

The University of Texas Health Science Center at Houston -
Office of Academic and Research Affairs

New Investigator Briefing

A Roadmap to Support UTHealth Investigators in
the Responsible Conduct of Research

George M. Stancel, Ph.D. Executive Vice President for
Academic and Research Affairs; Professor of Pharmacology,
Medical School and Graduate School of Biomedical Sciences



IMPARTIALITY

ACCURACY

EFFICIENCY

HUMAN TREATMENT
← ANIMAL SUBJECTS
HUMAN SUBJECTS →

MISCONDUCT

AUTHORSHIP
IRB APPROVAL

MENTORING

COOPERATION

LAB SAFETY

SHARE RESULTS
PROTECT DATA

CONFLICT OF INTEREST

ETHICAL LIMITS

G.P.

?

?

IRB

IRB

Research Investigator Briefing

Responsibilities, Accountabilities, and Expectations for Research at UTHealth

Office of Academic and Research Affairs, September 1, 2011

Preamble:

Why should investigators know and comply with regulations and policies related to research?

1. Many regulations and policies related to research issues are mandated by UTHealth, the University of Texas System, the State of Texas, and/or U.S. policies, laws, and regulations.
2. Failure to comply may result in penalties imposed upon the institution – some of which can be extraordinarily severe, e.g., loss of funding opportunities, fines, and/or restrictions on allowable institutional research. These penalties may apply to the entire university and may have a serious negative impact on one's institutional colleagues in addition to the individual who does not act properly.
3. Failure to comply may lead to loss of public confidence in UTHealth and the broader biomedical research community. This in turn can lead to decreased public support for biomedical research and the resulting progress and improvements in public health and welfare and contributions to society.
4. Failure to comply, or even in some cases, the appearance of failure to comply can be damaging to an investigator's career and require the investigator to spend large amounts of time and energy in investigations or remedial actions and/or severely restrict his/her research activities.

Bottom Line: There are many positive reasons to comply with policies and regulations related to research, and it's really the right thing to do.

Who within UTHealth provides the primary, initial assurance for professional conduct and compliance with institutional and external guidelines, policies, regulations, and laws related to the conduct of research?

The primary responsibility rests with faculty peers aided by community members and other institutional colleagues!

1. Committee for the Protection of Human Subjects
2. Animal Welfare Committee
3. Research Conflicts of Interest Committee
4. Safety Committees
 - a. Radiation Safety
 - b. Chemical Safety
 - c. Biosafety
5. Embryonic Stem Cell Research Oversight
6. Research Integrity
7. Institutional Anatomical Oversight Review Committee

Where can an investigator get support and information about the conduct of sponsored research, research resources, and other issues related to the conduct of research at UTHealth?

Institutional offices and units are in place to provide support and assistance to investigators

1. Department administrative staff
2. Dean's offices and individual school staff
3. UTHealth central administration
 - a. Research Finance
 - b. Effort Reporting
 - c. Cost Sharing
 - d. Sub-award monitoring
 - e. Export controls
 - f. Pre- and Post- award support (Office of Sponsored Projects and Contracts and Grants Administration)
 - g. Human Resources
 - h. Institutional compliance, auditing, and legal departments

The purpose of the UTHealth New Investigator Briefing is to

1. serve as an aid to investigators to navigate the road to the responsible conduct of research
2. provide an overview of policies and resources available to UTHealth investigators
3. provide new investigators an opportunity to ask questions relevant to their research

I. Responsibilities of all investigators that apply to any research performed at UTHealth

All research conducted at UTHealth is should be conducted in accordance with the general principles of Responsible Conduct of Research (RCR) developed by the NIH Office of Research Integrity. These are general principles that cover responsible conduct of research in nine broad areas.

1. Protection of Human Research Subjects (Office of Human Research Protection, OHRP)
2. Care and Use of Research Animals (Office of Laboratory Animal Welfare, OLAW)
3. Research Misconduct (Office of Research Integrity, ORI)
4. Conflicts of Interest (COI) and Commitment
5. Data Acquisition, Management, Sharing and Ownership
6. Publication Practices and Responsible Authorship
7. Mentor and Trainee Responsibilities
8. Peer Review
9. Collaborative Science

Each investigator is responsible for understanding these basic principles, and in addition to the summary overview provided in briefings for new UTHealth investigators additional two additional sources of information on these general principles include Introduction to the Responsible Conduct of Research which is published online by NIH's Office of Research Integrity (<http://ori.hhs.gov/documents/rcrintro.pdf>) and an online course available at no charge to UTHealth investigators from the Collaborative Institutional Training Initiative (CITI) at <https://www.citiprogram.org/rcrpage.asp> . CITI also offers a number of additional online courses that provide more in depth information and training for specialized purposes (e.g., Human Subjects Research, Safety, Animal Care and Use). Since UTHealth is already registered with CITI these resources are available at no cost.

In addition, all investigators also have responsibilities to comply with policies and regulations that apply to being an employee of UTHealth and the State of Texas. For example, UTHealth facilities may not be used inappropriately for research related to outside (i.e., non-institutional) projects or personal financial gain. These are listed in the UTHSC-H Policies and Procedures in the institutional *Handbook of Operating Procedures* (HOOP) and the attached list of major UTHealth research related policies, the *Practical Guide to Research at UTHSC-H*, and *Who to Turn to.*)

II. Additional professional responsibilities of investigators

UTHealth investigators may also have additional responsibilities related to their activities as a physician, dentist, nurse, or activities and duties as other health related professionals.

III. Responsibilities of investigators related to export regulations

Depending upon the nature of their research UTHealth investigators may also be subject to 'Export Regulations' of the U.S. Departments of Commerce or Defense. These involve the export of sensitive information and/or technologies to non-US citizens or permanent residents, foreign governments, etc.

IV. Responsibilities of investigators related to intellectual property

Results, materials with commercial value, and intellectual property generated or obtained as a result of research conducted at UTHealth should always initially be assumed to be the property of UTHealth and/or the UT System unless explicitly released.

V. Responsibilities of investigators for use and expenditure of research funds

1. Expenditure of federal funds is governed by regulations of the Office of Management and Budget and the Office of the Inspector General, other regulations of UTHealth, the UT System, and the State of Texas may also apply.
2. Pre-award grants and contracts applications and administration
 - a. Applications for sponsored research must be accompanied by an institutional review and approval form (a.k.a. "R & A Form", specifying that any special approvals and requirements are obtained and required (e.g., for the use of experimental animals, hazardous substances or procedures, studies involving human subjects, etc.)
 - b. Applications for sponsored research must include a statement about any real or potential conflicts of interest
 - c. Applications for sponsored research must indicate an appropriate statement of the % effort required by the principle investigator and other personnel
3. Post-award grants and contracts administration and management
 - a. Require accurate effort reporting and cost sharing if applicable
 - b. Expenditures must be in line with appropriate policies and regulations
 - c. Investigators and UTHealth may have responsibilities and obligations related to the award or receipt of sub-contracts with other institutions or agencies
 - d. Investigators are responsible for any required grant reporting
4. There may be special requirements and obligations for the accuracy of clinical research billing (i.e., so that costs related to the research are not billed as standard of care)

5. All applications, contracts, or other requests for funds must be submitted through the UTHealth Office of Sponsored Projects. Individual investigators may never submit official applications or requests directly to a potential sponsor. Requests for funds from private industries, certain foundations, or individual donors may require approval by the Office of legal affairs prior to submission.
6. Grant, contracts, and any other requests for research support submitted through the Office of Sponsored Projects must be accompanied by a Review and Approval Form. The purpose of the Review and Approval form is two-fold.
 - a. It provides a 'checklist' as an advance planning aid for investigators so they may obtain any needed reviews and approvals for the proposed research in advance of proposal submission so that their applications are not delayed or returned with requests for further information.
 - b. It enables UTHealth to capture information electronically that is important for institutional reports, negotiations with foundations and government agencies to obtain maximum allowable indirect costs, and other important uses. Capturing this information electronically enables UTHealth prepare needed reports and conduct negotiations while minimizing additional requests to faculty for information about their grants and contracts.

ATTACHMENTS

1. Introductory section of *ORI Introduction to the Responsible Conduct of Research*
2. A list of current UT Health Policies Related to Research
3. *A Practical Guide to Research at UTHSC-H*
4. UTHSC-H Office of Sponsored Projects Review & Approval Form
5. "Who To Turn To", Institutional Leaders Responsible for Research Oversight and Support and Resources for Investigators

[See also <http://www.uth.tmc.edu/research/practical.html> for links to electronic copies of the *Practical Guide to Research at UTHSC-H* and UTHealth website for the Office of Sponsored Projects Review and Approval Form]