Institutional Handbook of Operating Procedures Policy 6.5.0	
Section: Compliance Policies	Responsible Vice President: Senior Vice President and General Counsel
Subject: Compliance for Research and Export Controls	Responsible Entity: Office of Institutional Compliance

I. Title

Research Compliance Plan

II. Policy

The University of Texas Medical Branch is committed to conducting its business in an ethical and law-abiding fashion. We are intolerant of fraud, abuse, waste or other violations of any applicable federal, state, or local laws, and regulations. Responsibility and accountability for actual compliance with laws, regulations, and policies rests with each individual employee. The department chairman/head or leader of each operating unit is accountable for ensuring that their subordinates are adequately trained and for detecting non-compliance with applicable policies and legal requirements when reasonable management efforts would have led to the discovery of problems or violations.

To promote compliance and implement an institutional program we have developed an Office of Institutional Compliance (OIC). The OIC is responsible for developing an institutional compliance program that will promote compliance with all applicable legal requirements and institutional policies and to foster and help ensure ethical conduct, and provide education, training, and guidance to all employees and faculty. Our Institutional Compliance Plan and Program is designed to minimize the risk of accidental or intentional non-compliance with applicable laws, regulations, and policies; to detect such non-compliance if it occurs; to discipline those involved in non-compliant behavior; and to prevent future non-compliance. This Research Compliance Plan is a sub-component of UTMB's Institutional Compliance Plan.

III. Requirements for an Effective Research Compliance Plan

The purpose of UTMB's Research Compliance Plan is to ensure that the UTMB complies with state and federal laws, regulations, and guidelines, and all University of Texas System or UTMB policies, as applicable to the conduct of research. Our compliance program has been developed to include the seven (7) requirements of an effective compliance program, as included in the Federal Sentencing Guidelines. These requirements are:

1. Establish compliance standards and procedures to be followed by employees and faculty that are reasonably capable of reducing the prospect of criminal conduct;
2. Assign high-level personnel of the organization to have overall responsibility to oversee compliance with such standards and procedures;
3. Use "due care not to delegate substantial discretionary authority to individuals who the organization knew, or should have known through the exercise of due diligence, had a propensity to engage in illegal activity";

4. Effectively communicate compliance standards and procedures to all employees by requiring participation in training programs or by disseminating publications that explain in a practical manner what is required;
5. Take reasonable steps to achieve compliance with standards by utilizing monitoring and auditing systems reasonably designed to detect criminal conduct and by having in place and publicizing a reporting system whereby employees and other agents can report criminal conduct by others within the organization without fear of retribution;
6. Consistently enforce standards through appropriate disciplinary mechanisms, including discipline of individuals responsible for the failure to detect an offense; and
7. Take all reasonable steps to respond appropriately to detected offenses and to prevent further similar offenses.

The policies and procedures contained in this program are intended to establish a framework to help ensure compliance but are not to be considered all-inclusive.

IV. Standards of Conduct Guide

Working with integrity is every employee's responsibility. UTMB's Institutional Compliance Program was developed to ensure that our employees and students understand that they must conduct themselves in an ethical manner and comply with all applicable laws, policies, rules and regulations. Ethical conduct and compliance is a personal responsibility, and every employee will be held accountable for his or her conduct.

UTMB has developed a *Standards of Conduct Guide* to serve as a framework within which we are expected to operate. This publication embodies policies of UTMB, the University of Texas System, and the Rules and Regulations of the Board of Regents of the University of Texas System, known as *Regents' Rules and Regulations*. The policies of UTMB are in the UTMB Institutional Handbook of Operating Procedures (IHOP) and may be accessed via the Internet at http://www.utmb.edu/policies_and_procedures/toc.aspx. This booklet does not include all general compliance issues, nor does it contain the special compliance issues that are job specific. Instead, the *Standards of Conduct Guide* should be regarded as a set of guiding principles that apply to everything we do.

The *Standards of Conduct Guide* applies to UTMB's workforce, which includes staff, administration, faculty, fellows, residents and students. Moreover, the *Standards of Conduct Guide* is applicable to physicians not employed by UTMB, but who serve on UTMB Hospitals' medical staff, as well as to subcontractors, agents, independent contractors, vendors, consultants and volunteers.

V. Compliance Organization and Oversight

Responsibility for oversight of the Research Compliance Plan rests with a multi-disciplinary Executive Research Compliance Committee (ERCC), whose membership is appointed by the Executive Institutional Compliance Committee (EICC). Minutes of all ERCC meetings are maintained in a confidential manner and will be provided to the EICC on a quarterly basis.

A. Executive Research Compliance Committee (ERCC)

The ERCC is charged with the following tasks:

1. Prepare and submit to the EICC an annual work plan that outlines the major activities and initiatives of the ERCC for the upcoming fiscal year;
2. Prepare and submit to the EICC an annual report that summarizes the ERCC's progress regarding each work plan objective contained in the ERCC's annual work plan for the preceding fiscal year;
3. Review laws, regulations, statutes, policies and guidelines related to research compliance;
4. Serves as a resource across UTMB on substantive research compliance questions and issues;
5. Recommend the creation of new, and revisions to current, research documentation policies and procedures;
6. Develop and implement necessary changes in practice or procedures that assure adherence to established policies;
7. Recommend approved training sessions as directed by the Chief Compliance Officer (CCO);
8. Develop practical monitoring tools to optimize compliance;
9. Prepare reports to the EICC on the status of current and newly adopted policies, procedures and related materials;
10. Communicate regularly with the EICC regarding new and emerging issues related to research compliance;
11. Identify specific research compliance risk areas and recommend the development and implementation of necessary changes in practice
    and procedures to improve compliance with Research Compliance Plan requirements;
12. Respond to, and conduct and coordinate the investigation of, alleged non-compliance with the Research Compliance Plan requirements;
13. Complete and submit reports of findings regarding research compliance to the appropriate research-related committees, Department Heads, UTMB executive management, the *Board of Regents* of the University of Texas System, and any other appropriate authority as applicable;
14. Provide oversight of research compliance auditing and assurance activities, make decisions regarding appropriate action and initiate disciplinary action for non-compliance.

The Chief Compliance Officer (CCO) is designated as accountable for the day-to-day implementation of the Research Compliance Plan. The CCO is responsible for developing a risk-based process that builds compliance consciousness into daily business processes, monitoring the effectiveness of those processes, and communicating instances of non-compliance to the ERCC for corrective, restorative, or disciplinary action.

Moreover, the CCO is responsible for the plan, design, implementation, and maintenance of the Institution's Compliance Program and policies related to all compliance areas, including research.

B. Research Operations

The following departments, committees, and the CCO manage the research support-related operations in accordance with the Research Compliance Plan requirements:

1. Executive Research Compliance Committee (ERCC);
2. Office of Research Administration (ORA);
3. Office of Clinical Research (OCR);
4. Department of Environmental Health and Safety (EH&S);
5. Clinical Research Finance;
6. Hospital Patient Financial Services (HPFS);
7. Patient Business Services (PBS);
8. Office of Sponsored Programs (OSP);
9. Institutional Animal Care and Use Committee (IACUC);
10. Conflict of Interest Committee (COIC);
11. Institutional Review Board (IRB);
12. Institutional Biosafety Committee (IBC);
13. Effort Reporting Compliance Subcommittee;
14. Export Controls Compliance Committee (ECCC).

As applicable, the above-listed committees and departments are responsible for:

1. Recommending and creating new research policies and procedures and making revisions, on an as-needed basis, to current policies and procedures for approval by the appropriate parties;
2. Leading the implementation of new and revised research policies and procedures;
3. Developing and implementing methodologies, systems, and necessary changes in practices or procedures to assure adherence to the laws and regulations in their respective areas;
4. Developing and implementing mandatory education and training administrators; faculty and staff to fully understand, the implications of the Research Compliance Plan requirements;
5. Conducting a risk assessment to identify critical research risk areas;
6. Developing and implementing a written monitoring plan to effectively monitor specific research related risk areas and assure that research policies are being implemented and followed as intended;
7. Preparing and presenting reports, as necessary to the OIC, ERCC, EICC, Department Chairs, UTMB executive management, the *Board of Regents* for The University of Texas System, and any other appropriate authority, as applicable;
8. Taking all actions, including implementing corrective action plans, necessary to ensure UTMB's full compliance with the Research Compliance Plan requirements; and
9. Communicating regularly with the CCO and EICC regarding new and emerging issues related to research.

VI. Research Compliance Plan, Policies, and Procedures

This Research Compliance Plan applies to all UTMB faculty, administrators, staff, students, and other personnel involved in the design, administration, financing, conduct, or reporting of research or sponsored program activities at or through UTMB, regardless of the source of funding or the location where the activity is conducted.

A. Compliance with Federal and State Laws, Regulations, and Institutional Policies

UTMB faculty, staff, students, and administrators engaged in research activities shall comply with all applicable laws, regulations, and UTMB policies related to the conduct of research performed at UTMB. Those involved in research shall conduct their activities with the highest ethical standards and in accordance with the standards of the community.

B. Research Activities

The Principal Investigator (PI) is responsible for the scientific, technical, and financial direction of a sponsored project and related research activities.
Such responsibility includes, but is not limited to, the day-to-day management of the project or program, being accountable to the sponsor for the proper conduct of the project, and reporting deviations from research protocols approved by UTMB's Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC), regardless if the deviation was discovered as a result of a Research Compliance related audit.

The following is a non-exclusive list of specific areas which requires adherence by research personnel to specific laws, policies, or to obtain project/protocol approval by various UTMB research-related committees.

1. ***Protection of Human Subjects***
   Federal regulations and UTMB policies require that all proposed human research studies undergo review by a UTMB Institutional Review Board (IRB) prior to the initiation of the project to ensure that the Principal Investigator's (PI's) protocol complies with those regulations and policies. The primary role of the IRB is to protect the safety and welfare of human subjects. Research personnel engaged in research activities involving human subjects at UTMB must adhere to U.S. Department of Health and Human Services (HHS) regulations as well as U.S. Food and Drug Administration (FDA) regulations governing human subjects research including, but not limited to, 45 CFR Part 46, 45 CFR Parts 160 and 164, 42 CFR Part 50 as well as 21 CFR Parts 50 and 56. Principal Investigators and their staff are expected to comply with all federal laws and regulations, as well as IRB requirements and procedures, during all phases of research involving human subjects.
2. ***Animal Welfare***
   The care and use of all vertebrate animals for research, testing and education at UTMB is governed by the regulations sets forth in the Animal Welfare Act, the *Guide for Care and Use of Laboratory Animals*, other federal regulations and state and local laws when applicable. Any UTMB PI conducting research involving vertebrate animals must submit a protocol to the Institutional Animal Care and Use Committee (IACUC) for review and approval prior to beginning work on the research project. The IACUC is mandated by federal law to oversee UTMB's animal care and use program, facilities, and procedures to help ensure that all animals being used for research, testing, and education are receiving the appropriate care and being treated humanely. In addition to reviewing research protocols to ensure compliance with federal regulations, the IACUC inspects animal facilities and research laboratories and provides education and training to further ensure that research is being conducted with the highest of scientific and ethical principles.

3. ***Environmental Health and Safety in Research Activities***

Protecting the health and safety of UTMB personnel and the environment of the surrounding community is a fundamental responsibility of UTMB and its personnel. All research personnel shall ensure a safe and healthy environment by complying with the Occupational Safety and Health Administration (OSHA) guidelines and all applicable federal, state and local guidelines as well as Environmental Health and Safety policies, requirements and procedures related to laboratory standards and disposal of hazardous waste. All UTMB research personnel conducting research involving potentially hazardous or regulated materials must have knowledge of, and be responsible for, those materials and to handle them in a safe and effective manner.

The Environmental Health & Safety Office (EH&S), a division of Business Operations & Facilities, is designed to create and maintain a safe, functional, and pleasing work environment and to ensure compliance with UTMB policies and applicable federal, state, and local regulations regarding:

1. Biological safety;
2. Chemical safety;
3. Environmental safety;
4. Laboratory safety;
5. Occupational safety; and
6. Radiation safety.

To ensure that research personnel are properly trained in the handling and safe use of potentially hazardous materials, EH&S staff provide education and training to UTMB personnel conducting laboratory research. Additionally, EH&S provides specific training to PIs engaged in research activities at UTMB.

4. ***Radiation Safety and Use of Lasers in Research Activities***

The use of radiological materials at UTMB is regulated by federal and state laws. UTMB's Radiation Safety Program provides consultation and training to ensure that research personnel provide a safe working environment in which to use radioactive materials.

All research personnel possessing, receiving, using, storing, and transferring any radioactive materials and radiation-producing devices and lasers must possess a current radioactive material license or current certificate of laser registration, as applicable, issued by the Texas Department of Health. The use of radioactive material at UTMB requires authorization from the UTMB's Radiation Safety Committee (RSC). Any research personnel authorized by the RSC to possess, use, store, and transfer radioactive materials is responsible for complying with UTMB's radiation practices and for complying with applicable federal and Texas laws to ensure that adequate control of the radioactive material is maintained.

UTMB's Radiation Safety Officer (RSO) is available to assist with issues related to use of radioactive materials, radiation generating equipment, or lasers and is charged with overseeing laboratory compliance in this area by inspecting laboratories and reviewing records. All research personnel are expected to cooperate with the RSO.

C. Research Integrity

1. ***Ethical Conduct of Research***

   All UTMB personnel engaged in research activities have a fundamental obligation to maintain the highest of ethical principles and to ensure compliance with federal and state regulations and UTMB policies governing research. Not only does the ethical conduct of research satisfy a scientific moral code, but it also leads to better scientific results. Research misconduct, including fabrication, falsification, plagiarism, and deviations from other commonly accepted practices, is not tolerated at UTMB. Research personnel are expected to conduct their activities in accordance with the requirements of applicable funding agencies, federal and state laws and regulations, UTMB policy, and this Research Compliance Plan. Such research misconduct should be reported to UTMB's Scientific Integrity Official.

2. ***Responsible Authorship***

   Standards for authorship vary among disciplines, journals, and other outlets for communicating research. In general, however, authorship of material by UTMB personnel should be limited to those who made a direct and significant intellectual contribution to the concept, design, execution, or understanding of the work. Each department and PI should develop guidelines for authorship in their respective areas. Moreover, authors must not represent the words and data of others as their own without attribution in a form permitted by the specific publication. Such plagiarism not only violates an ethical standard of conduct, but may amount to a violation of law by infringing on a copyright held by the original author or publisher.

3. ***Responsible Conduct of Research***

   UTMB is strongly committed to maintaining the highest caliber of research among its faculty and researchers. Accordingly, all UTMB faculty, mentors, research personnel, students, postdoctoral scholars and others participating in research activities should be trained in the Responsible Conduct of Research (RCR) when engaged in Public Health Service-funded research projects. Adequate training in RCR ensures that affected UTMB personnel will carry out their research and professional activities in a manner that reflects the values of honesty, accuracy, objectivity, and integrity.

4. ***Data Management***

   The Principal Investigator is the custodian of all research data from sponsored or non-sponsored studies unless otherwise agreed upon in writing. The PI is thus responsible for the collection, management, and retention of research data which should be recorded and maintained in a reasonable, responsible, and honest manner. Data from sponsored studies must be recorded and maintained according to guidelines specified by the sponsor, UTMB policy, and departmental policy.

   Some research data is highly sensitive, such as Protected Health Information (PHI) including names or addresses associated with clinical information, or Personally Identifiable Information (PII) such as Social Security numbers, credit card numbers, or personal financial

data. The release of such data can lead to harm such as privacy violations, identify theft, financial liability for UTMB, and in some cases, individual liability for the person who released the data. Breaches and even suspected breaches must be reported to UTMB's Office of Institutional Compliance or UTMB's Information Security Department.

If you have questions concerning Protected Health Information, privacy or security requirements, or HIPAA policies, see the Notice of Privacy Practices website.

D. Conflicts of Interest

UTMB is committed to ensuring that its faculty and research personnel operate in an open and productive environment free from real or apparent conflicts of interest and in accordance with federal and state regulations and UTMB policies (IHOP **6.5.1** and **6.5.3**). A potential conflict of interest can arise when a UTMB employee has a relationship with an outside organization which could possibly pose a bias in a direction that would financially benefit the employee or a close family member.

Covered Individuals under each policy are required to avoid perceived and actual conflicts of interest in their relationships with outside organizations, unless a conflict has been disclosed and can be managed in accordance with an institutionally approved conflict Management Plan as required by UTMB policy.

UTMB's Research Conflicts of Interest policy in particular provides requirements for the disclosure of financial interests that comply with the disclosure requirements of federal regulations of the U.S. Department of Health and Human Services (HHS) and the HHS Public Health Service (PHS), but the policy is not limited to PHS-funded research. Rather, the policy applies broadly to research performed at UTMB, without regard to whether the research has external funding and, if externally funded, regardless of the funding source.

UTMB also has a Conflicts of Interest Committee (COIC). The COIC meets on a regular basis to review disclosures and other related issues brought to the attention of the Committee. The COIC makes recommendations as needed and designs and implements Management Plans to manage, reduce, or eliminate identified conflicts of interest. It is also charged with the responsibility to:

1. Promote research objectivity by eliminating or minimizing potential conflicts of interest;
2. Foster intellectual property through eliminating or minimizing potential conflicts of interest;
3. Develop campus-wide conflict of interest policies and procedures to identify, manage, and monitor possible conflicts of interest related to research and intellectual property;
4. Develop education and training programs related to conflicts of interest in research and intellectual property for the UTMB community;
5. Monitor federal requirements and periodically review and advise the UTMB administration of recommended revisions and modifications to UTMB's conflicts of interest policies and procedures.

E. Financial Stewardship of Research and Sponsored Project Funds

The Principal Investigator (PI) is responsible for all aspects of the research project or sponsored project, including the proper stewardship of research or sponsored project funds.

All funds must be spent in a manner consistent with the funding documents and notice of award (e.g., grants, contracts, research protocol) and in compliance with UTMB policies. Those in charge of research or other sponsored program budgets have an obligation to monitor records of expenditures for compliance with UTMB policies and procedures and to allow inspection of those records by appropriate parties or government agencies.

Effort reporting is a mechanism used to confirm that salaries and wages charged to each sponsored agreement are reasonable in relation to the work performed. Effort reporting at UTMB uses ECRT Effort Cards to document that the compensation charged to its Sponsored Projects is appropriate. To comply with federal and UTMB effort reporting requirements, research personnel should report their effort timely and accurately. Reporting timely means that the PI completes his/her effort report within thirty (30) days of the Effort Confirmation Period. Reporting accurately means that the PI always reports his/her actual effort each reporting period. For more information, visit UTMB's Effort Reporting webpage.

VII. Other Research Related Compliance Rules, Regulations, and Institutional Policies

A. Intellectual Property

Research Personnel are expected to comply with UTMB's policy regarding the conditions for ownership, legal protection, licensing, and development of any intellectual property conceived of or first reduced to, practice by any UTMB-associated personnel. The UTMB Office of Technology Transfer (OTT) administers the intellectual property policy for the UTMB. The OTT, in coordination with the Conflict of Interest Committee, the Office of Institutional Compliance, and the Department of Legal Affairs, where applicable and appropriate, will perform all duties with respect to the implementation of this policy. The President of UTMB will have ultimate responsibility for all decisions.

B. Compliance with Federal Export Control Regulations

UTMB has a long tradition of academic freedom, which includes the principles of openness in research. Since the events of September 11, 2001, the federal government has increasingly focused on the compliance of U.S. export control laws and regulations in the interest of national security. Export control regulations, which include the U.S. Department of Commerce's Export Administration Regulations (EAR), the U.S. Department of State's International Traffic in Arms Regulations (ITAR), and the U.S. Department of Treasury's Office of Foreign Assets Control (OFAC), cover the export of controlled physical items, such as scientific equipment or transfer of controlled information , including technical data, to foreign persons and entities outside the United States, which may require a license. The regulations also govern the "deemed export" of verbal, written, electronic, or visual disclosures of controlled scientific and technical information to foreign nationals within the United States, which may also require a license. UTMB PIs and other research personnel must have knowledge of, and comply with, federal export control regulations as well as UTMB policy. Non-compliance with export control laws can result in

severe civil and criminal penalties including imprisonment, loss of research privileges and monetary fines.

VIII. Information, Education, and Training

UTMB is committed to communicating our standards for ethical conduct and UTMB policies to all employees and students. The OIC and the Office of Research Services provide education and training to develop research compliance awareness and commitment. All administration, faculty, medical staff, employees, and student researchers must complete general compliance training. More specific compliance training may be required for PIs and other research personnel engaged in research activities.

A. Information

Occasional letters, articles in *Impact*, (the institutional semi-monthly newsletter), and other publications, regarding the institutional compliance program and the OIC are sent to all employees. E-mail notifications and communications are also sent to employees. The content of these publications may be related to specific or general compliance issues and other elements of the program. Every employee is required to read and acknowledge the UTMB Standards of Conduct Guide (SOCG). This acknowledgement is kept as part of every employee's training record and is a component of their performance evaluation.

B. General Education

Research compliance is one of UTMB's most important priorities. All researchers, their coordinators, staff, and others associated with research services must be knowledgeable about UTMB's Research Compliance Plan. More specific research related training is also offered and given to individuals or departments with identified needs.

C. Specific Training

Specific training is required for all new faculty physicians and practitioners. Employees are required to complete required training assigned for their specific position in accordance with appropriate timeframes and frequency. The content of the training includes laws and regulations applicable to specific job duties and responsibilities, as well as general guidance or best practices. As new developments or concerns arise, the OIC may require additional training for some or all UTMB employees. A variety of teaching methods, materials, tools, and languages will be utilized to instill compliance knowledge and awareness in every employee.

Some examples of specific training that is available include such topics as:

1. Institutional Review Board (IRB) training;
2. Animal research training;
3. Human subject research training;
4. Radiation safety training;
5. Effort reporting and certification training;
6. Conflicts of Interest training;
7. Grant proposals and submission training;
8. Protocol submission training; and
9. Clinical trial billing training.

D. Maintenance of Training Documentation and Disciplinary Action

Compliance training is required of all employees and is considered a condition of employment. Failure to meet education and training requirements will result in disciplinary action, up to and

including termination. All persons in supervisory positions are responsible for ensuring that each UTMB employee reporting to them has completed the compliance training applicable to that person. Completion of required compliance training will be closely monitored and documented. The UTMB Human Resources Department maintains training records and reports detailed training activities for employees. Summary reports of compliance with education and training requirements are provided to the EICC.

IX. Adherence to the Institutional Compliance Program as a Requirement for Promotion for Faculty and as an Element of Evaluating all Employees

A. Faculty

Adherence to the UTMB Institutional Compliance Program is a part of each faculty member's annual evaluation and is also used as a criterion for promotion in academic rank. It is understood that the Appointment Promotion and Tenure Committee of each UTMB school should consider participation in compliance training and any involvement in compliance infractions as a part of the promotion evaluation process.

B. Managers and Supervisors

Managers and supervisors include all individuals who have as part of their job descriptions the supervision of any UTMB employee. The promotion of, and adherence to, the institutional compliance program by all management and supervisors is considered an integral part of their job performance. At UTMB, employees' awareness of, and adherence to, the Institutional Compliance Program should be used as a measurement tool in the evaluation process for continuing employment and promotion.

1. ***Education and Training***

   Managers and supervisors are required to ensure and verify that employees complete all mandatory and elective training assigned to the employee including compliance training at UTMB. Managers and supervisors should inform employees that UTMB will take disciplinary action for violation of policies, procedures, and regulatory requirements, or for failure to complete mandatory training requirements. Moreover, employees are informed that strict adherence to the laws, regulations, and policies is a condition of employment.

2. ***Inform Employees***

   Managers and supervisors are responsible for informing employees of compliance policies and procedures specifically related to their job function and appropriately monitoring employees to help ensure adherence to policies and procedures.

   UTMB is committed to thoroughly monitoring and auditing research projects to ensure compliance with federal and state regulations and UTMB policies and procedures. To ensure successful implementation of the Research Compliance Plan requirements, the institutional operational units responsible for the various research areas with the support of the ERCC will conduct periodic monitoring of research operations to ensure compliance.

X. Ongoing Monitoring & Auditing

A. Monitoring

The institutional operational units responsible for the various research areas will:

1. Develop and implement a compliance risk-based written, and effective monitoring plan;
2. The monitoring plan will contain information on specific risks to be monitored, operating and monitoring controls to be relied upon, and communicate the results of monitoring activities to the CCO, the ERCC, EICC, and, as appropriate, to UTMB executive management.

B. Auditing

At the direction of the CCO, with the support of the ERCC, the OIC will conduct periodic audits to assess compliance with applicable Research Compliance Plan requirements. The types of reviews that will be utilized include:

1. *Random Selection*

In consultation with the Director of the IRB's office, research protocols may be selected using a defined criteria method for monitoring visits. Selections will generally be based upon risk, but may be determined by other criteria which may include, but not limited to, past non-compliance, number of participants enrolled, funding source, dollar value of grants, risk to patients, and familiarity of the researchers to UTMB conducted research. Random audits may vary and focus on specific areas of interest or concern (ex: appropriate informed consent, adherence to inclusion/exclusion guidelines) or be comprehensive in nature. The OIC has developed a Research Risk Matrix which may be utilized to select protocols for audit.

2. *Directed Review*

The protocols selected for directed review will be given to the OIC in writing, either by letter or email. Directed reviews may also include calls received via the Fraud, Abuse, and Privacy Hotline, or issues reported directly to the OIC.

3. *Requested Monitoring*

The Principal Investigator (PI), his/her staff, or the Department may contact the Director of the IRB to request a monitoring visit. PIs may identify specific protocols they would like to have monitored. Requests for monitoring can also come directly to the OIC.

XI. Reporting Violations or Questionable Conduct

A. Employee's Responsibility

It is every employee's responsibility to report suspected violations of laws, regulations, policies or questionable conduct. Remaining silent and failing to report any violation or potential violation that a person knows or should have known of may subject a person to disciplinary action, up to and including termination. UTMB has established methods for employees to report, confidentially and anonymously, any questionable conduct or possible violation(s). Individual employees may discuss concerns with their supervisor or directly with the CCO by contacting the OIC at: 409-747-8700. Additional methods for reporting are described below.

All employees with questions regarding the Research Compliance Plan, or other compliance requirements in general are encouraged to seek answers or clarification from the OIC.

B. Fraud, Abuse, and Privacy Hotline (1-800-898-7679)

UTMB has established a dedicated Fraud, Abuse and Privacy Hotline as an internal reporting mechanism for reporting suspected fraud, waste, abuse, or other illegal conduct of UTMB employees, students, vendors, volunteers, or independent contractors. The UTMB Fraud, Abuse and Privacy hotline is available 24 hours a day, 365 days a year, by calling (1-800-898-7679).

Individuals may also report suspected fraud, waste, and abuse involving state resources to the State Auditor's Office's Hotline at 1-800-TX-AUDIT (1-800-892-8348). The State Auditor's Office provides additional information on its website, http://sao.fraud.state.tx.us.

C. Confidential and Anonymous

UTMB will ensure the anonymity, to the extent allowed by law, of individuals who report violations or questionable conduct. All reported allegations or concerns will be investigated confidentially.

D. Intentional False Accusations

UTMB will consider it a serious violation of UTMB policy for employees to intentionally make false accusations. Such false accusations may result in disciplinary action, up to and including termination, against the accuser. All reports to the OIC should be made in good faith.

E. Non-retaliation Policy

Employees are encouraged to freely discuss and raise questions to managers or to any appropriate personnel about situations they may feel are in violation of applicable laws, regulations, rules, policies, or procedures. Moreover, all UTMB employees have a personal obligation to report any activity that appears to violate applicable laws, Regulations, rules, policies, or procedures. Employees wishing to remain anonymous may file a report via the UTMB Fraud, Abuse and Privacy Hotline (1-800-898-7679). UTMB will never intimidate, threaten, coerce, discriminate against, or take any retaliatory action against any individuals who in good faith report suspected wrongdoing to their supervisor or through the UTMB Fraud, Abuse and Privacy Hotline.

XII. Response to Allegations and Identified Problems

A. Investigation

All reports of potential violations of laws, regulations, policies or questionable conduct, from any source, shall be logged and presented to the CCO. The CCO will authorize, direct, or conduct the investigation. A report of the investigation, including findings and recommendations, will be created. A summary report of all investigations will be provided to the ERCC or the EICC periodically. Investigations resulting in extensive corrective action or disciplinary action shall be reviewed and approved by the CCO prior to implementation. The ERCC or the EICC will be informed of these actions, and following discussion, may direct further action.

B. Recommendations

1. *Corrective Action*

When an instance of non-compliance has been determined and confirmed by the CCO, a corrective action plan will be submitted to the CCO. The corrective action plan will focus on implementing changes in internal processes to improve, prevent, or detect compliance inadequacies. The CCO may notify and meet with the department Chair or the department management, the affected faculty member(s) or employee(s) and explain the corrective action to be implemented. The corrective action plan may include one or all of the following elements:

1. Specific areas requiring compliance attention;
2. Requirement of additional training;
3. Ceasing problematic process;
4. Change in policies and procedures;
   Repaying overpayments;
5. Reporting to the appropriate governmental authorities;
6. Further audit or investigation;
7. Determining whether the problem is systematic;
8. Disciplinary action; and
9. Notice to journals, publishers, or other media services concerning issues of research integrity.

2. *Disciplinary Action*

Disciplinary action may be imposed as a part of a corrective action plan for all UTMB administration, faculty, house staff, and employees.

3. *Obligation to Report*

Reports or allegations that may constitute intentional violation or reckless disregard of criminal, civil, or administrative law shall be referred to UTMB legal authorities for investigation and disposition. If the investigation produces credible evidence that provides a reasonable basis to conclude that a violation of law may have occurred, UTMB shall promptly provide all information to the appropriate legal authorities for a determination of prosecution. UTMB will refund appropriate overpayments to funding sources or governmental agencies identified through compliance monitoring activities, investigations, or other reviews.

C. Appeal

UTMB will impose disciplinary action on employees who fail to comply with applicable laws, regulations, and policies. The seriousness of the violation will determine the level of the disciplinary action.

1. *Faculty*

Appeal of a UTMB disciplinary action shall be according to the appeals procedure in Section 6 of the *Rules and Regulations of the Board of Regents of the University of Texas System*. No other internal appeal process is available to a disciplined faculty other than as provided by the *Regents' Rules.*

2. *Non-employee Medical Staff*

Non-employee Medical Staff are subject to the appeals procedures outlined in the UTMB Hospitals Medical Staff By-laws.

3. *House Staff*

Appeals for disciplinary actions administered to house staff are in accordance with the UTMB House Staff Work Agreement.

4. ***Administrative and Professional Staff***
   Administrative and professional employees are subject to the same appeals procedures and corrective actions (where applicable) as those governing faculty.

5. ***Classified Employees***
   Disciplinary action related to classified employees will be administered in accordance with the disciplinary action provided for in the *UTMB Institutional Handbook of Operating Procedures (IHOP) Policy 3.1.9 Discipline, Dismissal and Appeal for Classified Employees*. Any recommendations of disciplinary action shall be managed pursuant to IHOP and the *Rules and Regulations of the University of Texas Board of Regents.*

XIII. Non-employment or Retention of Sanctioned Employees

UTMB prohibits the employment of the following individuals:

1. Persons known to be under investigation related to health care violations;
2. Persons convicted of a criminal offense related to health care or research; or
3. Persons, listed by a federal or state agency as debarred, excluded, or otherwise ineligible for participation in federally funded programs.

XIV. Response to Allegations and Identified Problems

UTMB prohibits the retention of the following individuals:

1. Persons convicted of a criminal offense related to health care or research; or
2. Persons listed by a federal or state agency as debarred, excluded, or otherwise ineligible for participation in federally funded programs.

UTMB Human Resources (HR) screens the list of all employees monthly against the federal and state lists of persons who are debarred, excluded, or otherwise ineligible for participation in federally funded programs. UTMB HR checks references and verifies education and certification credentials of all new employees prior to employment. UTMB Purchasing department is responsible for ensuring that vendors used by UTMB are not ineligible.

XV. Responding to Inquiries

If any member of the UTMB workforce receives an oral or written inquiry regarding UTMB's compliance with any law or regulation, from any source whether governmental or private, the employee shall immediately notify the OIC prior to responding in any way to the inquiry.

OIC staff will:

1. Identify the person or entity making the inquiry;
2. Verify the authority for the inquiry;
3. Determine the nature of the inquiry; and
4. Work with appropriate personnel/departments within UTMB to determine an appropriate response.

XVI. Record Creation and Retention

The CCO ensures that all records created, maintained and safeguarded by the OIC are retained on an ongoing basis in accordance with *IHOP Policy 6.1.5 Records and Information Management and Retention*.

UTMB has adopted the following standards to assist the CCO with oversight of all documents required by law and necessary to its operations:

1. Institutional Compliance Program/Research Compliance Plan investigation files shall include the following information:
   a. alleged violation;
   b. investigative process;
   c. copies of interview notes;
   d. key documents;
   e. log of witnesses interviewed;
   f. documents reviewed;
   g. results of the investigation; and
   h. corrective action implemented, as needed
2. No employee may enter false or misleading information into UTMB records;
3. Records shall be organized in a manner that facilitates prompt retrieval;
4. All records shall be stored in a safe and secure manner for the period required by federal and state law or by UTMB policy, whichever is longer;
5. Records shall be destroyed when no longer needed to be retained under federal and state law or UTMB policy, whichever is longer;
6. Adequate records shall be developed and maintained to document UTMB's compliance with all applicable laws;
7. The confidentiality and security of records shall be appropriately assured and adhered to based upon federal and state laws and UTMB policies; and,
8. No employee may destroy or alter any UTMB record if the CCO or appropriate designee has notice of any pending litigation or governmental investigation, litigation, claim, negotiation, audit, open records request, administrative review, or if any other action involving such record is initiated before the expiration of the retention period and subsequent destruction of such record.

XVII. Revisions to the Research Compliance Plan

This Research Compliance Plan is intended to be flexible and readily adaptable to changes in regulatory requirements. The ERCC shall review the plan at least annually to assure that it remains current and effective. Changes to the plan may be proposed by members of the EICC, ERCC, departments, or individual employees. Any recommendations for changes to the plan must be approved by the ERCC. All changes to the compliance plan must be consistent with the Institutional Handbook of Operating Procedures and the *Rules and Regulations of the Board of Regents of the University of Texas System.*

XVIII. Relevant Federal and State Statutes

45 CFR Part 46
45 CFR Parts 160 and 164
42 CFR Part 50
21 CFR Parts 50 and 56
International Traffic in Arms Regulations (ITAR)
Office of Foreign Assets Control (OFAC)

Animal Welfare Act
Export Administration Regulations (EAR)

XIX. Related UTMB Policies and Procedures

Guide for Care and Use of Laboratory Animals
Institutional Compliance Plan
Standards of Conduct Guide
IHOP Policy 6.1.5 Records and Information Management and Retention
Environmental Health and Safety policies, requirements and procedures

XX. Dates Approved or Amended

Originated: 11/30/2011	
Reviewed with Changes	*Reviewed without Changes*
10/30/2014	
3/20/2015	

XXI. Contact Information

Research Compliance Office
(409) 747-8701
COI.In@utmb.edu