before working with any biological materials in the laboratory all staff and PI's are required to take Biosafety training through the UTK Biosafety Office. The IBC office provides training to all members of the GSM, UTMC, and University of Tennessee faculty, staff, and students working in laboratories on the Knoxville area campuses on a variety of topics both in person and online. Training is not offered to employees of external entities.

To determine which training you might need, please contact IBC Director, Brian Ranger (branger@utk.edu) or utbiosafety@utk.edu. **NOTE:** If you are a University of Tennessee employee and require a temporary pass to park in Lot 66 for any of the trainings offered through our office, contact the Biosafety Office at (865) 974-5547 or by email at utbiosafety@utk.edu to make arrangements prior to the training date.

Additionally, a registration application for the use of biological agents, such as BNA, transgenic mice, etc. is required before beginning research work.

The IBC Registration form can be found at: http://biosafety.utk.edu/wp-content/uploads/sites/30/2015/06/IBCRegistration_2.8.16.pdf

A Guidance document to assist with the preparation of this application can be found at: http://biosafety.utdev4.wpengin.com/wp-content/uploads/sites/30/2012/12/ibc_form_user_guide.pdf

After obtaining permission perform research with biological samples an annual update is required by the IBC. The Annual Update forms can be found at: https://utk.co1.qualtrics.com/jfe/form/SV_8k3GfioJRwbxi6N

More information on all aspects of Biosafety, including biohazardous waste management, bloodborne pathogens, shipping of biological samples, etc. can be found at, <http://biosafety.utk.edu/>

NOTE: The UTK-area Biosafety Program will be implementing iMedRIS, a web-based research compliance software package used for form submission, approvals routing, and data storage and management in July, 2017. Advantages and key features offered by iMedRIS include:

- Access to approved Institutional Biosafety Committee (IBC)/Biosafety registrations and supporting documents;
- Customizable smart forms and workflows, providing greater flexibility for information gathering and processing;
- Electronic communications and routing to reduce long-hand processes and approval lags;
- An archived history of compliance-related transactions, providing better transparency throughout the approval process;
- Mineable metrics and data analysis tools; and
- Easy access to the system via the UT LDAP (UT NetIDs and passwords).

During the transition from our current Adobe/Sharepoint platforms to iMedRIS the Biosafety Office has created several guidance manuals and video tutorials which will be available within the system. Additionally, the Biosafety Office will be offering several in-class iMedRIS training/orientation sessions in June 2017. The class schedule and enrollment instructions can be found at: <http://biosafety.utk.edu/events/>.

Principle investigators and/or those who routinely complete IBC/Biosafety-related forms are strongly encouraged to attend the training courses that are offered or consult with the Brian Ranger to seek assistance with the new processes.

Submission to the Radiation Safety Office:

The mission of the Radiation Safety Department is to support research compliance. This office strives to ensure safety for faculty, staff, students, and the public in regards to radioactive materials, x-ray devices, and Class IIIB and IV laser systems - <http://radiationsafety.utk.edu/>

Training

Any person who will handle or work near ionizing radiation is required to receive training regarding hazards and safe practices. Training is required before you are working with the items. Radiation and laser safety training programs require a periodic refresher – generally on an annual basis. You must complete the requirements for the refresher trainings so you will remain authorized to use or work around ionizing radiation. Some of the training programs are completed online. Contact the radiation safety office for your training requirements. In addition to training, all workers are required to be enrolled in the UTK dosimetry program and receive the appropriate dosimeter badges. **NOTE:** Even if you are enrolled in the UTMC dosimetry program as part of your employment duties you are required to enroll in the UTK dosimetry program (and obtain a separate dosimeter badge) when working with radiation and laser as part of your non-clinical research projects.

Open Source Training Class

The open source general radiation safety training is generally scheduled once a month. This training is for everyone working in a lab setting with open/loose sources of radioactive materials (powders, liquids, gases). The training schedule can be found at <http://radiationsafety.utk.edu/training/>. If you need training and cannot make one of the scheduled times listed, contact the radiation safety office - radiationsafety@utk.edu or at 865-974-5580. The training usually takes 3 hours to complete. It covers radiation hazard information, exposure monitoring, safe use practices, instrumentation, and basic procedures for radiation workers on campus. After the lecture and exercises, you will take an examination on the training material.

Online Training

Several of our initial and annual refresher training programs are available online through UT Canvas Software. These include: Radioactive Sealed Source, X-ray Machine, and Radiation Safety Training for the Veterinary Teaching Hospital. To gain access to these trainings, you must be registered by the Radiation Safety department. At present (June 2017) the GSM faculty have not been transferred to the Canvas system and training will be supplied using PDF copies until such time as this changes.

Access Training

If your job requires you to enter areas that are posted for radioactive materials or x-ray machines, contact the Radiation Safety department for access and applicable training requirements. **NOTE:** Other approvals or exceptions to these rules may apply to UTMC employees who routinely work with radioactivity or lasers as part of the hospital duties. If you need clarification or assistance

please contact Kristen Vandergriff in the Research Office, who serves as a liaison to the compliance offices.

How do I become authorized to possess radioactive materials or X-ray units?

Appropriate forms (<http://radiationsafety.utk.edu/x-ray-machine/>) must be completed and submitted to the Radiation Safety Department. Authorization for radioactive materials and some x-ray units has to be approved by the Radiation Safety Committee. If you have any questions when completing these documents, contact the radiation safety office or the Radiation Safety director, Marsha Smith, mmsmith@utk.edu.

New x-ray devices or tubes must be registered with the State of Tennessee, Division of Radiological Health within 10 days of installation. If that deadline is passed, we risk monetary fines. It is important to keep the Radiation Safety Department informed of any changes regarding research x-ray machines.

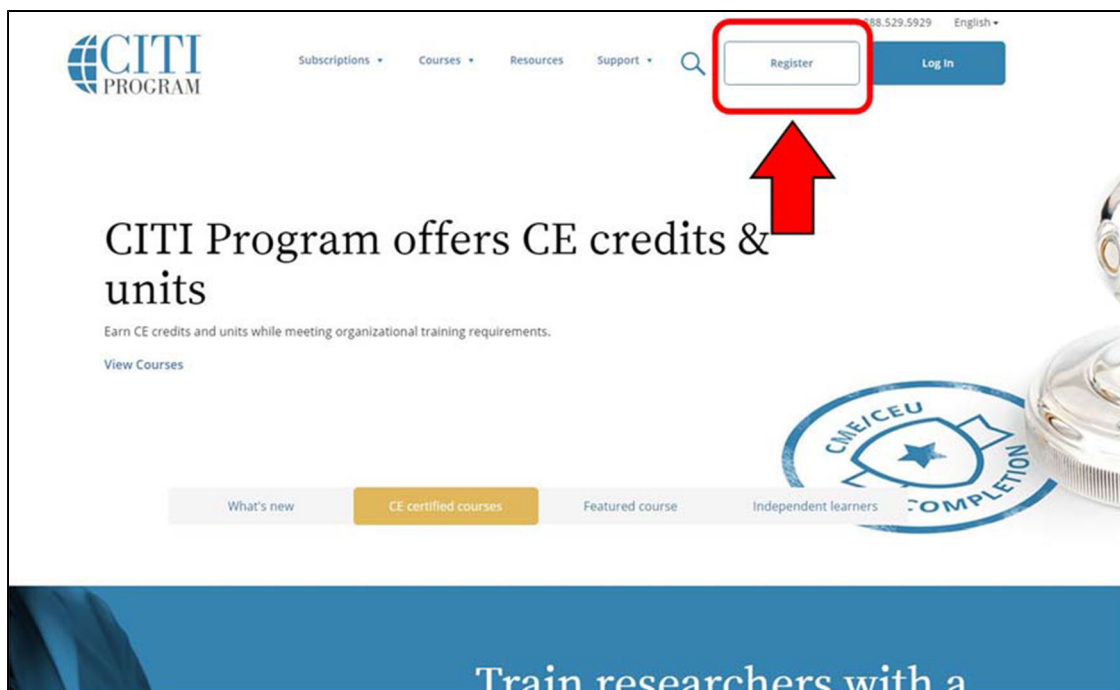
CITI training

The UT GSM IRB requires that everyone involved in human subjects research complete a computer-based training course in human subjects protection through the Collaborative Institutional Training Initiative (CITI - Unless you've completed the NIH Human Subjects Protection Course in the last 3 years).

Anyone working directly with human subjects or with identifiable patient protected health information (PHI) data or patient-derived specimens (e.g., tissue, blood, serum) for research purposes under UTGSM auspices must complete the training. Investigators, research nurses, coordinators, students, technicians working with identifiable data, and faculty advisors all need to obtain CITI certification. You may also need to do some human subjects training that is specific for a particular granting agency. If you've never taken a CITI Course before, please follow the instructions below for New Users. If you have completed a CITI course at another institution, please skip down to the second set of instructions for affiliating that account with the UT Health Science Center – Knoxville (UT GSM).

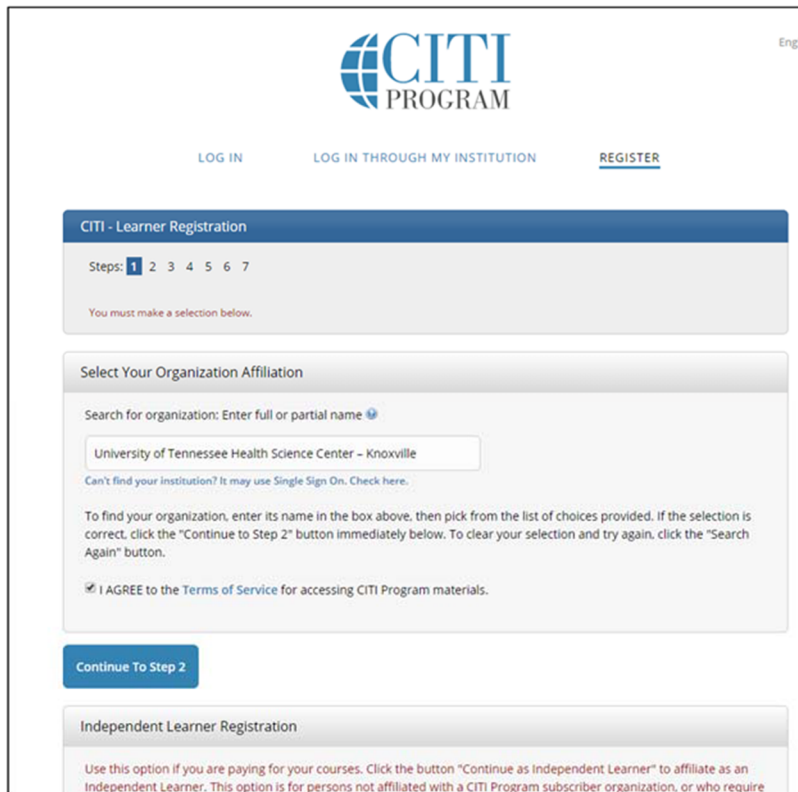
New Users

Go to www.CITIProgram.org and click "Register"



ANYONE WITH A NetID (UT or GSM Students, Residents, Fellows, Faculty, Staff, etc.) click on the link beside the Organization Search Box: "Can't find your institution? It may use Single Sign On. Check here."

Select **University of Tennessee Health Science Center – Knoxville** (currently #73, but this could change as the list is updated) and log in using your NetID and password. Remember your NetID & password are different from your hospital user ID and password (see the *How to Obtain a NetID* section if you do not remember or have one).



CITI PROGRAM

LOG IN LOG IN THROUGH MY INSTITUTION REGISTER

CITI - Learner Registration

Steps: 1 2 3 4 5 6 7

You must make a selection below.

Select Your Organization Affiliation

Search for organization: Enter full or partial name

University of Tennessee Health Science Center – Knoxville

Can't find your institution? It may use Single Sign On. Check here.

To find your organization, enter its name in the box above, then pick from the list of choices provided. If the selection is correct, click the "Continue to Step 2" button immediately below. To clear your selection and try again, click the "Search Again" button.

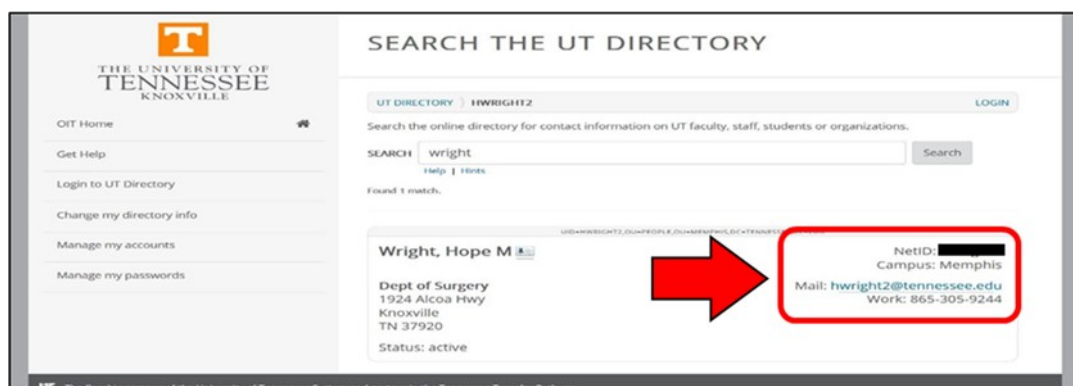
I AGREE to the Terms of Service for accessing CITI Program materials.

Continue To Step 2

Independent Learner Registration

Use this option if you are paying for your courses. Click the button "Continue as Independent Learner" to affiliate as an Independent Learner. This option is for persons not affiliated with a CITI Program subscriber organization, or who require

To find your NetID click on this link <https://directory.utk.edu/> and search your name. Your NetID will be located in the bottom right-hand corner of the directory information.



THE UNIVERSITY OF TENNESSEE KNOXVILLE

SEARCH THE UT DIRECTORY

UT DIRECTORY HWRIGHT2 LOGIN

Search the online directory for contact information on UT faculty, staff, students or organizations.

SEARCH wright Search

Help | Home

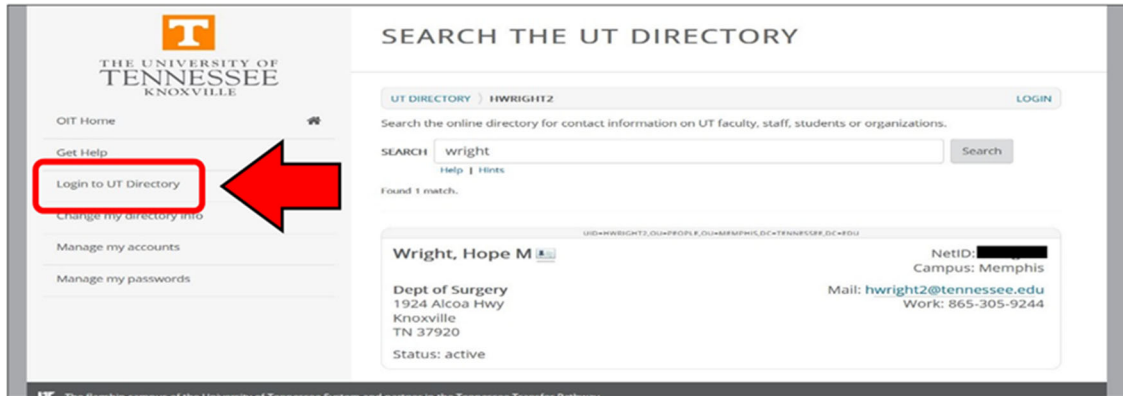
Found 1 match.

Wright, Hope M

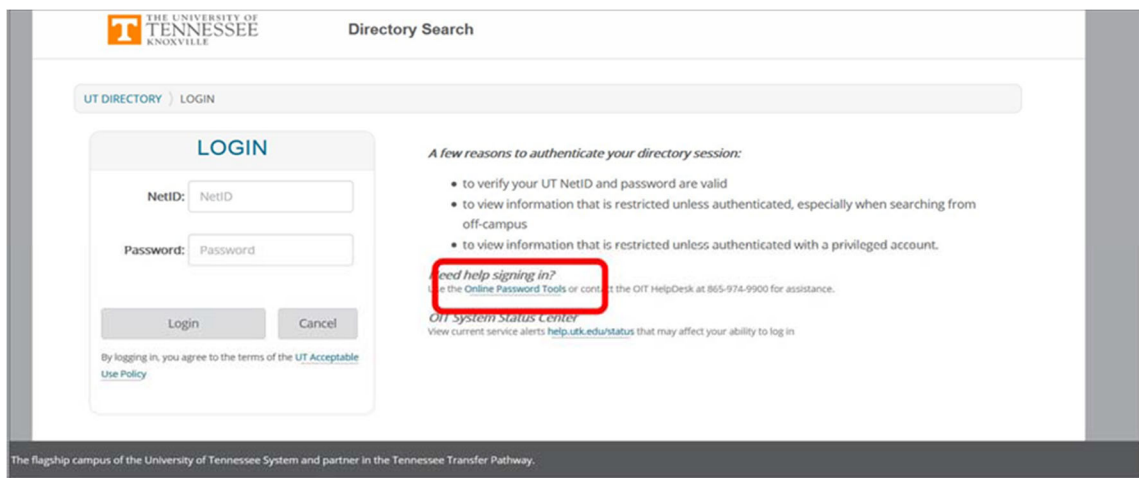
Dept of Surgery
1924 Alcoa Hwy
Knoxville
TN 37920
Status: active

NetID: [REDACTED]
Campus: Memphis
Mail: hwright2@tennessee.edu
Work: 865-305-9244

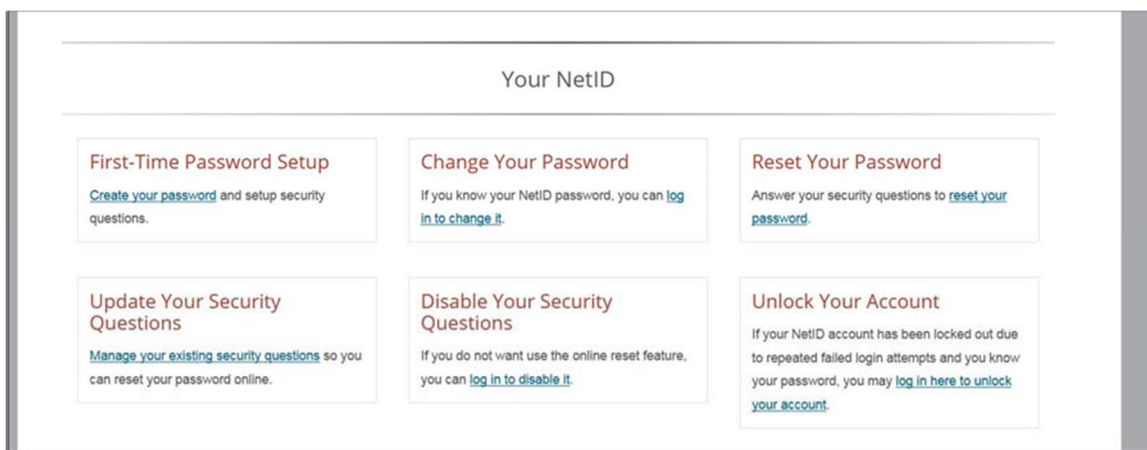
To setup or change your password click on "Login in to UT Directory" link which is located in on the left side of the same screen as your directory search.



Once you click on “Login in to UT Directory”, you will be taken to another page where you will click the link - “Online password tools”.

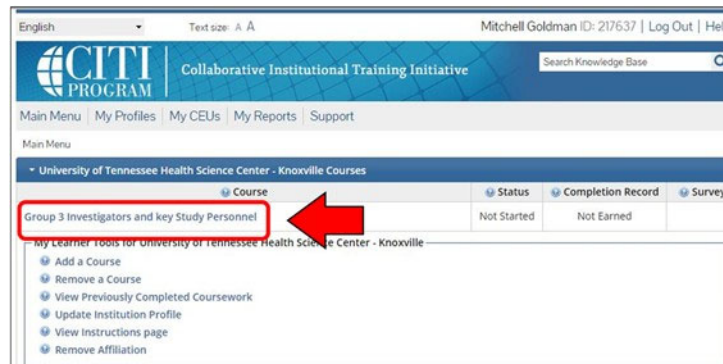


Select the desired link, “change password”, “setup password”, or “reset password”. It is highly recommended that when you do first time password set-up that you enable online reset password option.



If you do not have a NetID (and you cannot wait for one to be assigned to you) select University of Tennessee Health Science Center - Knoxville from the Organization Search Box and create your CITI account. You do not need to enter a personnel number; any number will do.

Choose **Group #3 Investigators and key Study Personnel for faculty & staff** or **Group #4 Fellows, Residents and Students**.



NOTE: The “Conflict of Interest” Module is only required if you are listed on grants going through the UTHSC Office or Research Administration (ORA) or you are named on a grant where the PI is at another University – otherwise, mark it “No” skip the animal question and click “Submit” at the bottom of the page.

On the home page, click “Start” next to the course name then click on the words "Integrity Assurance Statement" on the next page. Once you submit the "Integrity Assurance Statement" you will be taken to the list of modules.

Complete the required modules.

Pick three additional modules from the Elective list within Group 3 or 4.

If you originally took the CITI Course for Human Subjects Protection at another institution:

- i. You need to affiliate your registration with UTHSC-Knoxville so we can confirm your completion. By affiliating with us you get credit for the modules you've already taken toward your completion certificate for our site. You can be affiliated with multiple institutions. Follow the instructions below to get started:
- ii. Log into the CITI website <https://www.citiprogram.org> using your original user name and password. (Either the CITI officials or the administrator at your previous institution can help you if you've forgotten them).
- iii. At the top of the page click on “My Profile” and check the email address associated with your account and update it if needed.
- iv. Go back to your “Main Menu” and Click the "Affiliate with Another Institution" link at the bottom of your listed institutions.
- v. Under the "Participating Institutions" drop down box choose UT HEALTH SCIENCE CENTER - KNOXVILLE and click.
- vi. Fill out the Institutional Specific information page. Please include your department. We don't need your employee number; any number will do.

- vii. Choose Group #3 Investigators and key Study Personnel for faculty & staff or Group #4 Fellows, Residents and Students. **NOTE:** The Conflict of Interest Module is only required if you are listed on grants going through the UTHSC Office or Research Administration (ORA) or you are named on a grant where the PI is at another University – otherwise, mark it “No” skip the animal question and click “Submit” at the bottom of the page.
- viii. On the home page, click “Start” next to the course name then click on the words "Integrity Assurance Statement" on the next page. Once you submit the "Integrity Assurance Statement" you will be taken to the list of modules.
- ix. Complete the required modules.
- x. Pick three additional modules from the Elective list within Group 3 or 4.

CITI Conflict of Interest Requirements

If you are the PI or listed on a grant (particularly NIH and NSF) going through the UTHSC Office or Research Administration (ORA) or you are named on a grant where the PI is at another University, you are required to complete a Conflict of Interest documentation form. It can be found as a course on the CITI page: <https://about.citiprogram.org/en/series/essentials-of-research-administration/>. Log in and take the course. You may need to fill out a separate different form for other entities like the Medical Center or granting agencies. But this form is required for all funded research processed through UTGSM.

Agreements and Contracts:

Material Transfer Agreements (MTA)

What is a Material Transfer Agreement (MTA)?

MTAs are contracts with terms that govern the transfer of research materials and/or “know-how” between two or more organizations (universities, non-profit entities, or for-profit entities). The MTA defines the rights of the provider and the recipient with respect to the materials and any derivatives and modifications. As such, MTA’s can be either “Out-going”, where materials are being sent out by a researcher at the UT, or “In-coming”, where materials are being requested by a researcher at UT.

Why is an MTA necessary? (Source: Materials Transfer in Academic: 20 Questions and Answers, Council on Governmental Relations, 2003.)

The provider of material, know-how, or data may feel an MTA is needed in the following circumstances:

- The material and/or information is proprietary;
- The material or information is being maintained as a trade secret;
- The material is infectious, hazardous or subject to special regulations;
- The provider is concerned about potential liability; and/or
- The provider wishes to obtain rights to the results of the research in which the material or information is to be used.

How do I request research material from another institution?

- Whenever you request material from another institution, you may receive an MTA (“incoming MTA”) from the provider institution. You must submit that MTA, preferably in Microsoft Word format, with the provider’s contact information, to Kristen Vandergriff to enter into Cayuse and submit to UTHSC for review, approval, and signature.
- Check with Kristen Vandergriff ahead of time to see if the providing institution is a signatory to the UBMTA (Uniform Biological Material Transfer Agreement). If it is, and the other institution is agreeable, UTHSC may use a UBMTA Implementing Letter to expedite the review process.

The Uniform Biological Material Transfer Agreement (UBMTA) is a document approved by the Public Health Service and signed by a number of universities and non-profit institutions outlining approved terms of sharing biological materials. If both the provider and recipient institutions are signatories to the UBMTA, materials may be transferred under the terms of the UBMTA upon execution of an Implementing Letter for the particular transfer. Additional information about the UBMTA and a list of signatories is available at the [Association of University Technology Managers website](#).

- Route the MTA in the electronic routing system (Evisions/Cayuse) along with an Incoming MTA Questionnaire. This form provides necessary information used by UTHSC and University of Tennessee Research Foundation (“UTRF”) to review the document and

compare it to any other existing documents (e.g., funding agreements) to be sure no conflicts exist and to ensure that any university intellectual property is protected.

- When the UTHSC receives the MTA and Incoming MTA Questionnaire, it will review the document and negotiate any necessary changes and will also submit the MTA to the Biosafety Office and the Export Control Office for review and approval.

Biosafety must approve each material request, incoming or outgoing. Each time you request material to be sent to you or if you are sending material out, the material must be approved by the biosafety office, regardless of how harmless you may think the material is.

- Export Control reviews the documents and personnel involved to determine whether any export licenses are required.
- Make sure you include all animal protocol and rDNA numbers pertinent to the research involving the material. Please include the Biosafety # on the MTA questionnaire.
- For incoming MTAs with unusual intellectual property provisions or with ties to a Technology Disclosure, UTRF assists UTHSC in negotiating the terms of the MTA with the provider institution.

NOTE: If a colleague sends material to you without an MTA, you should check with the Biosafety Office to be sure there are no safety concerns and with the Export Control officer to be certain there are no export issues. To be certain there are no conflicts, you may want to contact Kristen Vandergriff, who will contact the institution providing the material to see if an MTA is required.

Someone has requested research material from me - what do I need to do?

- Whenever you receive a request to send material to another institution ("outgoing MTA"), you must submit the request in Cayuse **BEFORE SENDING THE MATERIAL**. Material should not be sent out without prior approval.
- Route an [Outgoing MTA Questionnaire](#) in the electronic routing system. This form provides necessary information used by GRA and UTRF to determine the type of MTA needed (the UBMTA, a simple MTA, or a special MTA if proprietary material is being requested). Once a determination is made about the type of MTA needed, GRA will upload the form into the electronic system.
- When the UTHSC receives the MTA via Cayuse, they will submit a copy to UTRF (if applicable), the Biosafety Office, and the Export Control office.
 - Biosafety must approve each material request, incoming or outgoing. Each time you request material to be sent to you or if you are sending material out, the material must be approved by the biosafety office, regardless of how harmless you may think the material is.

- Make sure you include all animal protocol and rDNA numbers pertinent to the research involving the material. Be sure to include the biosafety # on the MTA questionnaire.
- For MTAs that involve unusual intellectual property terms or if the material is related to a technology disclosure, UTRF assists UTHSC in negotiating the terms of the MTA with the recipient institution.

Who are the parties to an MTA?

- The parties to an MTA always include The University of Tennessee (UT) and the other institution. UTRF may be a party if the material to be provided by the University scientist has been disclosed to UTRF as part of a Technology Disclosure.
- **The University scientist is never a party to an MTA and should never sign the MTA for the University.** The recipient scientist at UT, however, may sign an acknowledgement of his/her obligations to abide by the terms and conditions of the MTA.

Who signs MTAs for UT?

- Most MTAs, like other contracts, are authorized for signature by a designated official at the UTHSC. In most instances, the authorized signatory is the Vice Chancellor for Research. However, all contracts, including MTAs that involve foreign entities require approval and signature by a system-level UT official.
- Faculty, Chairs, Deans, and other UT employees are NOT authorized to sign contracts (including MTAs) for UT. Only designated officials may sign contracts.

What are the main issues that may cause a delay in approval of the MTA?

- Sometimes negotiations are delayed because the MTA is not top priority for one party (usually the provider) or because approving officials are not available.
- Sometimes the material may not have been approved by the biosafety office. The investigator will have to work with the biosafety office to obtain approval.
- The primary reason for delays in MTAs is that the parties do not agree on the terms of the MTA. It sometimes takes weeks or months for the parties to negotiate terms that are mutually acceptable. This is especially true when the provider is a for-profit company. In rare instances, the parties may not be able to come to terms that are mutually agreeable, and the material may not be available to the University.
- Terms that are likely to extend the negotiation period include:
 - Indemnification/Liability- UT is an agency of the State of Tennessee and, as such, cannot agree to indemnify or hold harmless. UT can only agree to be liable for its own actions to the extent allowed by law (TCA 9-8-301 et seq.). In rare instances, the provider will not transfer material if they cannot be indemnified for UT's use of the material.

- Choice of Law/Jurisdiction- As a state institution, UT cannot agree to have the MTA governed by another state's law and cannot agree to the jurisdiction of another state. UT can agree to remain silent as to the choice of law, which usually resolves the issue. In rare instances (usually MTAs with foreign entities), however, the choice of law may be a deal breaker.
- Arbitration- As a state institution UT cannot agree to arbitration.
- Definition of material- Ideally, the MTA defines the material as including the material itself and any unmodified derivatives of the material. However, sometimes the MTA defines "material" as the original material AND modifications and derivatives of the original material. The provider normally retains ownership of the "material," as defined in the document; therefore, in such cases, the provider institution would own such modifications and derivatives, which may be inventions. By agreeing to such a definition, UT could put itself in the position of violating any applicable funding agreements, including both federal and non-federal grants or contracts. Also, if the provider claims ownership of derivatives and/or modifications, the provider could also own the results of the research. The investigator could be prevented from using his or her own research results in further research, transferring them to other organizations, meeting obligations to research sponsors or funding agencies, or ensuring that the results are made public. Federal regulations and other grantor policies require publication of the results of research and sharing of research material with other scientists.
- Intellectual property provisions- Some incoming MTAs state that the provider owns results and inventions arising out of the research (this usually happens with for-profit companies). Such terms, as an academic institution and recipient of external (including federal) funding. Also, if providers assert ownership over results and inventions, the investigator may be prevented from using results in future research and will have limited publication rights. Preemption of ownership rights could restrict the investigator's use of inventions in that it could limit the investigator's ability to interact with a future sponsor or may prevent the university from conveying rights to future licensees.
- Publication restrictions- Some MTAs require that the investigator obtain written consent from the provider to publish or the provider may request co-authorship. Such terms violate academic freedom and may conflict with funding agreements and journal requirements. Publication restrictions may also affect the investigator's ability to report results to sponsors or funding agencies. Sometimes delays in publication may be negotiated, provided that such delays are not excessive, are acceptable to the PI, and are not inconsistent with funding agreements.
- Illegal aliens- Pursuant to Tennessee state law, the University must require providers of material to attest that they shall not knowingly use illegal aliens in the performance of the contract (the MTA). This applies to all private domestic providers and international providers who have facilities in the US. Some providers do not wish to make such an attestation.

The parties have agreed upon the terms, now what?

- Once the parties agree upon the terms, the MTA is signed by all parties. Generally, the signature process takes a day or two. It may take longer if it is from a non-U.S. provider because the general counsel must review it, and a system-level official in Knoxville must sign it. In cases where exceptions to UT policy are required in order to sign the document, the signature process may take longer.
- Once the MTA has been signed by all parties, the provider should send the material. Sometimes it is necessary to send a reminder to the provider requesting that they send the materials and giving them shipping instructions.
- The provider should send the material to the investigator and the executed MTA to UTHSC. However, if the provider sends the executed MTA to the investigator with the material, the investigator should be sure to send the MTA to UTHSC; otherwise, UTHSC does not have a record that the contract is fully executed. Also, investigators should let UTHSC know that they have received the material.

Material Transfer Agreement (incoming)

- Proposed agreement
- MTA Questionnaire (incoming) available online at:
<http://www.uthsc.edu/research/gra/grants/documents/questionnaire-incoming-mta-rev-ds.pdf>
- Attestation re: Illegal Aliens for incoming MTAs with private domestic entities
- IBC approval if necessary, after reviewing the MTA Questionnaire.

Material Transfer Agreement (outgoing)

- MTA Questionnaire (outgoing):
<http://www.uthsc.edu/research/gra/grants/documents/questionnaire-outgoing-mta-rev-ds.pdf>
- IBC approval if necessary.

Material Transfer agreements are routed through Evisions/Cayuse. Please contact Kristen Vandergriff with MTA questions or to begin routing your MTA.

Confidentiality Agreements (CDA)

When researchers wish to work with entities, most often commercial companies, and discuss confidential or proprietary information (that is not protected, published, or otherwise in the public domain) a Confidentiality Agreement (CDA; or often referred to as a “Non-Disclosure Agreement”, NDA) may be required or requested. If this occurs, the sponsor contacts PI who then contacts either Kristen Vandergriff, or the Research Contracts unit of GRA at UTHSC. If GRA receives the document, GRA will forward it to the PI.

The PI will be sent a copy of the CDA/NDA from the other entity and then submits document via electronic routing system (Cayuse/Evisions) for department, college, and campus approvals – if

proprietary information is involved this may also be reviewed by the University of Tennessee Research Foundation (UTRF). The Office of Research at UTHSC reviews the document and negotiates final contract language, attaches final version and contract certification form in electronic routing system, and obtains institutional and sponsor signature.

Office of Research at UTHSC then uploads final executed contract in electronic routing system and notifies PI and Business Manager (and Sponsor if they signed first).

Confidentiality/Non-disclosure Agreements required information for routing:

- Proposed agreement – most often supplied by the external entity.
- Information about why UT is receiving or disclosing the information.

Contact information for the other party Confidentiality agreements route through Evisions/Cayuse. Please contact Kristen Vandergriff with CDA questions or to begin routing your CDA/NDA.

Sponsored Research Agreements

A Sponsored Research Agreement (SRA) is required when performing sponsored research with an external entity, generally a for profit company that requires research studies to be performed by a University laboratory. In general, the PI at the GSM and the external entity (“Company”) discuss the research project, following approval of a CDA/NDA. A detailed statement of work (SOW) including a budget, which should be prepared with the assistance of Kristen Vandergriff, and description of the studies to be performed is discussed with the Company.

After it has been decided that the Company will sponsor research in the PI’s laboratory an SRA document is required. This can either be initiated by the Company, or the PI may send a sample SRA document to the Company for review.

The PI, with the assistance of Kristen Vandergriff, initiates a Cayuse instance and uploads the detailed budget and SOW.

The SRA document will be reviewed by the UTHSC GRA and, if intellectual property might be involved, by lawyers at the University of Tennessee Research Foundation. This process may take many weeks to achieve.

Once a final, fully-executed SRA (signed by all parties) is in place, the PI can discuss with the business office (Deb Strahler) establishing a new account and invoicing the Company, as appropriate.

The PI is not a party to the SRA but is responsible for fulfilling the Universities responsibilities set forth in the document and therefore should be intimately involved in the development of the SOW and the SRA to ensure that everyone is aware of, and approves of, the requirements.

REDCap



REDCap is an acronym for Research Electronic Data Capture. REDCap originated out of the Vanderbilt Institute for Clinical and Translational Research.

REDCap is a web-based system for data collection. Data entry operators or people taking an online survey enter data in a web browser, either locally or from remote locations. The data is stored locally at UTGSM in a secure MySQL database.

The REDCap Consortium is comprised of over 1,700 active institutional partners from Clinical and Translational Science Awards, General Clinical Research Centers, Research Centers in Minority Institutions, and other institutions. The consortium supports this secure web application designed specifically to support data capture for research studies, but also used for many other secure online database needs. The REDCap application allows users to build and manage online surveys and databases quickly and securely, and is currently in production use or development build-status for more than 225,000 projects with over 317,000 end-users spanning numerous research focus areas across the consortium. For additional information, visit the [REDCap website](#).

If you are interested in beginning a research project using REDCap, please contact the UTGSM program administrators: GSMREDCap@utmck.edu.

Consultation for experimental design and biostatistical analysis

The Research Question: Quantitative Analyses

Researchers should come to statistical consultation with a research question that is defined using the PICO framework

- Population – Define the population of interest in regards to inclusion and exclusion criteria.
- Intervention – Explain the intervention or independent variable being studied.
- Comparator – Identify the comparison or control group.
- Outcome – State the outcome or dependent variable with its scale of measurement.

What type of research design should I use in my study?

The research design

Researchers should come to statistical consultation having decided if study data will be collected in a retrospective or prospective fashion

- Retrospective – The outcome of interest has already occurred.
 - -Case series, case-control, cross-sectional, retrospective cohort.

- Prospective – The outcome of interest will occur in the future.
 - -Prospective cohort, quasi-experimental design, randomized controlled trial.

What type of sampling methodology should I use in my study?

Researchers should think about the sampling methodology to be used

- Non-probability – Convenience sampling, purposive sampling (used with retrospective).
- Probability – Simple random sampling, stratified random sampling, clustered random sampling (used with prospective).

What variables should I collect in my study?

Researchers should come to statistical consultation with a list of variables they want to collect

- Demographic variables – Age, gender, ethnicity, income, education.
- Predictor variables – Grouping variables, treatment vs. control.
- Clinical or confounding variables – Comorbidities, personal history of disease, laboratory values, medications.
- Outcome variables – Primary and secondary outcomes.

How many people will I need in my study to achieve statistical significance?: Statistical power and sample size

Researchers should come to statistical consultation with a basic idea of what effect size they want to detect in the study.

An evidence-based measure of effect size is most preferable, use the values published in a study that is theoretically, conceptually, or physiologically similar to the study you want to conduct.

- Study design and outcome variable

- Between-subjects/Continuous outcome – What is the hypothesized mean and standard deviation of the outcome for each independent group being compared?
- Between-subjects/Categorical outcome – What is the hypothesized proportion of people in each independent group that will have the outcome of interest?
- Within-subjects/Continuous outcome – What is the hypothesized mean and standard deviation for each observation of the outcome/
- Within-subjects/Categorical outcome – What is the hypothesized proportion of people that will change across time?

How should I collect and store my study data for analysis? Database creation and management

Based on the demographic, predictor, clinical or confounding, and outcome variables, an Excel-based spreadsheet will be created for data entry and a data dictionary will be created to store variable coding schemes.

- Database.
- Data dictionary.

Qualitative Data Collection and Analysis.

The research question

- Population – Define the population of interest in regards to inclusion and exclusion criteria
- Sample – Define the sample that will be representative of your larger population
- Methods – Explain the way in which you will collect data from your participants (focus groups, observation or one-on-one interviews)
- Outcome – State the question you are trying to answer by conducting a qualitative study. (Answers “Why” or “How”)

The research design: What type of research design should I use in my study?

Qualitative studies require speaking with or observing a representative sample of the population you are trying to understand. The purpose of qualitative research is to gain insight and explore depth and richness in the problem or phenomenon of interest.

Qualitative studies are often designed to answer a “why” or “how” question rather than a “what” question. This can be achieved through observation, focus groups or one-on-one interviews.

Qualitative research can fall into one of five study methodologies:

- Case Study (most common in clinical research):
 - Purpose: To describe in-depth the experience of one person, family, group, community or institution.
- Narrative:
 - Purpose: To gain insight into a specific event or sequence of events typically from the perspective of one or two participants
- Phenomenology:
 - Purpose: To describe an event, activity or phenomenon
- Grounded Theory:

- Purpose: To provide an explanation or theory behind a specific event or sequence of events.
- Ethnography:
 - Purpose: To describe a culture's characteristics, challenges, motivations and goals

Sample size

Qualitative studies require fewer participants than quantitative studies. Qualitative studies can include anywhere from one to sixty participants. However, a typical qualitative case study will involve no more than twenty to twenty-five participants.

- More important than number of participants is achieving saturation in data collection
 - Data saturation is reached when there is enough information to replicate the study, when the ability to obtain additional new information has been attained, and when further coding is no longer feasible

How should I collect and store my study data for analysis? Data Collection & Analysis

Data can be collected in qualitative research by observing your population of interest or by conducting focus groups or one-on-one interviews.

- Observation:
 - **Field notes:** The researcher will log field notes and may make audio recorded notes when observing a population of interest. These notes will serve as your data for an observation-only study.
- Focus Groups:
 - **Participants:** Should represent your population of interest.
 - **Group Size:** Should consist of no more than six to ten participants (multiple focus groups may need to be conducted to achieve saturation)
 - **Moderator:** A trained moderator should lead the group in discussion
 - **Length:** Focus groups should last no more than forty-five to ninety minutes
 - **Questions:** A pre-determined set of questions should be included for the moderator to guide the discussion.
 - **Recording:** Focus groups need to be audio recorded to ensure accuracy
- One-on-one interviews:
 - **Participants:** Should represent your population of interest.
 - **Group Size:** One interview at a time (multiple interviews will need to be conducted to achieve saturation of data, unless a narrative approach is taken)
 - **Interviewer:** A trained qualitative interviewer should be recruited to conduct interviews.
 - **Length:** Interviews should last no more than forty-five to sixty minutes and can be conducted in person or via telephone.
 - **Questions:** A pre-determined set of questions should be included to guide the discussion.

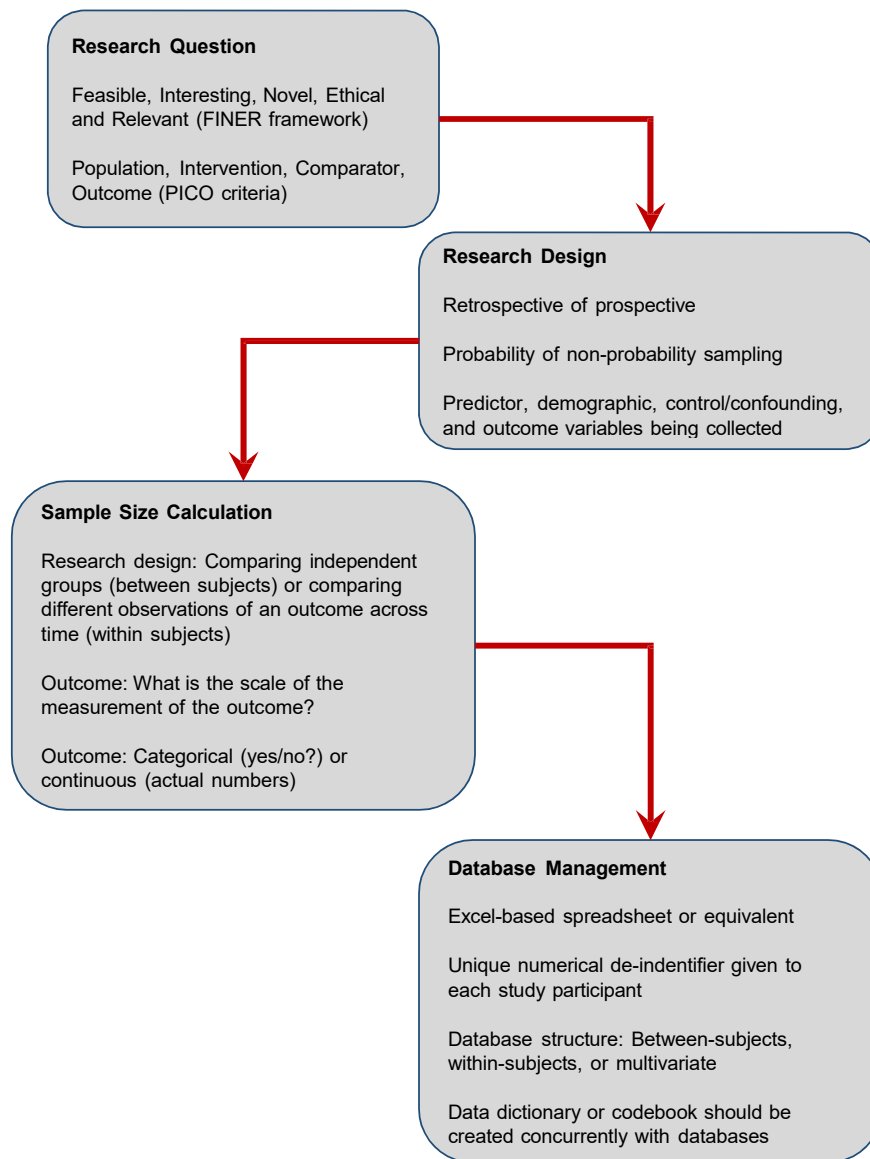
- **Recording:** Interviews need to be audio recorded to ensure accuracy

Qualitative data will be analyzed using transcriptions from audio files or by field notes.

- Audio files will need to be stored on a secure server.
- A transcription service will be required to transcribe participant audio files
- Transcriptions are analyzed by the researcher or qualitative analyst for reoccurring codes and themes.

Qualitative and quantitative designs can also be combined to conduct a “mixed-method” study.

Quantitative Analysis Workflow Chart



Working with animals at the GSM

The UT GSM Animal Facility

Prior to working with animals at the UT GSM, one should visit the lab animal facilities located in the basement of the Research Building. Ronnie Roberts (865-305-9451) is the manager of the lab animal facility at UTGSM and can explain the services that the facility provides and the type of animals which can be housed at the GSM. In general, mice and rats are the most common animals currently used at the GSM. If you need to use another species for your research, it may be necessary to coordinate with the College of Veterinary Medicine and/or another on-campus animal facility to provide housing facilities.

The animal facility provides bedding and food for the animals. In general, rodent cages are changed once per week. If you require more than one cage change per week, you will be charged accordingly. The current cage charges are as follows:

- Mice: \$5.25 per cage per month
- Mice: \$6.00 per cage per month for special care
- Rats: \$12.00 per cage per month

Up to five mice can be housed per cage and up to two rats per cage (depending on size).

Purchase and provision of specialty diets and bedding are the responsibility of the principal investigator. These items are not covered in basic cage charges. It is your responsibility to order and pay for these items and see that they are delivered to the animal facility with explicit instructions for their use. In certain cases, you may need to order additional cages, lids and/or tops for your animals.

Research animals housed in the animal facility are observed daily by the facility staff. Office of Laboratory Animal Care (OLAC) employees will also check each animal at least once per week to observe the health condition of the animal.

Any procedures (i.e., injection, bleeding, etc.) performed during the lifetime of the animal must be noted on the cage cards. If surgery is performed, you must maintain a surgical cage card and keep detailed surgical notes.

The animal facility staff do not perform any type of handling of the animals other than when cages are changed. In other words, if you need your animals weighed, body condition score noted, injected or any type of their manipulation associated with your approved research protocol, you are responsible – the animal staff are not on your protocol and do not perform animal manipulations. They will note if an animal is distressed, has a wound or sore, exhibits labored breathing or anything out of the ordinary. The principal investigator will initially be contacted should signs of distress be observed and a “red card” (sick animal card) will be filled out by the facility staff and the OLAC veterinarians will be contacted. Appropriate medical care will be recommended or the animal may need to be euthanized, if necessary.

When you are working in the animal facility, you will need to wear personal protective equipment (PPE). Minimally, this constitutes a clean lab coat and gloves. Closed toed shoes are also required.

Do not enter the UT GSM animal facility if you have previously been in another animal facility (on campus or the vet school for example). This will prevent cross-contamination of the animals.

Animal Training

Prior to writing an animal protocol, you will need to receive training from the Institutional Animal Care and Use Committee - IACUC (<http://iacuc.utk.edu/>) or the veterinarians at OLAC. The IACUC is a federally-mandated committee, qualified through the experience and expertise of its members, that oversees its institution's animal program, facilities, and procedures. It provides a framework for compliance with federal policies, guidelines and principles related to the use of animals in research, teaching and testing. There is a wealth of information on the IACUC website regarding all aspects of the appropriate use of animals in research projects.

At a minimum, the principal investigator and anyone working on a protocol will need to complete the online training: The American Association for Laboratory Animal Science (AALAS): Working with the UT Knoxville IACUC Course (<http://iacuc.utk.edu/training/>). Depending on the research goals, it may also be necessary to complete additional training. Detailed information of these requirements can be found on the IACUC website. IACUC training, for all personnel named on an active animal protocol, will need to be renewed annually.

Additionally, all personnel on a protocol will need to enroll in the Occupational Health Program and complete yearly updates. The OHP contact is Amy Knowles (aknowles@utk.edu)

If you do not have any experience with the techniques you plan to perform as part of your research, the OLAC veterinarians offer periodic training laboratories and can assist with personalized one-on-one training in specialized techniques if needed and/or possibly refer you to an experienced researcher.

Animal Protocol

You are now ready to write your IACUC protocol (also see IACUC protocol Section in this Guide).

The protocol form can be found at <http://iacuc.utk.edu/forms/>. This is a very extensive form – do not expect to fill it out in an hour! Take time to consider what you hope to accomplish in your research with animals and note all procedures you will be doing.

When you have completed the form, you will need to submit it, via email, to the IACUC coordinator, Elizabeth “Betsy” Bailey (ebailey@utk.edu). She will check over your form and then send it to Biosafety (if necessary), Radiation Safety (if necessary), OLAC veterinarians, then to the IACUC committee for comments and finally to a designated IACUC member reviewer. In some cases, animal use protocols will be called for full committee review. The IACUC meets on the second Tuesday of every month.

Approval of an IACUC protocol may take more than 4 weeks from submission and may require several rounds of iterative updates and protocol changes before it is suitable for approval by the committee.

NOTE: DO NOT deviate from specific methods described in the approved protocol. If you find that you have not noted a procedure (e.g., you need to inject IP instead of IV or you need to inject a different compound), you will need to fill out and file a protocol amendment form.

Annually, you will be required to submit the total number of animals used on each protocol to IACUC, so be sure to keep detailed records of your animal usage.

Once your protocol is approved, the OLAC Post Approval Monitoring (PAM) Officer will want to observe you while you are performing the procedures you have described in your protocol. They will be checking to make sure you are not deviating from the approved methods described in the protocol.

Animal Procurement and Transfers (Including Quarantine)

You are responsible for ordering your research or teaching animals that approved for use in your protocol.

A list of suppliers (for mice and rats) are provided, below. To acquire animals you will need to fill out an Animal Requisition form from the Office of Laboratory Animal Care (OLAC) (https://vetmed.tennessee.edu/research/Pages/olac_forms.aspx). Complete the animal requisition form and give a copy to Ronnie Roberts in the lab animal facility **before** the animals are ordered.

Ronnie will verify that the species, strain, and number animals are consistent with your protocol, the request form will then be sent to IACUC for approval. Additionally, the animal facility will need to be prepared to receive the animals from the courier. When animals arrive, the transport boxes are routinely sprayed with disinfectant before they are received into the facility.

If you will be receiving animals from a non-approved vendor (i.e., another country, a colleague at another institution, etc.), you are still required to fill out the above form; however, additionally, OLAC will request information from the non-approved facility such as recent health reports, etc. If the supplier does not meet suitability criteria (for example, questionable health status of the animals), your request will be denied.

Only after OLAC approves your request can you order animals. Animals from non-approved vendors (including other Universities) are required to go in quarantine for a minimum of six weeks and **CANNOT** be used (for experimental procedures or breeding) during this period.

https://vetmed.tennessee.edu/research/Documents/OLAC/policy_animal_procurementUTK_OLAC.pdf

Transport

Hopefully, you included a description of the transport procedures for your animals in your IACUC protocol. Even if you are just bringing animals to your laboratory (from the main animal facility) for a few minutes, you must include a detailed description of this in your protocol. To transport animals within UTMC, the animals need to be covered - towels work fine if you are only transporting within the research wing. However, if you are transporting animals through other areas of the hospital, (particularly where patients may be present) the animals will need to be ENCLOSED and on a transport cart. We have found that 15 gallon opaque Rubbermaid totes work well for this purpose.

NOTE: Remove the water bottles from the cages during transportation to prevent flooding of the bedding.

If you are transporting animals from GSM to another location (e.g., UTK campus), there is a Standard Operating Procedure (SOP) available on the IACUC website at <http://iacuc.utk.edu/policies-and-procedures/> to assist with requirements for this process. If you are transporting mice or rats, the cage will need to be placed in a lidded container (again Rubbermaid totes work well) and transported in a climate-controlled vehicle. Do not leave animals unattended in your vehicle. If you intend on returning animals to the GSM, you **CANNOT** return them to the main facility, they will need to be housed in a quarantine room, but in this case the animals are not subject to the 6-week restriction.

Satellite Laboratory

If you will be housing animals in your laboratory for more than 12 hours, you will need to apply to the IACUC to establish a Satellite Facility. You will submit your request to IACUC along with an extensive questionnaire describing your housing and husbandry plans. This includes but is not limited to: type of housing enclosure, food and water provided, temperature (control and monitoring), humidity (control and monitoring), ventilation, records, and security. This form can be found at <http://iacuc.utk.edu/forms/> under Policy and Application for Establishment of a Satellite Animal Facility. Once you have established a satellite facility, it will be subject to the same inspection schedule as your laboratory.

Breeding Colonies

If you will be breeding mice and establishing a colony, you will need to submit an IACUC protocol specifically for this purpose. It is advisable, although not an IACUC requirement, to maintain separate breeding and experimental animal protocols.

In the breeding protocol, you will need to detail your breeding strategy and expected percentage outcomes, procedures (such as tail snips), etc. When you set up your breeding cages, there are breeding cards that are specific for these cages. The animal facility staff will note on the cards when a litter is born. It is your responsibility to wean the litters (at three weeks for mice) and set up new cages for the weanlings housing males and females in separate cages. Do not combine males from separate litters (as they will fight); however, females will usually co-exist if you combine them from separate litters.

Depending on your strain, you may need to genotype your mice. You will need to collect DNA (usually by tail snip) and permanently mark your animal with an identifying number (usually by ear code punch or ear tag). Again, this process will need to be described in your breeding protocol.

You will need to transfer mice from your breeding protocol to your experimental protocol – if they are separate. Currently, internal transfer (within a laboratory) does not require an official notification or request to OLAC; however, transfer to a protocol held by another principal investigator (within GSM or UTK) does require a transfer request and approval from OLAC.

Semi-Annual IACUC Inspections

Now that your protocol is approved, be prepared for your laboratory to be inspected! If you will be transporting animals to your lab for procedures and/or maintaining a satellite facility, these areas will be inspected. The IACUC conducts semi-annual inspections of all laboratories that are included on an IACUC protocol. The inspection team will consist of two members of the IACUC committee. Any area where animal work is being performed should have been noted on your protocol and will be inspected. Some (but not all) of the items noted on inspection are: laboratory notebooks including surgical care cards, expiration date on drugs and/or any compounds used in animals, etc., certification of hoods, certification of vaporizers, correct disposal of needles/sharps, general cleanliness, training records, protocols, etc. Please contact Kristen Vandergriff or Tina Richey (trichey@utmck.edu) for assistance with certification of laboratory hoods or vaporizers.

Additional Resources for Animal Supplies

Equipment:

- Braintree Scientific: www.braintreesci.com
- Kent Scientific Corporation: www.kentscientific.com
- Ancare: www.ancare.com

Veterinary Supplies:

- Vet Med Direct: www.vetmeddirect.com

Surgical Tools:

- Fine Science Tools: www.finescience.com

Laboratory Animals:

- Taconic: www.taconic.com
- The Jackson Laboratory: www.jaxmice.jax.org
- Charles River Laboratories: www.criver.com

Food and bedding:

- Envigo: <http://www.envigo.com/products-services/teklad/>

Maintenance and other issues in the Research Building

The research coordinator, Kristen Vandergriff, is responsible for the management of our research facilities. This includes, but is not limited to:

- Key requests.
- Laboratory cleaning requests – e.g., special cleaning requirements such as waxing the laboratory floors.
- Water/sink issues.
- Electrical issues.
- Eye wash issues.
- Refrigerator maintenance/issues.
- Paper towel dispenser problems.

For any maintenance issues, please contact Kristen Vandergriff.

For maintenance of your laboratory equipment, you will need to use UT Biology Service Facility, not hospital maintenance. The website and online submission form for UT BSF can be found here:
<http://bsf.utk.edu/index.php>

Ordering supplies and purchasing equipment

- The ordering of most supplies and equipment should be done on the UT Marketplace website. See below for step-by-step instructions on ordering from the Marketplace. There are also training videos available on the site for new purchasers. All new staff will have access to the Marketplace by using Mozilla Fire Fox or Google Chrome to log into <https://irisweb.tennessee.edu> with your UT NetID and password.
 - Note: There will be exceptions when the vendor that you want to order from is not listed on the Marketplace site. In this case you may generate your own Purchase Order and order directly from the company as long as that vendor is in the UT system. Contact Deb Strahler in the UTGSM Business Office to determine if the requested vendor is in the UT system before ordering. Attached is a sample of a blank purchase order.
- If you plan to purchase any equipment over \$10,000 from a source other than the Marketplace, you must first acquire a quote from multiple vendors. Send quotes from 2-3 vendors and any specifications on the requested equipment to the UTGSM Business Office. The Business Office will take into consideration your specs and item pricing and will purchase the item on your behalf.
 - Note: If you are ordering equipment on the Marketplace you are not required to go through the quote process or have a bid approved for items less than \$100,000. For items over \$100,000 contact the UTGSM Business Office to help facilitate the approval process through the Comptroller's Office.
- Retain all packing slips when your supply/equipment order has been received. All invoices received by the UTGSM Business Office are forwarded to the appropriate laboratory or office for approval. The PI/supervisor should sign each invoice to approve for payment, supply the grant/account number of the funds to be used, and staple all packing slips to the invoice to confirm receipt of item(s). Send the original invoice and packing slips back to the Business Office for payment. Always retain copies for your lab's records.
- For any questions about ordering or procurement contact Kristen Vandergriff or Deb Strahler in the Business Office at 865-305-6192.

PURCHASE
ORDER

TO:

SHIP TO:

P.o. number	P.O. DATE	Cust. #	Telephone	fax
			(865) 305-	(865) 305-

qty	unit	description	unit price	total

Send Invoice To: University of Tennessee
 Graduate School of Medicine
 Business Office, U-100
 1924 Alcoa Highway
 Knoxville, TN 37920

Step-By-Step Instructions for Using the Market Place

Getting Started

Using Mozilla Fire Fox or Google Chrome, log into <https://irisweb.tennessee.edu> with UT NetID and password.

Click on “Shop” tab.

Disable Pop---Up Blocker (click on “options” and select “allow pop ups for irisweb.tennessee.edu”).

First Log In

- Set up default ship to and bill to addresses:
 - Menu → Profile → Locate default ship to address (right side of page) and click “edit”.

- Enter first letters of department name. If address is there, select and click “update”.
- Repeat for bill to address.
- If department address is **not** found under default or is not correct:
 - Return to “Shop” page. Click on “Add or Update Bill to and Ship to Address”.
 - Complete all fields and click “Submit”.
 - An email notification will be sent when addresses have been added or updated.
 - After receiving this email notification, return the Menu → Profile to set your address as default.
- For shoppers only, set “Transfer cart” selection.
 - *Cart should be transferred to the person who will complete the order.*
 - Menu → Profile → Locate “cart transfer to” (lower middle of page) and click “edit”. Type all or part of the person’s email address, select and click “update”.

Shop

- Select vendor. Select items and specify quantity.
- Follow the vendor’s prompts to submit the order. The items will be sent to a Market Place cart.
 - *Items from multiple vendors may be placed in the same cart. Market Place will sort the items into separate vendor transactions for check out.*
- Select “cart” to review items. Click “continue” to send cart to the person who will complete the order.

Check Out

Departmental Specialists and Approvers may modify, delete, or release an order here.

An email notification will alert the specialist or approver that a cart has been forwarded for checkout.

CLICK 1 to the left of a transaction to display the three sections: header, line items, and footer. *Red asterisks indicate required information, other cells may be used as needed by the department.*

Transaction Header

Transaction Name:	Use the system generated name or edit as needed.
Payment Form:	Select one. Credit card details are entered prior to check out.
Asset:	Select one. For assets \geq \$5,000.00, payment form must be PO (invoice).
Ship to – Attn:	Defaults to the person who created the order. Edit as needed.
Account Assignment:	Click “details”. Enter account# in fund cell. Click “update” and “apply”.

Once an account# has been entered, it may be selected from the account assignment drop down.

Transaction Line Items

Account Assignment: If particular line items are to be assigned to various accounts, edit here.

Transaction Footer

Bill To --- Attn: Enter name.
Ship To/Bill To: Click "edit" to change the default bill to or ship to addresses as needed.

Completing an Order

For a PO (invoice) purchase: click "validate", "check", "release", "continue", "place order".
For a CC purchase: click "validate", "check", "prepare", enter credit card information, "continue", "place order".

Helpful Market Place Tools

Order Summary

Includes transaction#, create date, requestor, supplier, status, system note, and total value.

Menu → Order Summary → select fields by which you wish to search → enter criteria → click "search". Click "export" to receive an Excel copy of the report via email.

Reports

Includes date, transaction#, supplier, item/service purchased, account#, quantity, unit cost, order total, payment form, and requestor.

Two reports to choose from: "Credit Card Transactions" or "All Transactions"

Menu → Reporting

Click expand button to the left of "University of Tennessee General Reports".

- Select the desired report.
- Select preferred format from the "execute" drop down button located above the report options.
- In "filter by" box, highlight "transactions fiscal date", then enter beginning and ending dates in the fields below.
- Highlight "item account codes" and enter all or part of the account number.
- Click "OK".

Additional Resources

Market Place Training Videos: <http://marketplace.tennessee.edu/training.html>

Contact for Support: BJ Roberts – broberts@tennessee.edu

Karen Binkley – kbinkley@utk.edu Phone: 865---974---3311

Space allocation policy and procedures

The UTHSC space allocation policy can be found at: <https://www.uthsc.edu/research/about/reports-and-publications/documents/space-plan-2016.pdf>

Grants

Evisions Research Suite

Effective 12/28/2015, all federal grant applications will be submitted using the Evisions Cayuse 424 grant preparation system rather than the 424 Adobe packages, unless the Funding Opportunity Announcement (FOA) requires a different means of submission. Cayuse 424 is an online system that links the 424 grant package with the sponsored projects (SP) routing system.

To prepare a grant, the PI, with assistance from Kristen Vandergriff (and other members of the research team, e.g., who may provide statistical methods, editing, or proof-reading) generates each component (see below) for uploading into the online 424 package and enters the information in the online 424 form pages.

IMPORTANT: Contact Kristen Vandergriff as soon as you know that you will be submitting a grant application that requires electronic submission so that she can begin working with you on the budget and preparation of content to ensure that the grant package is complete and that everything is ready before the internal routing deadline, which is 5 working days prior to the submission deadline.

Cayuse SP

Internal routing is required prior to submission of ALL grant applications, including those with electronic submission systems that allow the PI to enter data directly into the agency web site. In most instances, an institutional official must sign off on the application, either electronically or in paper form, before it is accepted by the agency.

The SP module of the Evisions Cayuse 424 system, which replaced PAMS, is used to electronically route all documents that require review and/or signature by the Office of Grants and Research Agreements (GRA) at UTHSC.

Cayuse 424

To gain access to the Cayuse SP 424 system, contact the departmental business office (Deb Strahler) who will enter information into the human resources database to allow you access to Cayuse either as a "researcher" or "administrator." If you need to be included on proposals as a member of the project team, you should be identified as a "researcher."

Grant Deadlines

The UTHSC Faculty Senate has approved a 5-working-day internal deadline for all grant applications, including those that must be submitted electronically. The **FINAL** version of the application is due to be routed in SP on that date. This means that the final version of the grant needs to be submitted to Kristen Vandergriff 7 days ahead of the deadline to allow sufficient time for uploading into the system. **NOTE:** Allow sufficient time for errors and unforeseen complications to be corrected and addressed during this time. **NOTE:** That in cases in which an agency has a deadline past 5 p.m. Central time, UTHSC deadline is 5 p.m. Central. Grant applications that arrive past the 5-working-

day advance deadline will be reviewed as time permits but are not guaranteed to meet the agency submission deadline

The following articles and general guidance for preparing grant applications to the NIH are available from UTHSC at: <http://www.uthsc.edu/research/gra/grants/grant-writing-tips.php>

- “The Buck Starts Here”, By Karen M. Markin: From the Chronicle of Higher Education issue dated February 21, 2005
- Choosing an Appropriate NIH Funding Instrument and Funding Mechanism: NIH
- Descriptions of the IRGs, Study Sections, and Small Business Activities of the Center for Scientific Review: NIH Center for Scientific Review
- Peer Review Guidelines and Information: NIH Center for Scientific Review
- Preparing Grant Applications: NCI
- Quick Guide to Grant Applications: NCI
- Quick Guide to the Preparation of Grant Applications
- Complementary and Alternative Medicine (NCAM)
- Resources for New Investigators: NIH Office of Extramural Research
- SBIR/STTR Policy and Grantsmanship Information: NIH Office of Extramural Research
- “Words Worth Their Weight in Cash”, By Karen M. Markin: From the issue dated April 8, 2005
- Vertebrate Animal Section - PHS Grant

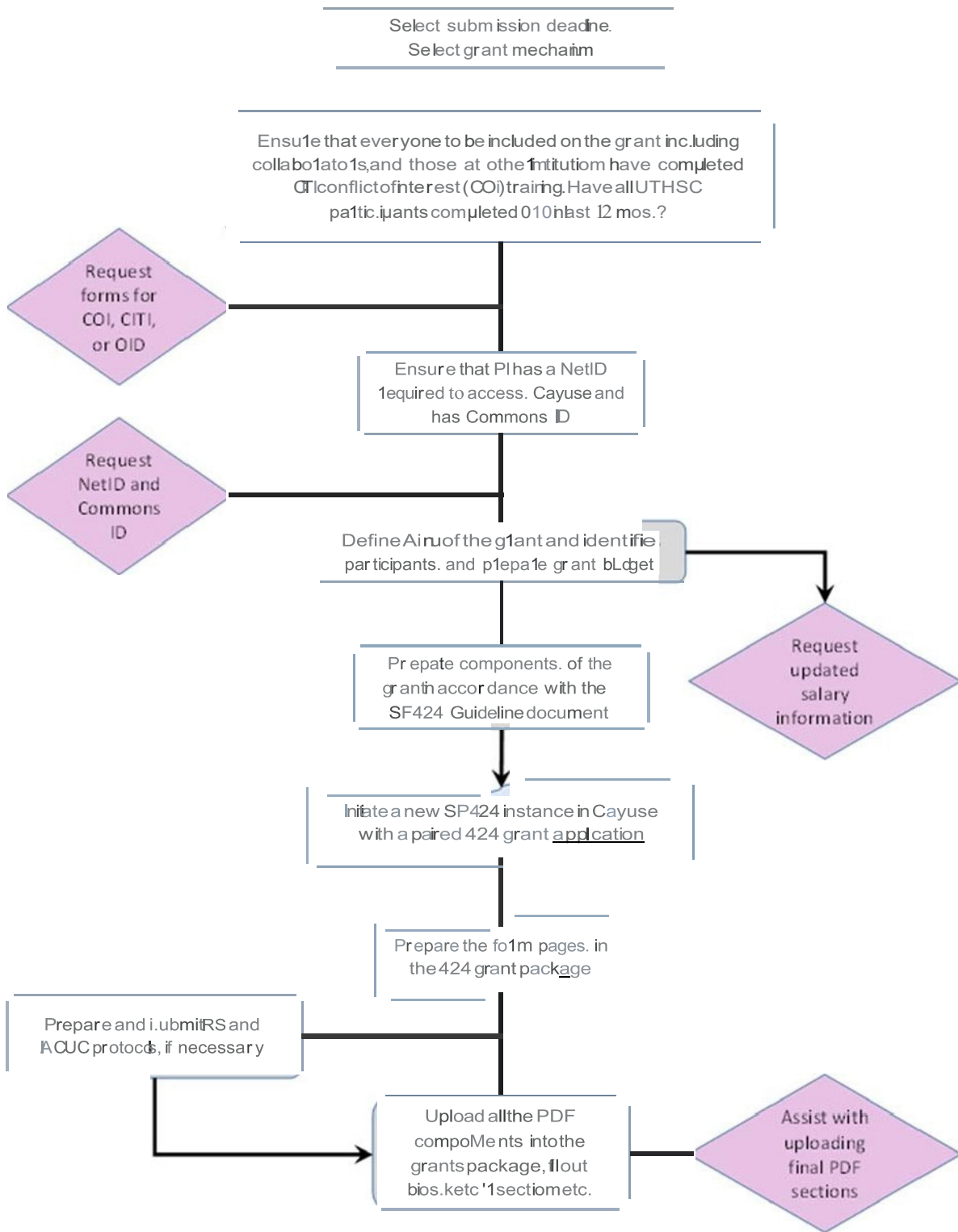
Guidance on submitting an NIH Grant:

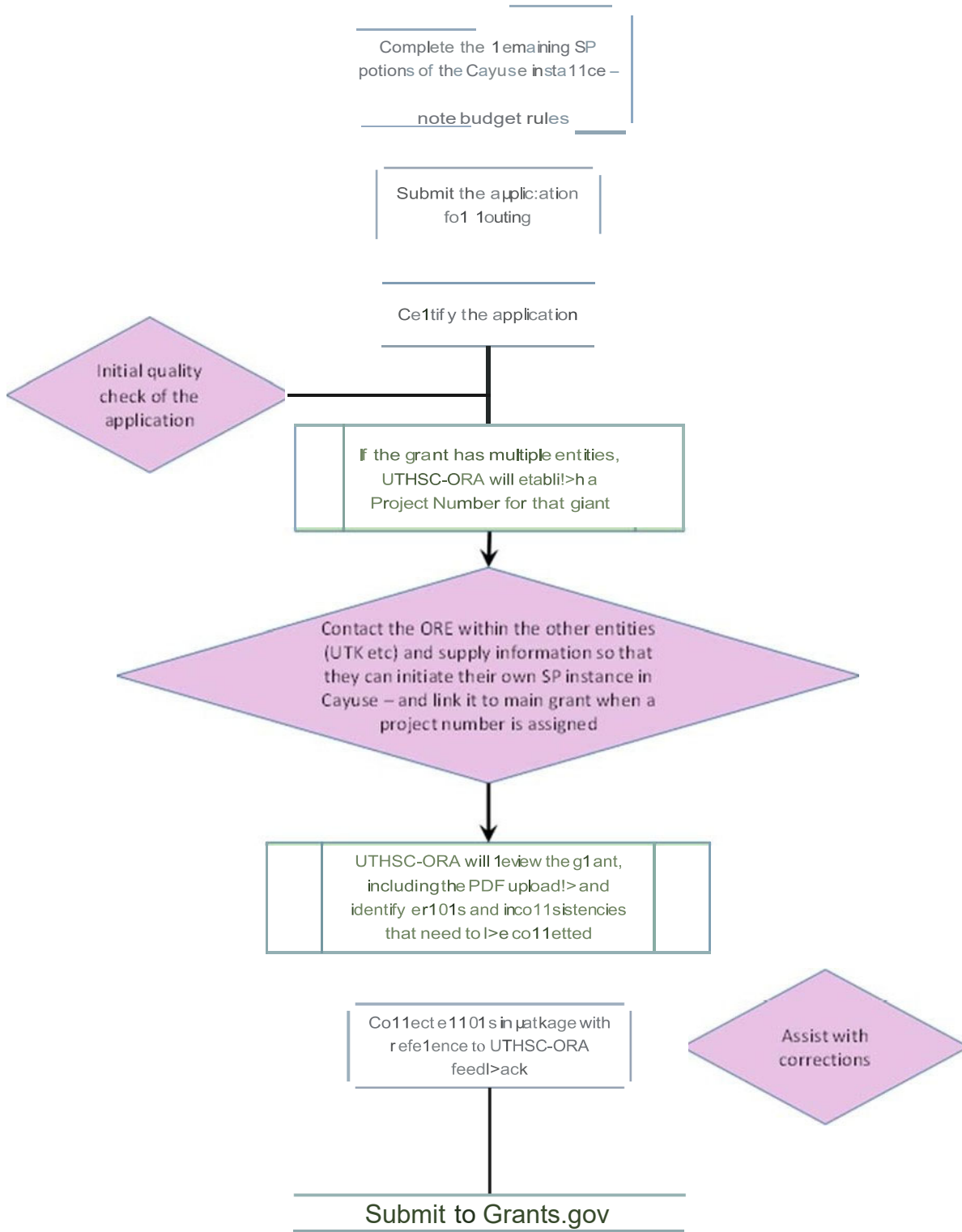
- PI: Selects the target submission deadline. There are 3 deadlines a year (every 4 months).
- PI: Should allow sufficient time for preparation and review of the application. Generally, preparation of the application (R01) takes 2 months (at 25% effort). Review and preparation of package at UTMC takes 1 – 2 weeks, review by UTHSC takes 1 week.
- PI: Selects grant mechanism, most commonly –
 - R03 – Up to 2 yrs. \$50,000 direct per year. 6 p research strategy. Only certain Institutes participate. Parent application is, PA-16-162.
<https://grants.nih.gov/grants/funding/r03.htm>
 - R21 - Up to 2 yrs. Total \$275,000 direct for whole application. 6 p research strategy. Only certain Institutes participate. Parent application is, PA-13-303.
<https://grants.nih.gov/grants/funding/r21.htm>
 - R01 - Up to 5 yrs. Total \$500,000 direct per year (without special request). 12 p research strategy. Parent application is, PA-11-260.
<https://grants.nih.gov/grants/funding/r01.htm>
- PI: Ensures that everyone mentioned on the grant including collaborators, and those at other institutions have completed CITI conflict of interest (COI) training and has proof of such.
- PI: Ensures all UTHSC participants have completed (within last 12 months) an outside interest disclosure form and that this is on record.
- PI: Ensure that they have a NetID required to access Cayuse for grant preparation.

- **NOTE:** Contact pre-award and research coordinator (Kristen Vandergriff) if the PI does not know their NetID.
- **NOTE:** If it is the first time submitting or participating on a research project it may take 2-3 days to request access to Cayuse from UTHSC. Kristen Vandergriff will request this if necessary
- PI: Ensures that they have been assigned a Commons ID – obtained by Kristen Vandergriff
- PI: Defines Aims of the grant and identifies participants.
- PI: Asks Kristen Vandergriff to supply details on the salary for each person to be included on the grant. For personnel at other entities (UTK, CVM etc) PI requests salary information from those personnel.
- **NOTE:** Salary allowed on NIH grants does not include longevity pay.
- PI: Prepares the budget with Kristen Vandergriff's input and guidance to ensure the correct fringe and F&A rates are used and applied where appropriate.
- **NOTE:** There is no F&A on equipment costs and certain other budget categories.
 - F&A for UTMC on campus research is 40%.
 - Fringe rate is 34.5% (average) – must use individual fringe if personnel have higher rate.
 - Add 3% to base salary for Yr 1 of grant to account for potential pay increase prior to award start date.
 - Increase annual base salary for UTMC personnel by 3% each year.
 - Only apply F&A to first \$25,000 of sub-awards.
 - UTK and CVM are not considered sub-awards on UTHSC grants.
- PI: Prepares components of the grant in accordance with the SF424 Guideline document (<https://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/research-forms-d.pdf>)
- There are ~ 15 sections (for R01) to be generated and converted to PDF files for uploading into the grant package:
 - Cover letter – signed
 - Project summary/abstract (no more than 30 lines).
 - Narrative (3 sentences only).
 - Bibliography.
 - Facilities and Other resources.
 - Equipment.
 - Biosketch for all key personnel – Use new format (Form D - OMB No. 0925-0001 and 0925-0002 [Rev. 11/16 Approved Through 10/31/2018]) - 5-page max per person.
 - Budget justification.
 - Specific Aims – 1 page
 - Research strategy (12 pages for R01)
 - Protection of human subjects' statement - if necessary.

- Vertebrate animals section – if necessary.
 - Resource sharing plan.
 - Authentication of key Biological resources (suggested 1 page limit).
 - Letter of support from collaborators, consultants etc.
 - Sub-award agreement form for entities other than UTK and CVM (if necessary) – <https://www.uthsc.edu/research/gra/grants/documents/subrecipient-commitment-form.pdf>
 - Multiple PI plan statement (if necessary): - <https://www.uthsc.edu/research/gra/grants/documents/sample-nihm-p-iplan-all-ut.pdf>
- **NOTE:** See also the FAQ page at UTHSC for more information - <https://www.uthsc.edu/research/gra/grants/faq.php#electronic-submissions-site>
 - **NOTE:** The PI is responsible for preparing and obtaining approval for protocols from the IRB and IACUC before funds are awarded by the NIH and work can begin; however, an NIH grant can be submitted prior to obtaining IRB and IACUC approval for the project.
 - PI and/or Kristen (with PI's input): Initiate a new SP424 instance in Cayuse with a paired 424 grant application.
 - **NOTE:** All NIH grants are now prepared online through the Cayuse portal.
 - **NOTE:** A NetID is required for the PI to access the Cayuse portal.
 - PI and/or Kristen (with PI's input): Prepare the form pages in the grant package – See “Cheat sheet” [to be prepared] for SF424 form page data
 - PI: Uploads all the PDF components into the grants package, fills out biosketch sections etc. Alternatively, the PI can supply all the PDF files (final versions only) to Kristen Vandergriff who will upload them into the grant package. This process takes 15 min and is easily achieved by the PI.
 - **NOTE:** The PI has a copy of all the components of the grant package, because he/she prepared them. If the PI supplies PDFs to Kristen Vandergriff for uploading he/she should only supply the final copies to avoid confusion with older versions.
 - PI and/or Kristen (with PI's input): Completes the remaining SP portions of the Cayuse instance which includes Institutional information and a summary of the UTHSC portion of the NIH budget.
 - **NOTE:** If there are multiple entities on the grants UTHSC, UTK, and CVM then each has a base budget with its own F&A rate and an individual fringe rate. The budget components from the non-UTHSC entities are excluded from the budget before adding it to the SP portion of the instance.
 - PI and/or Kristen (with input from the PI): Will contact the ORE within the other entities (UTK etc.) and supply information so that they can initiate their own SP instance in Cayuse – and link it to main grant when a project number is assigned (see below). Material supplied to the entity includes the budget (for that entity), the abstract (prepared by the PI), the budget justification for the entity personnel (prepared by the PI), and pertinent grant details (typically - title of the grant, start and end dates, number of years, and the program announcement link).

- Once the grant and SP forms have been completed the grant is routed
- **NOTE:** The PI is required to login to Cayuse and certify the SP submission immediately after the routing process has begun.
- **NOTE:** At that point Kristen Vandergriff can perform an initial check to ensure there are no errors in the SP portion - the grant is then routed to ORE in Memphis.
- ORA-UTHSC grant expert (Mira Mihajlovich): If the grant has multiple entities, Mira will establish a Project Number for that grant
- **NOTE:** The Project Number will be supplied to the other entities by Kristen Vandergriff so that they can link their SP instances to the main application.
- **NOTE:** The grant cannot be submitted by UTHSC until all entities have approved their components and have linked their SP instances to the main grant.
- ORA-UTHSC: Will review the grant, including the PDF uploads and identify errors and inconsistencies that need to be corrected.
- **NOTE:** The PI should be prepared for errors in the package. This is inevitable and the PI should be available and prepared, during the time of grant review to address problems.





The Physicians' Medical Education and Research Foundation (PMERF)

Research Grant Application

Overview

In the mid-1960s, Knoxville area physicians joined as a group to support medical education and research in the community.

This group of physicians chartered the Physicians' Medical Education and Research Foundation (PMERF). They believed that the future of health care in this region depended on the local education of aspiring healthcare providers, local research (basic science, translational and clinical) and the local control of funds raised to meet these aims.

The Physicians' Medical Education and Research Foundation is a charitable, nonprofit medical educational foundation that provides funds (in the form of peer-reviewed grants) for the support of clinical research, education, and training. The Board of Directors will consider investigator-initiated proposals for clinical/biomedical research, educational enhancement requests, as well as proposals from any benevolent charitable organization engaged in the development, promotion, or enhancement of community based medical education and research.

Grant Application Procedure

Application forms are available from the PMERF office at The University of Tennessee Medical Center Knoxville, 1924 Alcoa Highway, Office U-75, Knoxville TN 37920 (865-305-9003), or by email THartman@UTMCK.edu.

The application is brief, with the project description limited to two pages. APPLICATIONS WHICH EXCEED THE STATED PAGE LENGTH WILL BE RETURNED WITHOUT REVIEW. Applications are submitted in response to a twice-yearly announcement and are reviewed in an expedited manner.

For applications from members of the University of Tennessee (UT) or Graduate School of Medicine (GSM) staff or faculty; requests must be approved by the Department Chair and submitted to the EVISIONS/Cayuse system prior to submission to PMERF. A letter of approval and an EVISIONS/Cayuse submission number must be provided.

Applications from outside organizations or researchers associated with institutions not associated with the University of Tennessee do not require submission to EVISIONS/Cayuse. However, requests must be accompanied by a letter of approval from the appropriate chair or organizational officer. Research applications from University of Tennessee or the UT Graduate School of Medicine, require a statistical evaluation prior to submission by Dr. Robert E. Heidel (rheidel@utmck.edu), Office of Medical Education, Research, and Development (or an equivalent from the applicant's organization, if not UT or GSM).

Conditions of Award

- Clinical and/or biomedical research grants are not renewable and must be completed within three (3) years of the initiation of the work or four (4) years from the date of grant approval.

- The total direct costs should not exceed \$7,500
- No indirect costs are allowed
- Request for funds for major items of equipment are discouraged
- Support of salaries will not be considered
- Reimbursement for expenditures not itemized in the approved submitted budgets will not be honored
- Each grantee is required to submit quarterly progress reports to the PMERF office
- Each research grant application must include an educational component with the designation of a resident, fellow, or graduate student as an integral part of the research
- Each research grant application from UT or GSM must contain documentation from the Office of Medical Education, Research, and Development, stating the proposed research has been evaluated for proper statistical power or pilot/preliminary study designation (or an equivalent from the applicant's organization, if not UT or GSM).
- If applicable, IRB/ACC approvals must be obtained and submitted to the PMERF office with the application. If the approvals are still pending at application submission, funds will not be distributed until the approval certificate(s) are provided to PMERF and any grant approval will be subject to receipt of the approval certificate(s).

Acknowledgment of Support

The following statement, or its equivalent, must be used in all publications, abstracts, or scientific presentations reporting data obtained with a PMERF grant. "This investigation was supported (in part) by a grant from The Physicians' Medical Education and Research Foundation, Knoxville TN."

Student researchers

The University of Tennessee Medical Center Guidelines for Outside Learner/Observer

Purpose:

The purpose of these guidelines are to provide an environment that is safe for patients, staff, students, and observers; respects patients' rights to privacy and confidentiality; allows for continued provision of patient care; and enhances the research or educational experience of the outside learner/observer.

Scope:

These guidelines apply to any Outside Learner/Observer (hereafter referred to as observer) 18 years of age or older with high school diploma or successful GED entering the UT Medical Center to participate in an educational experience or observership who is not enrolled in a health-related program through an "affiliated" educational institution. This guideline also applies to all sponsors of individuals seeking observational experiences.

Identification:

Identification badges are important for our patients and visitors to be able to identify those providing care or working for the Medical Center. Affiliated educational badge or an identification badge must be obtained from Human Resources prior to commencing any research or educational experience or observership. Identification badges must be:

- properly worn at all times when on the hospital campus;
- worn at the lapel level on the outside of the outermost garment or upper pockets;
- visible at all times with the picture and name showing on the outside;
- unaltered in any way (pins, stickers are not allowed); and cared for as to avoid discoloration, mangling, or splintering.

An access card is the only item that can be placed on the badge clip with the identification badge. If the access card is on the clip, the front side of the identification badge must be visible to others at all times.

Patient Confidentiality:

Privacy is a basic right in our society. Safeguarding that right is your ethical obligation if you work/observe within the healthcare system.

Confidential information may include, but is not limited to, information on patients, employees, students, other workforce members, donors, research, and financial and business operations. Some of this information is made confidential by law (such as "protected health information" or "PHI" under the federal Health Insurance Portability and Accountability Act) or by UT Medical Center policies. Confidential information may be in any form, e.g., written, electronic, oral, overheard or observed. Access to all confidential information is granted on a "need-to-know" basis only. A "need-to-know" is defined as information access that is required in order to engage in studies or to complete an approved observership. No confidential information may be removed from the UT Medical Center campus at any time.

You must take all reasonable safeguards to keep Confidential Information private.

A reasonable safeguard is a precaution that a prudent person would take to protect PHI. It is a common sense safeguard. Reasonable safeguards include pulling curtains in patient care areas, speaking quietly and in a private location if possible, and asking visitors to step out of the room when discussing PHI. The patient must consent to the presence of ANY visitor before discussing any PHI.

- **DO NOT...** Send text messages/pictures containing PHI to cell phones as the text messages are NOT secure.
- **DO NOT...** Use or store PHI on any 3rd party mail system (e.g., Gmail, Hotmail, Yahoo, etc.) or cloud fileserver (e.g., Google Drive, Dropbox, OneDrive, etc.). These 3rd party systems do not conform to HIPAA requirements for storage of PHI.
- Postings made on social media accounts (Facebook, Instagram, Twitter, Snap Chat, etc.) must be in adherence with all local, state and federal laws as well as all policies and guidelines of UTMC. Posting the following types of information on a social media site is prohibited, and, in some cases, may be a violation of law (not an exhaustive listing):
 - Patient information of any type, narrative or pictorial
 - Photographs of patients, or patient care environments
 - Reference to information as it relates to a patient/family or touches upon a patient/family emotion, reaction or event while at UHS
 - UTMC logos and/or proprietary information of UHS or a business partner where use of the logo or proprietary information could reasonably be construed as an endorsement of the posting
 - Defamatory, false and/or malicious statements about UHS or UHS staff
 - Defamatory, false and/or malicious comments regarding other health care providers or their leadership teams
 - Defamatory, false and/or malicious statements about physicians, dentists or other health care professionals who practice in the region
 - Speaking or posting on behalf of UTMC without express authorization
 - Postings that violate other UHS policies, including the Code of Conduct, anti-harassment policies, and anti-discrimination policies

University of Tennessee Medical Center does not permit disclosure, by any means, including photos of any sort, any confidential or proprietary information. Such information may include, among other things, electronic or written patient records, patient lists, strategic plans, marketing information, supplier information, and financial information and records.

University of Tennessee Medical Center does not permit, even in response to a personal request, accessing the medical record of friends, relatives, coworkers or other individuals when not relevant to job function is strictly prohibited.

If the activities of your assignment require access to or the use of proprietary information, you may be asked to acknowledge the restrictions regarding the use of such information by completing a separate Confidentiality Agreement.

Safety/Infection Prevention and Control:

The following general guidelines have been developed for students with their safety in mind. If you have any questions about this information, ask your point of contact at the hospital.

Safety

Students may not enter any area that they have not been authorized to enter. Access may be restricted for your safety or that of the patient or others. If you become lost at the hospital, ask any staff member for directions. Keep the name, phone number and department of your point of contact handy.

Infection Prevention and Control

The Infection Prevention and Control program is committed to preventing the spread of infection to you and our patients. In that regard, you should be up to date on diphtheria, tetanus, pertussis, hepatitis B, measles, mumps, rubella, and varicella vaccinations; including influenza vaccination (Oct-Mar). Non-compliance with the

Universal Influenza Vaccination Policy (<https://insite.utmck.edu/policies-forms/950/universal-influenza-vaccination.html>) will result in exclusion from assignment at University of Tennessee Medical Center until documentation of vaccine or approval exception is provided. Any individual with an approved exception from the universal influenza vaccination policy will be required to wear a surgical mask for the duration of flu season (typically October 1st through March 31st). Please be aware that access to certain areas of the hospital/day surgery may be restricted for employee, visitor and/or patient safety. You may not enter an Airborne Isolation patient room unless you have been fit tested to wear an N-95 respirator. In other situations, you may be asked to wear personal protective equipment such as a gown, shoe covers, head cover, gloves or mask may be required. Hand hygiene, as defined by policy, is required in all patient care areas and for personal hygienic purposes. Please follow appropriate signs, and if you are unsure about restricted entry or the need for personal protective equipment, ask your point of contact.

Cell Phones:

Cell phones may be used in the hospital/day surgery, unless signs prohibit their use. Cell phones may interfere with medical equipment and should be turned off in posted areas.

Tobacco Free Workplace:

Effective January 1, 2011, staff, physicians, students and vendors of the University of Tennessee Medical Center, UT Graduate School of Medicine and all our partners are not permitted to smoke or use any tobacco products (including electronic cigarettes) on any UTMC campus facility or grounds. The campus restriction begins once the student or arrives on any UTMC road or parking lot. Smoking or using tobacco products of any kind inside and outside the hospital or any owned or leased UTMC building will not be permitted including the parking areas.

Signs:

Signs throughout the medical center campus provide information and directions. Please observe these signs.

Disruptive Behavior:

University Health System believes that all individuals within the hospital should be treated courteously, respectfully and with dignity. To that end, students must conduct themselves in a professional manner. Safety and quality of patient care are dependent on teamwork, communication and a collaborative work environment. To assure quality and to promote a culture of safety, UHS will address behaviors that threaten the performance of the healthcare team.

Unacceptable Behaviors:

Use, possession, or being under the influence of drugs or alcohol is strictly forbidden. The possession of a weapon of any type is prohibited.

Slips, Trips and Falls:

There are a number of potential circumstances that could lead to a fall, such as wet floors and extension cords used during building maintenance. Always be aware of the walking surfaces and watch for potential hazards. Clean up any spill you cause or ask for assistance.

Moving About the Hospital:

There is considerable pedestrian traffic in the hospital that includes carts, stretchers, patients in wheelchairs, group tours, and equipment delivery. Please stay to the right when walking in hallways and be alert for equipment or patients that are being transported. NEVER RUN. Many intersections in the hospital have mirrors that can be used to check for oncoming pedestrians and equipment.

Bloodborne Pathogens:

You may encounter blood and/or body fluids at the hospital/day surgery. Stay clear of these fluids. Do not attempt to clean up spills. If you come in contact with blood or body fluids, wash the contaminated area immediately and report this information to your point of contact immediately.

Fire:

The hospital/day surgery has a detailed plan to address fires, and fire drills are conducted periodically. If the fire alarm sounds in your area or if a "Code Red" is announced over the intercom, please follow the directions of the staff in the area.

Workers' Compensation:

Student is not an employee University Health System, Inc. or The University of Tennessee Medical Center and is not entitled to workers' compensation benefits. Student individually or student's parent(s)/guardian is responsible for the cost of any medical care or other services that may be required as a result of any injury or illness student may incur while participating in an educational experience or observership at UT Medical Center. Any injury or illness that may occur should be reported to the point of contact.

Liability:

Student and student's parent(s)/guardian (if applicable) agree at all times to be responsible for the actions of student in conjunction with this agreement and understand that UHS, Inc., The University of Tennessee and their employees and agents shall have no liability for the actions of student and further agree to waive all rights of action, for any injury or illness that student might incur in conjunction with this agreement even if such injury or illness is believed to result from the negligence of UHS, Inc., The University of Tennessee or their employees or agents.

University of Tennessee Outside Learner/Observer Experience Application:

<https://form.jotform.com/62625961101955>

Applicants must complete the below online Outside Learner/Observer Experience Application at the below link before participating in the observation. Before clicking the submit button, print (3) copies for distributions as listed below:

University of Tennessee Medical Center Outside Learner/Observer Experience Application

Distribution of printed Administrative Requirements Form for the University of Tennessee Outside Learner/Observer Registration:

- Copy to be maintained in department file
- Copy to Human Resources if identification badge is required
- Copy to outside learner/observer

Flowsheet for Outside Learner/Observer at University of Tennessee Medical Center (available on from computer within UTMC): https://insite.utmck.edu/files/23197/flowsheet-for-utmc-outside-learner_observer_9-27-16.pdf

UTK undergraduate students

Undergraduate students can gain research experience with the research laboratories at UTMC. This can either be for credit (e.g., using course # BCMB 452) or as volunteers to gain experience in a research laboratory. In all cases, undergraduates are required to adhere to and complete the paperwork associate with the Outside Learner Program (above). This mechanism has been established to ensure student safety and their appreciation of the regulations.

In addition, to the Outside Learner requirements, the PI of the laboratory (or his designee) is required to provide site-specific safety and biosafety training for the student that should be documented (in the Biosafety Laboratory Notebook).

If the student will be performing work with animals or radioactivity, then additional training is required and the student needs to be added to the appropriate IACUC protocol BEFORE research activities can be performed (see Guide Sections above).

Graduate students

There are a number of graduate student programs in the Knoxville area, e.g., BCMC, GST and the Comparative and Experimental Medicine (CEM) Program, which is the joint graduate program of the UT College of Veterinary Medicine and the GSM. Faculty at the GSM can serve as PI for a student enrolled in a graduate program, if:

- The faculty member has been approved by the appropriate graduate program to direct doctoral dissertations. This process involves submission of a “request to direct” application and a curriculum vita, which are then reviewed by the Graduate Program Directors.
- The faculty member has sufficient funding to maintain the student (stipend, graduate school fees, insurance, etc.). Or, the student has received funding from the graduate program or other source.
- The Faculty member and the student agree on a research proposal.

The requirements for each student enrolled in a graduate program are specific for each program and can be found in the appropriate graduate program handbook, e.g.:

CEM:

https://vetmed.tennessee.edu/research/Documents/CEM/Grad_Handbook_%202016_2017.pdf

GST:

<http://gst.tennessee.edu/wp-content/uploads/2017/03/GST-Handbook-2016.pdf>

BCMB:

<http://bcmb.utk.edu/wp-content/uploads/2017/02/BCMB-Grad-student-Handbook.pdf>

Post-doctoral researchers

Postdoctoral researchers. Postdoctoral researchers in UTMC laboratories are hired to positions through the UTHSC. They are considered to be special employees and the rules and procedures are found on the Postdoctoral office website: <http://www.uthsc.edu/postdoc/faculty.php>. Amanda Wilson, MBA, in the UTGSM Office of Faculty/Staff Affairs (865-305-6482) is the “business manager” for the process and she will help with offer letters and renewals. No offer should be made without approval of the Dean of the Graduate School of Medicine.

Foreign Students

UTGSM permits international visiting scholars to the various academic departments. The process is outlined below and is coordinated by the Office of Faculty/Staff Affairs (865-305-6482).

International Visiting Scholar Process

- Department Chair should submit a request for Visiting Scholar to the Office of Faculty/Staff Affairs.
- Approval is obtained by the Office of Faculty/Staff Affairs to sponsor the visiting scholar.
- Department that will sponsor the scholar is notified and will receive an application packet for J1 visa (if applicable).
- Chair of the sponsoring Department sends a letter of invitation to potential scholar via email with J1 application information to be filled out by the potential visiting scholar.
- When paperwork is received back from the candidate, it is sent to the Office of Faculty/Staff Affairs for approval.
- Notify candidate if paperwork is in order or request additional information.
- Prepare 2 letters that will need to go with the J1 application to the UTHSC Office of International Affairs Director <http://www.uthsc.edu/international/> (currently Connie Childs) (instructions are with the J1 application).
- Department Chair fills out the 1st section of the J1 application.
- Send all required documents listed on the instructions for J1 to oia@uthsc.edu or current address for the Office of International Affairs.
- When paperwork is received back from the candidate, it is sent to the Office of Faculty/Staff Affairs for approval.
- Notify candidate if paperwork is in order or request additional information.
- Prepare 2 letters that will need to go with the J1 application to the UTHSC Office of International Affairs Director <http://www.uthsc.edu/international/> (currently Connie Childs) (instructions are with the J1 application).
- Department Chair fills out the 1st section of the J1 application.

- Send all required documents listed on the instructions for J1 to oia@uthsc.edu or current address for the Office of International Affairs.
- You should receive the DS2109 within 2 days (per Office of International Affairs).
- Use Fed-Ex international to send the DS2109 Form to your visiting Scholar. (Do not use any other method to send this document internationally). If you give the Office of International Affairs all the information needed and the Department's Fed-Ex Account number, they will ship it directly to the visiting scholar for you. You are not allowed to send this form via email.
- Send information on housing options to potential visiting scholar via email.
- Send information on rental car and driver's license information to visiting scholar via email if they will be here for more than 30 days.
- Send information regarding KAT bus routes/passes if they will be using public transportation.
- Contact Donna Patty at UT Medical Center to ensure compliance with their process on "Outside Learners".

Once you receive arrival information:

Set appointment for Campus orientation and notify the visiting scholar that orientation is set for: Date/Time & Location. Orientation is through the UTK Office of International Affairs, and typically occurs every Friday from 1-3 PM. Call Dave Lawson at: 974-3177 to confirm a date and time.

When Scholar arrives:

- Scan the following documents and send to: oia@uthsc.edu and take a copy to Office of Faculty/Staff Affairs.
 - DS-2019 Form, front and back.
 - Copy of passport.
 - Copy of Visa with arrival Stamp.
 - Include in the body of the email: Visiting Scholars address while in US.
 - Copy of Visiting Scholar's Health Insurance card or paperwork.
- OIA may provide an I-9 document to give to the visiting scholar. Make a copy for your files and give the scholar the I-9 for his records.
- Have the Visiting Scholar fill out the Personal Data Form and submit this to the Office of Faculty/Staff Affairs.

Outprocessing:

- Get a termination letter from the visiting scholar
- Supply the Visiting Scholar with a completion of assignment letter from the sponsoring department
- Complete the: UT Graduate School of Medicine Separation Clearance Form
- Collect ID Badge and any equipment, ie: (Keys, etc.), from the Visiting Scholar
- Submit the termination letter, the completed UT Graduate School of Medicine Separation Clearance Form and ID Badge in to the Office of Faculty/Staff Affairs.

Collmann Students

I. Reid Collmann, M.D. Medical Student Educational Endowment:

I. Reid Collmann, M.D. was a former Dean of the Graduate School of Medicine and established this fund in hopes of empowering medical students with the same knowledge he himself acquired as a young medical student.

The program requires an 8-week summer commitment from a small number of students to work alongside nationally recognized researchers on an array of projects learning firsthand how research impacts patient care. The awareness of research's impact on patient care is information that will build a solid foundation for the remainder of the student's medical career. Space for this program is limited and preference is given to M1 and M2 students from the UTHSC College of Medicine and UTK pre-med students.

Applications are accepted December 1st - February 28th each year. Work assignments are given as soon as possible after the application deadline. Information and application information are at the website: <http://gsm.utmck.edu/students/assistantships.cfm>

Clinical Trials

Industry Initiated Trials

Industry sponsored clinical trials at UTMC are managed in four ways:

UTMC Office of Clinical Trials

The Office of Clinical Trials (OCT) is a department within the University Health System, Inc. (University of Tennessee Medical Center) established to provide support services to UHS/UPA Physicians who desire to work with pharmaceutical, biotechnology, and/or device companies (sponsors) in order to offer their patients access to the various phases of drug or device development for potential medical benefit not yet available in the medical market place.

Services provided by the OCT include but are not limited to:

- Identification of and contact with sponsors that have trials which are active and are recruiting patients and for which a Physician has expressed interest to offer to patients.
- All support services necessary to fulfill legal, regulatory, contractual, and budgetary requirements as specified by the FDA and dictated by Good Clinical Practice (GCP) and the sponsor.
- Study Coordinator Clinical Research Nurses certified by federal programs in GCP research.
- Regulatory Coordinators working with a variety of Institutional Review Boards (IRB) throughout the course of the study for initial and continuing approvals of the protocol and patient informed consent form in addition to other regulatory requirements during the active phase of the study and in follow up after the study ends.
- Trained Data Coordinators who compile data as may be required by the sponsor for analysis and enter the same into the sponsors' electronic data capture systems to determine safety and efficacy of the agent in a human population.

UHS policy requires all industry sponsored clinical trials conducted on the UTMC campus and/or with UTMC patients to be registered with the OCT or performed with VRG.

The OCT works with all Centers of Excellence at UHS and may be contacted as follows:

Main Office: Bldg. F, Suite 344
Director: Kimberly Mason, PharmD
Email: kmason@utmck.edu
Phone: 865-305-9712, 865-305-6194

Volunteer Research Group

Volunteer Research Group (VRG) is a privately owned multispecialty clinical research site located within the University Medical Center. Established in 1999 as one of the clinical research arms of the medical center, the site offers support services to physicians involved in clinical research, as well as conducting trials independently. VRG's recent merger with the Alliance for Multispecialty Research (AMR) network, consisting of 19 clinical research centers, gives it extensive outreach capabilities and access to a business development team making it possible to better identify clinical trials in areas of

interest to University physicians. The site performs procedurally complex studies and consistently

exceeds enrollment goals and industry standards. With our vast Phase 1 experience and location within the medical center, the site is thought of as among the safest facilities to conduct First-in-Human research.

VRG's staff of over 55 professionals offers extensive support services for conducting research, including:

- The ability to conduct all phases of research, both inpatient and outpatient trials.
- Assistance with and design of protocols to make execution more efficient with Sponsors as well as Investigators.
- Independent and specialized departments for recruitment, budget and contract, regulatory, data entry, specimen handling and quality assurance.
- All research staff are CITI GCP certified.
- Ability to use Crescent City Institutional Review Board, and other central IRBs as required by the study Sponsors.
- Research experience with government entities including BARDA and DOD; FWA# 00011917
- Assist with Investigator initiated and NIH trials.

VRG works with all Centers of Excellence at UHS and may be contacted as follows:

Main Office: Bldg. B, Suite 107

CEO: William B. Smith, MD

Email: wbsmd@noccr.com wsmith@utmck.edu

Phone: 865-305-9100 x246

In your private office

If you have a private office, not owned by UHS, and are using your own patient records you may use any contract research organization (CRO) you wish. However, you should, if you are using UTMC records, in patients or out patients in UTMC clinics, you may need to get permission from UTMC. Before beginning any trial, it is appropriate to consult with Bennett Cox, General Counsel University Health System, Inc. (865 305-6925) for guidance. All clinical trials performed in the outpatient offices run by UTGSM must go through the UTHSC contracting process (contact Kristen Vandergriff for information regarding this process) and the UTGSM IRB.

Under the aegis of the UTHSC

Contact the first two options directly both if you want to participate in an ongoing trial or if you want to sponsor or initiate an industry sponsored trial. You can visit Clinical Trials.Gov <https://clinicaltrials.gov/> to find out what trials each group is managing. Both organizations provide administrative support, coordination, compliance oversight and IRB support.

In general, UTGSM is running few industry-sponsored clinical trials. However, some sponsors, especially the federal government, prefer to have their clinical trials managed by a University system. If that is the case, you must seek approval of the trial from the GSM IRB (<http://gsm.utmck.edu/irb/main.cfm>) and notify the pre and post awards personnel (Kristen Vandergriff and Deb Strahler) and the Cayuse system. Running a trial through the GSM may be

more time consuming, require more departmental resources and require more coordination on the part of the PI.

Investigator-Initiated Trials

Investigator-initiated trials – Faculty with a GSM appointment, all Residents, Fellows and UHS staff will submit the trial to the GSM IRB – following approval by the Food and Drug Administration (if necessary). Most trials of this type will also require approval of an exploratory- or full investigational new drug (IND) application by the FDA or approval by the internal Radioactive Drug Research Committee (RDRC – for imaging studies utilizing radionuclides or ionizing radiation where appropriate safety data in human subjects has already be attained). See IRB SOP #003 at <http://gsm.utmck.edu/irb/sop.cfm>

Dealing with intellectual property

Overview

The discovery process starts with the inventors working in labs, clinics, greenhouses, offices and classrooms throughout UT. From offices based in Knoxville and Memphis, the University of Tennessee Research Foundation (UTRF) serves as a bridge between these researchers and industry, entrepreneurs, and investors.

UTRF facilitates the transfer of inventions, generated during the course of work performed at UT, to the private sector, providing public benefit of new products which are the result of academic-research funding. This creates new jobs and new companies that boost the economy, and it also produces income for the inventors and the university. <https://utrf.tennessee.edu/inventor-resources/>

The University of Tennessee Research Foundation is responsible for handling intellectual property (inventions, trademarks, and copyrights) developed by UT employees developed during the course of their employment with the University. There are two UTRF offices – Memphis and Knoxville – and employees of the GSM work with the office based in Knoxville. As an employee of the University, you are required to disclose all inventions that arise as a result of your employment to UTRF. The UTRF also provides educational materials regarding entrepreneurship, grants to develop intellectual property and assists with start-up companies based on UTRF intellectual property disclosures: <https://utrf.tennessee.edu/inventor-resources/>

Working with UTRF

To disclose an invention UTRF has established a secure online portal – IDEA – for UT faculty, staff, and students to submit invention disclosures to the UT Research Foundation (<https://idea.tennessee.edu/>). When you submit your invention disclosure, you are notifying UT and UTRF that you have discovered or invented something with the potential to become a successful commercial product. Your invention disclosure is the first step in the technology transfer process.

Once submitted, your disclosure will be electronically approved by your Chair, Dean, and local Research Administration Office, and then assigned to a UTRF case manager. For more information about technology transfer at UT, and what to expect when working with UTRF, please visit our website at <http://utrf.tennessee.edu>

How to request work clinical tests from the Clinical Laboratory and Pathological specimens

Pathological Specimens

Anatomic pathology specimens for IRB-approved research may be obtained either by collaboration with a member of the pathology department or if no collaboration is available by contacting Anne Harbin at 305-9724 (aharbin@utmck.edu).

Laboratory Tests

To have laboratory tests performed for IRB-approved research when the tests are not part of usual clinical care, contact Barry Brown at 865-305-9151 (bebrown@utmck.edu) and he will help coordinate obtaining the appropriate testing and walk you through the process. Phlebotomy services for research are not available through the clinical laboratory.

Collaborating with the Department of Radiology

Radiology Research Collaboration

A number of processes have been created to better facilitate research studies that originate externally (outside the Dept. of Radiology) or from inside the Department with the intent of determining whether adequate staffing and resources can be dedicated to your project. Additionally, this process is designed so that members of the Radiology Research Committee can assist with the planning and design of studies requiring Dept. of Radiology resources. This process applies to **ALL** studies that use Dept. of Radiology resources including investigator initiated research studies and clinical trials from all local and external clinical trials offices.

Radiology Research Collaboration Workflow

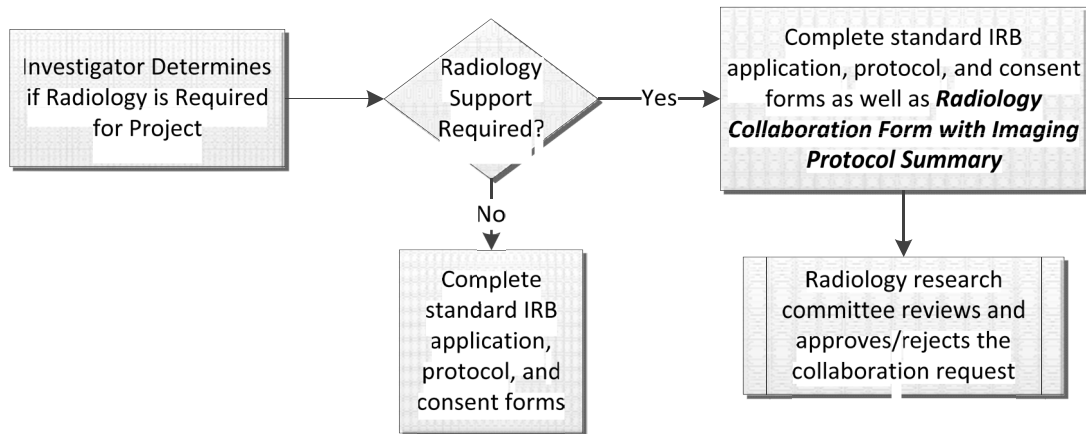
External Collaborators (non-Dept. of Radiology personnel)

The initial step is to establish a collaborative research agreement with the Dept. of Radiology in which the applicant should provide all the appropriate information required to properly assess the study for resource needs. The steps for this process are outlined below (see flowchart).

If radiology imaging services or any Dept. of Radiology resources are required to conduct a project, it is necessary to fill out and submit a Radiology Research Collaboration Form (see below). In addition, the following materials are required for the review:

- A summary of the project that includes the requested modalities.
- Anticipated imaging schedule.
- Department resource requirement.

These materials should be submitted to the Chair of the Radiology Research Committee (Dustin Osborne, PhD - radiologyresearch@utmck.edu) for departmental review. If the project requires GSM IRB approval, the signed and completed collaboration form is due no later than the second Monday of every month to enable adequate time for review and comments prior to IRB submission in the following month. If the project requires external (non-GSM) IRB approval, please be aware of the committee timelines to prevent delay of your project. Some studies may require additional support or resources which may be recommended by the radiology research committee upon review. Provision of these resources are the responsibility of the investigator.



Internal Radiology Collaborators

Those interested in research that are part of the Dept. of Radiology and have questions about facilities, resources, or general research planning, should contact the Chair of the Radiology Research Committee (Dustin Osborne; dosborne@utmck.edu) or the Chair or Radiology for initial project review.

Radiology Research Committee Timelines

- Radiology research documentation should be submitted to the Committees no later than the 2nd Monday of the month.
- Radiology Research Committee meets on the 3rd Tuesday of each month.

Research Collaboration Workflow Outline

- The researcher determines whether radiology services are required for the research project.
- Imaging protocol, imaging schedule, radiology resource requirements, and a summary of the project must be submitted for by the Radiology Research Committee for review before the 2nd Monday of each month to ensure timely review prior to submission of the project to the GSM IRB Office.
- The protocol will be approved or rejected with comments and recommendations by the committee.

When is the Radiology Research Collaboration Form Required?

Any time radiology resources are needed as part of a research project, a Radiology Research Collaboration Form should be completed by the investigator and submitted to the Chair of the Radiology Research committee for departmental review. A review is required prior to use of radiology facilities, staff, physicians, and equipment. This includes use of Molecular Imaging & Translational Research Program facilities and resources which fall under the Department of Radiology.

Request for Radiology Department Collaboration for Research

Investigator_

Department_

Title of Project _

Contact Person (Coordinator) _

Phone Number: _

Approximate Start Date _

Duration:

Expected Enrollment: _

#1 Standards of Care or Special Circumstances

Will this study use only clinical standards of care?

Yes

No

If NO Please indicate participating Radiologist

Radiologist agreeing to participate: (Printed Name)_

(Signature) _

#2 Imaging Protocol:

This study requires the following modalities (check all that apply):

- | | | | |
|--------------------------------------|--------------------------------------|---|-------------------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="checkbox"/> X-ray | <input type="checkbox"/> Fluoroscopy | <input type="checkbox"/> CT | <input type="checkbox"/> Ultrasound |
| <input type="checkbox"/> PET | <input type="checkbox"/> PET/CT | <input type="checkbox"/> Nuclear Medicine | <input type="checkbox"/> MRI |
| <input type="checkbox"/> Mammography | <input type="checkbox"/> DEXA | <input type="checkbox"/> Interventional Radiology | |

Will this study use Molecular Imaging & Translational Research Support? Yes No

Please attach complete imaging protocol to the collaboration form

#3 Resources:

Description

Are grant, contract, or other funds available to defray expenses of any additional services? Yes No

Will extra staffing be required: Yes No

Is the protocol expected to significantly impact upon regular services: Yes No

Has AUR administrator been notified to assess professional services fee(s)? Yes No

Additional pages may be used to add details regarding resource considerations.

How will billing be handled?

Service Requested: **Responsible Party:** **Billing Method:** **Agreed upon Technical Charge:**

- 1.
- 2.
- 3.
- 4.
- 5.

Signature

Date

Investigator: _____

Chair, Radiology: _____

Chair, Radiology Research: _____


VP, Radiology: _____

Please send a completed copy of this form to the Chair of the Radiology Research Committee

Writing scientific papers

There are many options for getting editorial help in paper or manuscript writing. First you may call Jennifer Russomanno, Martha Earl, or Pamela Rowland (see contact information on p. 9) for a consultation, editing and other general assistance.

Alternatively, UTHSC has established an Office of Scientific Writing under the direction of Richard Redfearn, PhD (<https://www.uthsc.edu/research/scientific-writing/>). They require a two-week lead time and the investigator must first complete a request form (below) and provide a complete first draft to initiate the process. The sample request form (below) can be found at <https://www.uthsc.edu/research/scientific-writing/forms.php> UTHSC

	Office of Scientific Writing Richard Redfearn, Ph.D., Director
University of Tennessee Health Science Center Office of Scientific Writing Copy Editing Request Form	
<i>This form is for assistance with basic copy editing of your manuscript or the project narrative (project description) of your grant proposal. If you require assistance with the scientific content of your manuscript or proposal, please use the OSW Scientific Writing Request Form.</i>	
Date:	<input type="text"/>
Name:	<input type="text"/>
Department:	<input type="text"/>
<i>If you are a postdoctoral associate or student:</i>	
Mentor:	<input type="text"/> (write "NA" if not applicable)
email Address:	<input type="text"/>
Campus Phone #:	<input type="text"/>
Manuscript or Grant Proposal Title:	<input type="text"/>
Journal or Funding Agency document is being submitted to:	<input type="text"/>
Submission Deadline (if applicable):	<input type="text"/> (Note: if this is a resubmission, please provide the reviewers' comments or summary statement, if possible.)
Requested turnaround time:	<input type="text"/>
For Grant proposals:	
Evisions SP #:	<input type="text"/> (Please provide SP # after proposal has been routed.)
Type of Grant:	R01 <input type="checkbox"/> R21 <input type="checkbox"/> U-Series <input type="checkbox"/> K-Series <input type="checkbox"/>
Other	<input type="checkbox"/> <input type="text"/>

Facilities and Administration (F&A) Fee Waivers

Facilities and Administration (F&A), also called “overhead” or “indirect costs” is a component of almost all grants and contracts. Our institutional rate for NIH grants is 40% and must be used on grant applications unless the agency specifies a different allowable-rate.

The F&A on sponsored research agreements and small grants can be returned to the investigator and used as direct costs that can be spent on salary, supplies and equipment with permission from Vice Chancellor for Finance and Operations at UTHSC (Anthony A. Ferrara). To request a waiver and return of F&A a justification letter, submitted by Kristen Vandergriff, is required.

NOTE: Waivers are not given for federal grants and contracts or large awards. The issuance of a waiver is decided in a case by case basis and is at the discretion of the Vice Chancellor.

How to get a NetID

Access to iMedRIS, Cayuse and many other university systems is managed through the UT NetID system so all key study personnel (KSP) associated with a project must have a UT NetID. GSM employees, residents and fellows all have a NetID that can be looked up here:

<https://directory.utk.edu/index.jsp>. For users who do not currently have a UT NetID (UHS employees, outside researchers, etc.), a University or GSM Dean, Director, Department Head or authorized sponsor will have to sponsor the non-UT individual into the UT system. This may be accomplished through the following steps:

- Go to <https://oit.utk.edu/accounts/forms/Pages/default.aspx> and Under “Need a NetID?” download and fill out the following forms.
 - Request a NetID (Network Identifier) for a Person.
 - Request to Sponsor a Person for OIT Services.
- The UT Contact on the form should be: Kristen Vandergriff, KLVandergriff@utmck.edu
- The UT Contact on the form for submissions to the IRB should be: Becky West bwest1@utmck.edu or Cindy Langley clangley@utmck.edu
- Print the forms, have them signed by the appropriate sponsor; a sponsor list is included at the bottom of the page. Fax them to the numbers provided on the forms (**NOTE:** the forms go to different fax numbers)
- This process usually takes OIT 24 - 48 hours and OIT will notify either Kristen, Becky or Cindy when the NetID is active, who will then notify the user on how to set up their password and add an email address. Once the password has been set up the user will be able to log into iMedRIS, Cayuse and other University systems.

NOTE: New NetID accounts do not have emails associated with them. You, or Kristen Vandergriff must contact the Memphis HELP Desk at 1-800-413-7830 to have an email address added to your account. Without an email address, the system cannot send you communications regarding your research projects.

Sponsors: UHS Nursing – Suzanne Sawyer, MSN, RN, APN, ACNS-BC, RN-BC. The GSM Department Chair for the department in which the research is based. If neither of the above fits your project call Kristen Vandergriff (305-9749) to discuss who would be the appropriate sponsor.

APPENDIX I

Useful Numbers:

IORG Registration Number	00000051
GSM Federal Wide Assurance (FWA) Number	00022698
UTHSC Federal Wide Assurance (FWA) Number	00002301
IRB Registration Number	00006910
Animal Welfare Assurance Number (UTHSC)	A3325-01
Animal Welfare Assurance Number (UTK)	A3668-01
Organizational DUNS Number	941884009000
EIN Number	1626001636-B3
UTHSC CAGE code	1BW75
UTHSC Congressional district	TN-009
GSM Congressional district	TN-002
UTHSC DUNS	94 1884009
UTHSC Entity ID	1-626001636-B3
UTHSC Federal tax	62-6001636
UTHSC FICE	003530
GSM IPF	578304-GSM
USDA Registration	63-4
UTHSC ACUC PHS # Expiration Date:	7/31/2020
UTHSC AAALAC Accreditation Date:	7/10/2012
GSM NIH F&A rate	40%