MD Anderson's Standards of Conduct

# Dothe Right Thing







Max Weber, J.D., M.B.A.

### Do the Right Thing.

### It's a short phrase with a long history at MD Anderson.

Our mission is personal, complex, and dynamic. Patients and families seek us every day to help them on their cancer journeys. And layers of laws and regulations guide every step we take.

To help you navigate this ever-shifting path while putting our patients first, my team and I created this handbook.

Health care, especially for academic research institutions like ours, is a constantly moving, highly regulated industry at all levels. From our front desk specialists to our senior faculty leaders, we must be mindful of the rights of our patients, our colleagues, and our community.

And as employees of the State of Texas, even more is expected of us. We're required to be good stewards of state resources. We're called on to make sound, ethical decisions. We're asked to be on the lookout for those who wish to take our hard-earned knowledge for their personal gain. We're warned that the technologies designed to help us can hurt us if not properly protected.

In the midst of these difficult demands, we're driven to pursue our goals to Make Cancer History™ and stand by our core values of Caring, Integrity, and Discovery.

It's because of these demands that my team and I are here. Each of you is an expert in your field, pursuing your work to the best of your abilities. My focus is to give you an Institutional Compliance Program that partners with you and supports your efforts.

I'm inspired by your work to serve you in ways relevant to what you're trying to achieve. I'm humbled by your dedication to our patients to give you tools that best suit your needs. And I'm motivated to help you address the challenges you face while growing our knowledge and expertise.

I'd like you to think of this handbook as your trail guide to health care compliance in an evolving environment. But when you find you're off the trail, please speak up. We're here to help set your feet back on the path -- with compassion, understanding, and encouragement.

Together, we can Do the Right Thing every day.

All the best, Max

Max Weber, J.D., M.B.A. Vice President & Chief Compliance and Ethics Officer Chair, Executive Institutional Compliance Committee



# Building a Culture of Compliance Begins with You.

### Mission

The mission of The University of Texas MD Anderson Cancer Center is to eliminate cancer in Texas, the nation, and the world through outstanding programs that integrate patient care, research and prevention, and through education for undergraduate and graduate students, trainees, professionals, employees and the public.

### Vision

We shall be the premier cancer center in the world, based on the excellence of our people, our research-driven patient care and our science. We are Making Cancer History®.

### **Core Values**

### Caring

By our words and actions we create a caring environment for everyone.

- We are sensitive to the concerns of our patients and our coworkers.
- We are respectful and courteous to each other at all times.
- We promote and reward teamwork and inclusiveness.

### Integrity

We work together to merit the trust of our colleagues and those we serve.

- We hold ourselves, and each other, accountable for practicing our values.
- We communicate frequently, honestly and openly.
- By our actions, we create an environment of trust

### **Discovery**

We embrace creativity and seek new knowledge.

- We help each other to identify and solve problems.
- We seek personal growth and enable others to do so.
- We encourage learning, creativity and new ideas.

## We are MD Anderson.

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### Institutional Code of Conduct

MD Anderson is committed to full compliance with all applicable laws, rules and guidelines. To such end, we are all required to conduct ourselves in accordance with the ten principles of our Institutional Code of Conduct.

### Know and follow the rules

Know and follow the letter and the spirit of applicable laws, rules and guidelines, as well as UT System and MD Anderson rules, policies, procedures and compliance plans.

### Think and act ethically

Follow our ethical standards and those of your professional organizations. Before you say or do something, ask yourself: How would this look to our patients and our community? Would this harm our reputation?

### **Keep it confidential**

Handle all MD Anderson information, especially patient information, in ways that meet applicable laws, rules, guidelines and document retention schedules. Treat our information the same way you treat yours.

### **Commit to research integrity**

Perform all research efforts in ways consistent with applicable legal, ethical and professional requirements, as well as MD Anderson rules, policies and procedures.

### **Avoid gifts**

In general, you can't accept or give gifts, favors, benefits, services or items of value — especially in return for preferential treatment or patient referrals.

### **Bill accurately**

When you document and bill for the care you've provided, be accurate, be thorough, be honest — and be timely.

### Focus on Making Cancer History®

Don't use any MD Anderson resources, including your time and your colleagues' time, in a wasteful manner, for personal benefit, to harm someone, for political activity or for illegal activity.

### Be true to our mission

Avoid outside influences: Don't engage in activities or enter into contracts that could or could seem to interfere with your MD Anderson work, make you disclose confidential MD Anderson information or affect your independent judgment.

### Be a good colleague

Act with honesty and good faith in all matters. Don't engage in discriminatory, harassing, retaliatory, inappropriate, intimidating or disruptive behaviors.

### When in doubt, point it out

If you think or discover that someone isn't following our Code of Conduct, promptly notify the chief compliance and ethics officer or the Institutional Compliance Office. And always cooperate fully with all inquiries and investigations related to reported issues.

Violations of our Instituional Code of Conduct, including failure to report a breach of the Institutional Code of Conduct, may be grounds for disciplinary action up to and including termination. For information on how to report a violation of our Institutional Code of Conduct, see Your Rights and Responsibilities.

### Other Standards and Codes of Conduct

In addition to our Institutional Code of Conduct, other Institutional Policies, standards or codes may apply to you and your activities.

- MD Anderson's Institutional Code of Ethics
- MD Anderson's Faculty
   Standards of Conduct Policy
   (#ACA0043)
- MD Anderson's Principles for Ethical Scientific Research Policy (#ACA0014)
- The Board of Regents for The University of <u>Texas System's Standards of Conduct</u> (Rules and Regulations of the Board of Regents, Rule 30103)
- The University of Texas System Policies and Standards - UTS134: Code of Ethics for Financial Officers and Employees (UTS134)
- <u>Texas Standards of Conduct and Conflict</u> of Interest Provisions (<u>Texas Government</u> <u>Code § 572.051</u>)

For information regarding additional standards or codes of conduct, see "Professional Standards" in the Resources section.









## Institutional Compliance Program

continually

### **Our mission**

MD Anderson's Institutional Compliance Program supports MD Anderson's mission, vision, and core values, and helps the Institution fulfill its responsibilities to the people of Texas in an environment based upon ethical behavior and compliance with applicable laws, rules and guidelines.

To that end, the Institutional Compliance Program will provide all MD Anderson workforce members with the most accurate, concise and up-to-date information and advice to assure that they are aware of their responsibilities with respect to sustaining such an environment.

The Institutional Compliance Program helps the institution foster an environment of open communication by educating workforce members about their obligations to report compliance concerns, and by protecting workforce members from retaliation if they in good faith report suspected wrongdoing; participate in or with an institutional investigation pertaining to alleged wrongdoing; or assist appropriate authorities in investigating possible wrongdoing.

The Institutional Compliance Program also continually assesses its effectiveness and quality to assure that all MD Anderson business is conducted with integrity — and in compliance with the law.

### **Our program**

Consistent with its commitment to excellence, MD Anderson has developed a comprehensive compliance program that continually monitors high-risk areas and everchanging federal and state statutes, regulations and health care program requirements. The Institutional Compliance Program was developed in response to federal guidance and The University of Texas System standards to address compliance with state and federal requirements.

Based on the elements of an effective compliance program identified by the U.S. Sentencing Commission and the U.S. Department of Health and Human Services Office of Inspector General, the Institutional Compliance Program comprises seven key elements:

- Designating a compliance officer and compliance committees
- Developing written compliance plans and policies, and standards of conduct
- · Monitoring and auditing compliance risk areas
- Developing open lines of communication, including hotlines and other forms of communication
- Conducting appropriate training and education
- · Enforcing disciplinary standards
- · Responding to detected deficiencies

## Integrity

The Institutional Compliance Program consists of the Chief Compliance Officer, the Deputy Chief Compliance Officer, the Executive Institutional Compliance Committee and other compliance committees, the Institutional Compliance Office and MD Anderson's compliance plans.

### The Institutional Compliance Office

MD Anderson's Institutional Compliance Office addresses general compliance issues, as well as issues related to research compliance, billing and reimbursement compliance, privacy compliance, and corporate compliance. In addition, the Institutional Compliance Office responds to reported compliance concerns and those identified through ongoing monitoring and auditing activities.

The Institutional Compliance Office maintains a Compliance Hotline that workforce members may use to report compliance concerns on a confidential basis. Such requests may also be made on an anonymous basis. To maintain MD Anderson's culture of compliance and achieve its Mission, the Institutional Compliance Program provides all workforce members with regularly scheduled and specifically requested trainings on state and federal legal and regulatory matters, as well as Institutional Policies and Procedures.

For more information regarding MD Anderson's compliance plans and the Institutional Compliance Program, see:

- MD Anderson's Handbook of Operating <u>Procedures at</u> inside.mdanderson.org/institutionalpolicies
- The Institutional Compliance Office site at inside.mdanderson.org/institutionalcompliance



### **Contact Information**

**Mailing Address** 

Unit 1640

The University of Texas

MD Anderson Cancer Center

P.O. Box 301407

### **Numbers**

Phone: 713-745-6636 Fax: 713-563-4324

Via the Page Operator: 713-792-7090 Compliance Hotline: 1-800-789-4448

### **Email**

Institutional\_Compliance@mdanderson.org
Billing&ReimbursementCompliance@mdanderson.org
CorporateCompliance@mdanderson.org
ResearchCompliance@mdanderson.org
PrivacyCompliance@mdanderson.org

### **Websites**

inside.mdanderson.org/ institutionalcompliance www.mdanderson.org/hop

### Houston, TX 77230-1407

### Location

7007 Bertner Ave. Suite 1MC6.3427 Houston, TX 77030



### Trainings Offered

Conducting appropriate education and training is an essential element of an effective compliance program. At MD Anderson, the Institutional Compliance Program provides workforce members with both general and specialized educational courses regarding institutional compliance and applicable laws, regulations, rules, guidelines, and institutional policies.

### Mandatory Compliance Education and Training

New Employee Orientation Program (NEOP) provides education and institutional orientation to classified and administrative staff. Among other things, NEOP educates new employees regarding MD Anderson's history, mission, vision, core values, institutional policies and procedures, safety issues, and quality/service expectations.

**New Faculty Compliance Orientation** (NFCO) provides education to new, returning and promoted faculty members regarding institutional compliance and applicable laws, regulations, rules, guidelines and institutional policies.

The Employee Education Event (EEE) is an annual mandatory self-administered computer based training on issues of critical importance to the achievement of institutional goals, as such goals relate to patient care, treatment, service, accreditation, and regulatory requirements. Our Leadership Outreach program provides new leaders, including department chairs, division heads and executives, information on key compliance issues and reference materials regarding selected elements of MD Anderson's Institutional Compliance Program.

Our Billing Compliance Documentation Guidelines course provides training to billing professionals, residents, and fellows regarding general Evaluation and Management Documentation Guidelines or documentation guidelines by specialty area (e.g., Radiology, Pathology, Surgery).

Our Effort Reporting course provides Primary Individuals and Effort Coordinators information regarding compliance and applicable laws, regulations, rules, guidelines, and institutional policies on effort reporting requirements.

### **Other Compliance Training**

Several specialized compliance courses are available in the areas of billing and reimbursement compliance, corporate compliance, privacy compliance and research compliance. Our course list is on the Institutional Compliance Office intranet site under "Trainings Offered." You also may contact the Institutional Compliance Office at 713-745-6636 for more information.

### Code of Conduct check: Know and follow the rules

Know and follow the letter and the spirit of applicable laws, rules and guidelines, as well as UT System and MD Anderson rules, policies, procedures and compliance plans.

### Code of Conduct check: Think and act ethically

Follow our ethical standards and those of your professional organizations. Before you say or do something, ask yourself: How would this look to our patients and our community? Would this harm our reputation?

### Privacy, Confidentiality, and Security

At MD Anderson, we're committed to safeguarding the privacy of our patients and workforce members, as well as safeguarding state resources. To such end, the protection of private and confidential information is an institutional priority.

### **Patient Information**

Maintaining the confidentiality of protected health information (PHI) is driven by two of MD Anderson's core values: Caring and Integrity. All uses and disclosures of PHI must be made with respect and sensitivity for our patients and the law. The most sensitive aspects of a patient's life may be documented in the medical record, and understandably, this makes privacy, confidentiality, and security of PHI a priority for our patients. Therefore, it is critical that all workforce members understand their role in maintaining the confidentiality of PHI and compliance with privacy laws.

Although the Health Insurance Portability and Accountability Act of 1996 (HIPAA) is the most recognizable privacy law, other federal and state laws play a significant role as well. In addition to violating MD Anderson policy, the inappropriate use or disclosure of PHI is a violation of federal and state law. Consequences for violations may include jail time, monetary penalties, and/or disciplinary action, up to and including termination of employment.

PHI is health information paired with identifying information that is created, stored, or maintained

by MD Anderson. Identifying information includes 18 types of information, the most common being:

- · Name and contact information;
- Medical Record Number (MRN) and Social Security number (SSN);
- Financial account number(s), insurance, and billing or payment information;
- Treatment dates, birth date, death date;
- Voice recordings and identifiable photographs and images; and
- Any other information that can be used to identify a particular patient.

See MD Anderson's <u>Patient Privacy: De-</u> <u>Identification Of Protected Health Information</u> (PHI) <u>Policy (#ADM1180)</u>.

### **Uses and Disclosures of PHI**

Privacy law requires that PHI only be used or disclosed when the patient has given a written authorization or when it is permitted by law, such as for treatment, payment or health care operations.

Examples of impermissible uses and disclosures of PHI may include, but are not limited to:

 Accessing a co-worker's medical record to determine his diagnosis when there is no legitimate business reason to do so;



- Mailing or emailing PHI to the wrong address;
- Disclosing too much information to an insurance company;
- · Posting patient photos on social media sites;
- Using the medical record or any other information system to find a friend's contact information;
- Disclosing PHI about a patient to media outlets, or anyone else, without authorization from the patient;
- Using PHI in the medical record or any other MD Anderson database for research purposes without patient authorization or Institutional Review Board approval; and
- Accessing more information than necessary to perform a task.

### **Email**

Workforce members should exercise certain precautions when using email to send PHI.

When using email to send PHI, workforce members should review, understand, and follow MD Anderson's <u>Information Security Office</u>

Policy for the Use and Protection of Information

Resources (#ADM0335) and the Information

Resources Security Operations Manual.

Remember:

- Communicate with patients using MyChart, MD Anderson's secure messaging portal.
- Encrypt all external email communications containing PHI; use [SEND SECURE] at the beginning of the subject line.
- Don't send PHI to your non-MD Anderson email account.

For assistance regarding email or encryption, please contact the Information Security Office at 713-745-9000.

### Minimum Necessary Standard

When PHI is used, requested or disclosed, we must ensure that it contains only the

minimum amount of information necessary to complete the intended purpose.

The Minimum Necessary Standard means determining what or who "needs to know." In other words, for each use or disclosure made (with the exception of uses or disclosures made for treatment purposes), you must determine the smallest amount of PHI required to accomplish that purpose.

For example, if an employee needs assistance processing a patient's financial forms, the employee may share the forms with a supervisor or co-worker. However, it would not be permissible to email the forms to a large group with a general request for assistance. Additionally, if a document contains more information than is needed, the extra information should be removed or redacted before disclosing.

### Friends and Family Involved in a Patient's Care

HIPAA doesn't prevent discussion of a patient's care with his or her friends and family, as long as the patient doesn't object.



For example, a patient's caregiver may pick up the patient's prescription, or a nurse may speak with a caregiver about the patient's post-surgical care. However, it is important to limit the information disclosed to that which is relevant to the person's role. Just because a patient's daughter pays her medical bill does not give the daughter a right to access the patient's entire medical record. Additionally, it is always a good idea to ask the patient for permission before speaking about his or her health in front of another person.

### **Patient Rights**

Privacy law also establishes specific patient rights with regard to PHI, including the right to:

- Request a restriction on the use and disclosure of his or her PHI;
- Request an amendment to his or her designated record set;
- Request an alternative communication method;
- Inspect and copy the designated record set;
- · Obtain an accounting of disclosures of PHI; and
- Obtain either a paper or electronic copy of the Joint Notice of Privacy Practices.

### Notification Requirements: Discovery of a Breach of PHI

It is critical that any known or suspected breach be immediately reported to the Institutional Compliance Office at 713-745-6636 or through the Compliance Hotline at 1-888-337-7497.

Pursuant to federal and state law, MD Anderson is required to notify any individual whose PHI has been breached. Generally any unauthorized access, use, or disclosure, which compromises the security or privacy of the PHI, would constitute a breach. Notice to the individual must be given without unreasonable delay, and in any case no later than 60 days from the discovery date of the breach.

### **Business Associates**

Federal law requires MD Anderson to enter into

a Business Associate Agreement (BAA) with any person/entity who: (1) creates, receives, maintains, or transmits PHI on behalf of MD Anderson for institutional activities such as claims processing or administration, data analysis, processing, or administration, utilization review, quality assurance, patient safety, billing, benefit management, practice management, and repricing; or (2) provides legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, or financial services where the services involve the disclosure of PHI to the outside person/entity. For example, even contracts involving cloud service providers, recycling vendors, copy machine suppliers, or any other vendor or application service provider with potential access to PHI likely require a BAA. MD Anderson must enter into a BAA prior to contracting with a vendor or purchasing any services from an entity/person who qualifies as a "Business Associate."

If you need to obtain a BAA or have questions about whether a potential vendor/service is a "Business Associate," contact MD Anderson's Legal Services Department at 713-745-6633.

### **Social Security Numbers (SSNs)**

Federal and state laws, as well as UT System Information Resources Use and Security Policy (UTS165), regulate acceptable uses and disclosures of SSNs. Protecting the confidentiality of SSNs is critical to prevent identity theft and fraud. To that end, MD Anderson workforce members are required to:

- · Reduce the use and collection of SSNs;
- · Inform individuals when SSNs are collected;
- · Reduce the public display of SSNs;
- · Control access to SSNs;
- · Protect SSNs with security safeguards; and
- Establish accountability for protecting the confidentiality of SSNs.

For more information regarding the use or disclosure of SSNs, see the Institutional

Compliance Office site at inside.mdanderson.org/institutionalcompliance.

### MD Anderson's Information

Much of the information obtained, developed, or produced by MD Anderson's workforce members, as well as information supplied by outside entities for the benefit of MD Anderson, is considered confidential and/or proprietary.

This information should not be disclosed to anyone outside MD Anderson, or used for personal benefit or gain, unless you have specific authorization to do so.

It is a violation of MD Anderson policy to:

- Share your user ID (login) and password for any MD Anderson system, and
- Breach the confidentiality of any data contained on any MD Anderson system.

Always take reasonable steps to prevent unauthorized use or disclosure of copyrighted, trademarked, or licensed materials, and to safeguard MD Anderson information.

MD Anderson information, especially patient information, must be stored in institutionally approved storage locations (MD Anderson servers and drives; Box for MD Anderson) or on instituionally managed and encrypted devices.

### **Facility Information**

Information related to MD Anderson's facilities, including files or documents that describe or identify the building or room name, location, type, purpose, or any negotiated contract pricing in any format are considered confidential. Such facility information must be protected from unauthorized access, use, disclosure, and/or dissemination. Specific facility information may relate to:

- · Floor plans;
- · Design plans;
- · Schematic plans;



- · Site plans;
- · Building and/or room specifications; or
- · Any such image.

For more information regarding protecting MD Anderson's information, see MD Anderson's Intellectual Property Policy (Policy #ADM0345) and the Texas Public Information Act located in Chapter 552 of the Texas Government Code.

### Information Collected from the Public

In accordance with state law, MD Anderson workforce members must include the following notice when collecting information from the public by means of a form (either electronic or paper):

- With few exceptions, the individual is entitled on request to be informed about the information MD Anderson collects about the individual.
- Under Sections 552.021 and 552.023 of the Texas Government Code, the individual is entitled to receive and review the information.
- Under Section 559.004 of the Texas
   Government Code, the individual is entitled to
   have MD Anderson correct information about
   the individual that is incorrect.

### **Document Retention**

All information obtained, developed, or produced by MD Anderson's workforce members should be maintained in compliance with MD Anderson's document retention schedule.

For more information regarding document retention, see MD Anderson's Records

Management Policy (#ADM0107) or the Records

Management Department site at:
inside.mdanderson.org/departments/
records-management/

### Questions and Answers

Question: I am a nurse at MD Anderson. A patient texted me asking for her lab results. May I text

her back with the results?

Answer: No. You should communicate with patients only through MyChart (my.MDAnderson.org),

which is secure. A phone call to the patient also would be appropriate.

Question: I am a nurse and I noticed that a neighbor is scheduled to have a medical procedure.

May I tell her other friends so that we can all support her in her time of need?

**Answer:** No. Although this seems like a supportive gesture, it is important to respect your

neighbor's privacy. You should not mention to your neighbor or other friends that you are aware of her condition. In addition, if you are not directly involved in the patient's care, you should not access the patient's medical record at all. It is a violation of MD Anderson policy and federal law to access a patient's information without a legitimate medical or

business need.

Question: Am I allowed to disclose a patient's room number to someone who asks for the patient

by name?

Answer: Generally, yes. You may disclose a patient's location and general condition (e.g., "stable")

to those who ask for a patient by name — unless the patient has requested a "confidential patient type" to be placed on his or her account. Information about confidential patients

should not be disclosed to anyone but the patient.

### Code of Conduct check: Keep it confidential

Handle all MD Anderson information, especially patient information, in ways that meet applicable laws, rules, guidelines and document retention schedules. Treat our information the same way you treat yours.

### Privacy, Confidentiality, and Security

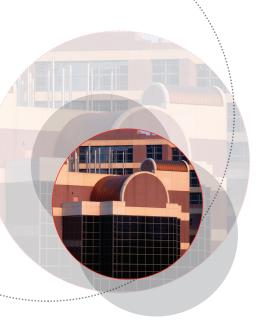
### **Policies and Procedures**

- Business Associate Agreement Policy (#ADM0342)
- Confidentiality Policy (#ADM0264)
- Corrective Action Policy (#ADM0256)
- <u>Disposal of Confidential or Sensitive</u> <u>Information Policy (#ADM0389)</u>
- Information Security Office Policy for the Use and Protection of Information Resources (#ADM0335)
- News Media Assistance Policy (#ADM0414)
- Non-Retaliation Policy (#ADM0254)
- Patient Privacy: Authorization for the Use and Disclosure of Protected Health Information Policy (#ADM0396)
- Patient Privacy: Breach Notification Policy (#ADM1033)
- Patient Privacy: De-Identification Of Protected Health Information (PHI) Policy (#ADM1180)
- <u>Patient Privacy: Disclosures of a Patient's</u>
   <u>Protected Health Information to Individuals</u>
   <u>Involved in the Patient's Care Policy (#ADM1032)</u>
- Patient Privacy: Fundraising Policy (#ADM0162)
- <u>Patient Privacy: Joint Notice of Privacy</u>
   <u>Practices Policy (#ADM0395)</u>
- Patient Privacy: Marketing Policy (#ADM0353)
- <u>Patient Privacy: Right to Access Protected</u>
   Health Information in the <u>Designated</u>
   Record Set Policy (#ADM0391)
- Patient Privacy: Right to Receive Accounting of Disclosures Policy (#ADM0392)

- Patient Privacy: Right to Request Amendment of PHI Policy (#ADM0390)
- Patient Privacy: Right to Request Privacy
   Protections and Other Restrictions on the
   Disclosure of Health Information Policy
   (#ADM0393)
- Patient Privacy: Safeguarding Paper PHI Policy (#ADM1176)
- Patient Privacy: Uses and Disclosures of Protected Health Information Policy (#ADM0401)
- Policy Regarding Use of Institutional Images (#ADM1050)
- Retention of Official Medical Records Policy (#ADM0386)
- Social Media Policy (#ADM1112)

For other policies relevant to privacy, confidentiality, and security, see MD Anderson's Handbook of Operating Procedures at inside.mdanderson.org/institutionalpolicies.





### Research Compliance

Research is key to achieving MD Anderson's Mission to eliminate cancer and is driven by our core value of Discovery.

In pursuit of its Mission, MD Anderson is committed to providing an institutional compliance program that works in concert with our academic research endeavors. One of the goals of the program is to ensure that all research is conducted according to the highest ethical standards and in compliance with all applicable laws, rules, guidelines, and institutional policies. To that end, it is imperative that workforce members engaged in research:

- Understand the principles and laws that govern research.
  - Maintain a working knowledge of MD Anderson's research-related policies and procedures.
    - Conduct research in compliance with the applicable laws,
       MD Anderson policies and procedures, and other governing documents.
- Notify the Chief Compliance Officer of any suspected or discovered violations of research related laws, rules, guidelines, or institutional policies.

For information on clinical research billing, see the Billing and Reimbursement section.

### **Human Subjects Research**

Human subjects research is defined as any of the following: (a) research that involves a living individual about whom an investigator conducting research obtains (i) data through intervention or interaction with the individual, or (ii) identifiable private information; (b) research that involves the use or disclosure of Protected Health Information; (c) an experiment involving one or more human subjects, in which a drug is administered or dispensed to, or used; or (d) a clinical investigation or research that involves one or more human subjects to determine the safety or effectiveness of a device. Thus, human subjects research includes research on disease mechanisms, biomarker studies, therapeutic interventions, clinical trials, prevention studies, epidemiological and behavioral studies, tissue and data banking, outcomes research, and health services research.

The U.S. Department of Health and Human Services exercises authority over human subjects research and MD Anderson has signed an assurance statement committing our institution to compliance with the applicable regulations.

To ensure that human subjects research at MD Anderson is conducted in an ethical manner and in compliance with the law, MD Anderson has:

- Established Institutional Review Boards (IRBs) to safeguard the rights and welfare of research participants.
- Developed a Human Subject Research Manual that contains information, procedures, and guidance.
- Established and implemented mandatory human subjects protection training.

When conducting human subjects research, keep in mind:

- IRB approval and protocol activation are required before human subjects research activity is permitted. IRB oversight is mandatory.
- It is a violation of both federal law and MD Anderson's policies if you:
  - Conduct human subjects research without IRB approval.
  - > Do not adhere to an IRB-approved protocol.
  - > Implement any change to an IRB approved protocol without IRB approval.

- Before agreeing to participate in human subjects research, the researcher is responsible for ensuring that individuals clearly understand everything that will happen to them, how their information will be used, and their financial responsibilities before they agree to participate in human subjects research.
- Individuals are free to choose whether or not to participate in human subjects research and must not be pressured to participate in such research.

### **Animal Research**

MD Anderson's Institutional Animal Care and Use Committee (IACUC) is responsible for the review and approval of all research involving animals at MD Anderson. It is imperative that workforce members engaged in research involving the use of animals:

- Understand the principles and laws that guide and govern the use of animals in research.
- Are familiar with the requirements described in the MD Anderson Animal Care and Use Handbook for Investigators and the Guide for the Care and Use of Laboratory Animals.
- Conduct animal research in compliance with MD Anderson's policies and procedures, federal and state laws, rules, guidelines, and ethical principles.

When conducting animal research, keep in mind:

- IACUC approval is required before animal research activity is permitted. IACUC oversight of animal research is mandatory.
- It is a violation of federal law and MD Anderson policies and procedures if you:
  - > Conduct animal research without IACUC approval.
  - > Do not adhere to an IACUC-approved protocol
  - Implement any change to an IACUCapproved protocol without IACUC approval.

### Recombinant DNA; Select Agents and Toxins; Biohazardous Agents

Review and approval by the Institutional Biosafety Committee (IBC) is required for use of recombinant DNA, select agents and toxins, and/or biohazardous agents in any research at MD Anderson.

Remember, if you possess, use, and/or transfer select agents and toxins without IBC approval and registration, you will:

- · Be in violation of institutional policy; and
- Put the institution at risk of violating federal laws.

### Human Embryonic And Induced Pluripotent Stem Cells

The use of human embryonic and induced pluripotent stem cells for research at MD Anderson is governed by the <u>Human Embryonic & Induced Pluripotent Stem Cell Policy (#ACA1164)</u>. The Human Embryonic & Induced Pluripotent Stem Cell Research Oversight (HEIPSCRO) Committee advises on and oversees research involving

human embryonic stem cells (hESC) and induced pluripotent stem cells (hiPSC).

Remember, if you use hESCs or hiPSCs for research without HEIPSCRO Committee approval, you will:

- · Be in violation of institutional policy; and
- Put the institution at risk of violating federal laws.

### **Expenditure Of Federal Research Funds**

The expenditure and management of federal research funds are governed by cost principles set forth in Federal regulation in 45 C.F.R. Part 74 Appendix E. Charging any costs directly or indirectly to the federal government, including personnel and non-personnel costs, must be done in compliance with these cost principles.

Any person who authorizes or is responsible for authorizing the expenditure of federal research funds is responsible for understanding the cost principles contained in 45 C.F.R. Part 74 Appendix E, and for ensuring that any cost charged to a



federal sponsor is: (1) allowable; (2) allocable; and (3) reasonable.

All costs must be handled consistently across the institution, *i.e.*, a particular cost may not be charged as a direct cost by one department and as an indirect cost by another department.

Remember: Non-compliance with the cost principles can lead to: (a) disallowance of federal grant funds; (b) financial penalties; and/or (c) severe civil and criminal penalties.

### Effort Reporting and Certification; Effort Commitment

Effort is the proportion of time spent on any activity expressed as a percentage of total institutional activities for which an individual is compensated by MD Anderson. Total effort for an employee must always equal 100 percent, regardless of part-time or full-time status, and regardless of number of hours worked.

As previously noted in the section on expenditure of federal research funds, the expenditure of federal money for personnel costs, *e.g.*, salaries, wages, and fringe benefits is governed by federal cost principles in 45 C.F.R. Part 74 Appendix E. Thus, the use of grant funds for such personnel costs is permissible only if the payments conform to the requirements in these federal cost principles.

As required by these cost principles, MD Anderson requires employees who devote effort on sponsored projects, confirm the percentage of effort spent in support of each sponsored project and other institutional activities for a given period of time. This confirmation is called effort reporting and certification.

MD Anderson uses the online Effort Certification and Reporting Technology (ECRT) system for effort reporting and certification on a quarterly basis.

### Remember:

- Accurate and timely certification of effort reports are required by: (a) the federal government under applicable Federal cost principles; and (b) MD Anderson's <u>Effort</u> Certification Policy (#ACA0016).
- · All faculty must certify their own effort.
- Effort reports for all non-faculty must be certified in accordance with institutional policy.
- Actual/certified effort percentages must be based on a reasonable estimate of work performed during the applicable reporting period.
- Effort certification must be based on first-hand knowledge of the work performed.
- Effort reports are subject to audits by the federal government and the Institutional Compliance Office.

Important: Non-compliance with effort reporting and certification and effort commitment requirements can result in: (a) disallowance of federal grant funds; (b) financial penalties; and (c) criminal penalties against the individual who certifies falsified effort.

### Code of Conduct check: Commit to research integrity

Perform all research efforts in ways consistent with applicable legal, ethical and professional requirements, as well as MD Anderson rules, policies and procedures.

### **Research Misconduct**

The Institutional Research Integrity Officer handles research misconduct allegations and reports findings involving Public Health Service (PHS) funds to the Office of Research Integrity (ORI).

Research misconduct is fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or in reporting research results. Honest errors or differences of opinion are not considered research misconduct. Penalties, up to and including loss of employment, are determined by the President of MD Anderson. The ORI may impose additional penalties such as debarment from eligibility for federal funds for grants and contracts, prohibition from service on PHS advisory or peer review committees, submission of a correction, or retraction of a published article.

### **Conflict of Interest**

MD Anderson is committed to conducting research that is unbiased and in compliance with federal and state laws, rules, and guidelines, as well as institutional policies regarding conflict of interest.

PHS regulations require that all research funded under PHS grants or cooperative agreements be free from bias resulting from an investigator's financial conflicts of interest (FCOI). An investigator is defined as the project director or principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded by the PHS. These regulations define FCOI as a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research. MD Anderson is required to submit FCOI reports to PHS, manage investigator FCOI prior to expending any funds under the affected PHS-funded research project, and ensure public

accessibility of FCOI held by senior/key personnel on a PHS-funded research project.

FDA regulations require that clinical investigators certify the absence or disclosure of certain financial relationships to sponsors of FDA regulated trials. This information is used by the FDA to assess the reliability of clinical trial data.

Institutional policy requires all investigators, faculty members, faculty supervisors, trainees, and institutional decision makers to disclose specified financial relationships to the institution. These disclosure requirements are based on and in certain cases may be more strict than those in the PHS and FDA federal regulations.

### Remember:

- All investigators, faculty members, faculty supervisors, trainees, and institutional decision makers must keep all required disclosures of financial relationships current.
- Non-compliance with the conflict of interest regulations can result in disallowance of federal research funds and civil and criminal penalties.

If you have a fraud and abuse-related concern contact the Institutional Compliance Office at 713-745-6636 or the Compliance Hotline at 1-800-789-4448.

### Gifts

Every year, thousands of patients come to MD Anderson. Our ability to recruit patients from, or refer patients to, other providers should be consistent with MD Anderson's core value of Integrity, therefore gifts must not be

a factor in the recruitment or referral of patients.

**Patients** 

MD Anderson and its

workforce members should
refrain from giving any gifts,
gratuities, or other items of value
(collectively referred to as "gifts") to
patients if such gifts will likely influence the patient
to seek or continue to seek health care services
from MD Anderson or MD Anderson workforce
members.

The offering of gifts to patients could be a violation of federal and state laws. Therefore, only inexpensive gifts (*i.e.*, gifts that have a retail value of no more than \$15 individually and no more than \$75 annually per patient) may be given to patients who are beneficiaries of federal and/or state health care programs. In addition, MD Anderson workforce members may not transfer gifts of cash or cash equivalents to such patients.

**Note:** The Civil Monetary Penalties Law contains various prohibitions, including: offering remuneration to a Medicare or Medicaid beneficiary that the person knows or should

to influence the beneficiary to obtain items or services billed to Medicare or Medicaid from a particular provider. "Remuneration" ving items or services for free. As of enalty may include up to \$15,270 m or service and 3 times the amount

know is likely

includes giving items or services for free. As of 2017, the penalty may include up to \$15,270 for each item or service and 3 times the amount claimed for each item or service (or 3 times the amount of the remuneration). This figure may be adjusted annually; please contact the Institutional Compliance Office for details.

### **Patient Referrals to MD Anderson**

In addition to refraining from giving gifts or other inducements to patients, MD Anderson and its workforce members must also refrain from engaging in giving any gifts, gratuities, or other items of value to anyone in exchange for patient referrals. MD Anderson may accept a referral from any physician or other health professional as long as such referral is not in exchange for a gift or a kickback of any kind.

## Integrity

### **Gifts**

In addition, gifts, gratuities, or other items of value, including payments or non-cash benefits, given to physicians, health professionals, or others providing services to MD Anderson must comply with federal and state regulations.

**Note:** The federal anti-kickback statute provides that it is a crime to knowingly and willfully solicit, receive, offer, or pay remuneration of any kind (e.g., money, goods, services) for the referral of an individual to another for the purpose of supplying items or services that are covered by a federal health care program; or for purchasing, leasing, ordering, or arranging for any good, facility, service, or item that is covered by a federal health care program, unless the arrangement meets a "safe harbor" or is determined to be permissible after an analysis; contact the Institutional Compliance Office for details. The penalty may include the imposition of a fine of up to \$25,000, imprisonment of up to five years, or both.

### **Patient Referrals** to Other Entities

MD Anderson and its workforce members must not accept gifts, gratuities, or other items of value from anyone, including vendors, in exchange for patient referrals to that individual or vendor. There are certain circumstances where it is permissible for MD Anderson or its workforce members to accept gifts, gratuities, or other items of value as long as the arrangement complies with federal and state regulations. However, under no circumstance is it permissible for MD Anderson or its workforce members to accept these gifts in exchange for patient referrals.

For information on gifts to state employees, see the State Ethics Laws section.



### **Questions and Answers**

Question: A pharmaceutical company's representative who services my department would like to

sponsor a holiday lunch for the department. Is this okay?

Answer: No. Meals or other types of food directly funded or provided by medical service

representatives are prohibited. Food for non-educational events such as faculty meetings must not be accepted under any circumstances. See MD Anderson's <u>Funding for Non-CME</u>

Conferences and/or Meetings Policy (#ADM1020).

Question: A pharmaceutical company's representative would like to provide lunch for monthly

mid-level provider meetings. Is this okay?

Answer: No. Meals or other types of food directly funded or provided by medical service

representatives are prohibited. Food for non-educational events such as faculty meetings must not be accepted under any circumstance. See MD Anderson's <u>Funding for Non-CME</u> Conferences and/or Meetings Policy (#ADM1020), and Commercial Funding for CNE

Programs Policy (#CLN0669).

Question: To get more patients to come to our department, we would like to raffle an iPad.

Is this okay?

**Answer:** No. It is against federal and state law to offer gifts or free services to a patient in order to

get the patient's business. In addition, there are special rules regarding raffles in the State of Texas. Please contact MD Anderson's Legal Services Department for more information

at 713-745-6633.

### Code of Conduct check: Avoid gifts

In general, you can't accept or give gifts, favors, benefits, services or items of value — especially in return for preferential treatment or patient referrals.

## Billing and Reimbursement Compliance



Documentation of medical and business records and billing practices at MD Anderson should be consistent with MD Anderson's core values of Caring and Integrity. Documentation and billing that are accurate, complete, and timely help MD Anderson demonstrate its commitment to high quality patient care in a manner that maintains the valued trust of our patients and our colleagues.

To that end, MD Anderson has developed policies and procedures regarding documentation and billing practices that are consistent with our core

Among other things, MD Anderson's policies and procedures require that all medical and business records be accurate, complete, and not contain any false information. In addition, these policies and procedures require each patient's billing claim to completely and accurately reflect the health care services provided, as documented in the medical record. Examples of unacceptable billing practices include, but are not limited to:

values and comply with applicable federal and/or state laws and private

payor requirements.

- Billing for items or services not accurately documented in the medical record,
- Billing for items or services that were not actually rendered,
- Billing for items or services not appropriately ordered,
- Billing for items or services that were not medically necessary,
- Billing for items or services rendered without the appropriate supervision,
- · Always assigning the same level of service,
- · Unbundling procedure codes,
- · Submitting duplicate bills, and
- · Filing false or inaccurate cost reports.

**Note:** The Civil False Claims Act prohibits us from knowingly presenting a false or fraudulent claim for payment or approval. "Knowingly" includes actual knowledge; deliberate ignorance of the truth

Integrity

or falsity of the information; or reckless disregard of the truth or falsity of the information; and it requires no proof of specific intent to defraud. The penalty may include three times the overpayment plus \$5,500 to \$11,000 for each item or service presented for payment.

If you believe any documentation and/or billing practice is inconsistent with MD Anderson's documentation and billing policies and procedures, discuss the issue with your immediate supervisor. If you do not feel comfortable discussing the issue with your supervisor, you may discuss the issue with higher-level management, contact the Institutional Compliance Office at 713-745-6636, or call the Compliance Hotline at 1-800-789-4448.

Remember, improper documentation or billing practices may be considered fraudulent activities resulting in disciplinary action for those committing such behaviors. MD Anderson has "zero tolerance" for unacceptable billing practices. Disciplinary actions may also be imposed against individuals who have knowledge of improper documentation or billing practices and who remain silent or fail to report such behavior.

For more information regarding documentation and billing practices, see MD Anderson's:

- Billing Compliance Plan
- Fraud, Waste, and Abuse Policy (#ADM0157)
- Medical Documentation Policy (#CLN0555)
- Delinquent Documentation Penalty Policy (#CLN0510)
- Legal Medical Record Policy (#CLN0554)

### Clinical Research Billing

It is the policy of MD Anderson that research related items and/or services provided to human subjects research participants are accurately billed in compliance with all relevant laws, rules, and guidelines. Billing for services provided to human subjects research participants can be very complex since both the sponsor and the

participant may be responsible for various costs of the study. Any time that the sponsor provides funding for items and/or services, such items and/or services may not be billed to the human subjects research participant or the participant's insurance carrier. Knowingly submitting bills for items and/or services paid for by the sponsor constitutes fraud and can result in criminal and civil penalties under federal and state law. MD Anderson workforce members involved in human subjects research are responsible for ensuring that the:

- Clinical Research related billing is based on actual services rendered.
- Clinical Research related billing is allowable by law.
- Clinical Research related billing is consistent with the informed consent document signed by the human subjects research participant.
- Clinical Research related charges are billed to the appropriate party.

For more information regarding clinical research billing, see MD Anderson's:

- Billing Compliance Plan
- Clinical Research Billing Policy (#ADM1047).
- Study Calendar & Coverage Determination Policy for Clinical Trials (#ADM1138).

For other policies relevant to appropriate documentation and/or billing, see MD Anderson's Handbook of Operating Procedures at inside.mdanderson.org/institutionalpolicies.

If you have a fraud and abuse-related concern or question contact the Institutional Compliance Office at 713-745-6636 or the Compliance Hotline at 1-800-789-4448.

### Questions and Answers

Question: Can I use the teaching physician addendum when providing services with a fellow who has

an unrestricted medical license in an unapproved training program?

**Answer:** No. Fellows with an unrestricted medical license in an unapproved program are not

considered a "fellow or resident" for Medicare purposes. Instead, they are viewed as another physician fully capable of rendering and billing the service themselves. Therefore, the attending physician should document and bill for his/her own service without the use of a teaching physician addendum. Or, in the alternative, the fellow with an unrestricted medical license in an unapproved program may document and bill for his/her own service. Please also refer to the Fellow and Resident Supervision In Patient Care Delivery Policy

(#CLN0620).

Question: You notice that a patient's record does not include all procedures performed on the patient.

You ask your co-worker about the discrepancy. Your co-worker tells you that this type of

thing happens all the time and to ignore it. Should you ignore the errors?

**Answer:** No, this is a clear violation of the Institutional Code of Conduct, and may violate state or

federal rules and regulations. You should notify your supervisor of the situation immediately.

**Question:** What are the most common errors that can prevent physicians or other providers from

being paid?

**Answer:** The most common errors that can prevent payment include:

No documentation for services billed.

- Missing signatures.
- Always assigning the same level of service.
- Failing to have appropriate orders signed.

- · Misinterpreted abbreviations.
- · No chief complaint documented.
- Billing for services included in the global fee as a separate professional fee.
- Use of an inappropriate modifier or no modifier for accurate payment.

### Code of Conduct check: Bill accurately

When you document and bill for the care you've provided, be accurate, be thorough, be honest — and be timely.

Question: The physician I work for has asked me to do something that I feel is improper and against

the Billing Compliance Plan. I don't want to do something that is improper, but I'm afraid I  $\,$ 

may lose my job if I don't do what I have been told. What should I do?

**Answer:** First, consider discussing the request with the physician to be sure you understand the

facts and that he or she is aware of your concerns. If you feel that you cannot comfortably discuss the request with the physician, notify your supervisor or contact the Institutional Compliance Office. Do not take part in any improper or illegal activity. Please also refer to MD Anderson's Non-Retaliation Policy (#ADM0254) for additional information regarding

protections against retaliation.

Question: My supervisor told me to bill a patient's insurer for health care services we provided and not

to bill the patient for the co-pay and deductible amounts. What should I do?

**Answer:** Medicare and most private payors require MD Anderson to collect a patient's copay(s)

and deductible amount(s) when billing the insurer for services. Waivers of co-pays and deductibles could result in liability under federal and state laws. If your supervisor insists on waiving the co-pay or deductible, you should contact the Institutional Compliance Office.



## Use of MD Anderson Resources

The institution is committed to using its resources so as to best further its mission and strategic vsion as set by the citizens of the State of Texas. As a state institute of higher education, MD Anderson's resources, including employee time, are considered public resources that are subject to special laws, rules, and guidelines.

In this regard, MD Anderson workforce members may not use MD Anderson resources, including time, funds, equipment or other resources:

- · In a wasteful manner,
- · For personal benefit or gain,
- To harm another person,
- · For political activity, or
- · For illegal activity, such as bribes or kickbacks.

Limited use of public resources for personal purposes, such as telephone calls and emails, is permitted under the following circumstances:

- The use does not result in a cost to MD Anderson
- · The use does not interfere with official duties
- · The use is brief in duration
- The use does not disrupt or distract from the conduct of official business
- The use does not compromise the security or integrity of MD Anderson information

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For more information, see MD Anderson's <u>Use</u> of State-Owned Property, Equipment, Services, Funds, and Resources Policy (#ADM0340).

### **Non-Solicitation**

Solicitation includes the sale, lease, rental or offer for sale, lease, rental of any property, product, merchandise, publication, or service, whether for immediate or future delivery; an oral statement or the distribution or display of printed material, merchandise, or products that is designed to encourage the purchase, use, or rental of any property, product, merchandise, publication, or service; the receipt of or request for any gift or contribution; or the request to support or oppose or to vote for or against a candidate, issue, or proposition appearing on the ballot at any election held pursuant to state or federal law or local ordinances.

This includes, but is not limited to: any oral or written communication (electronic or hard copy) that advocates or requests a contribution of money, time, effort, in-kind goods (e.g., coats for the homeless, books for literacy programs), personal involvement of a workforce member, or offers any item or service for auction and includes charitable fundraising by workforce members.

MD Anderson policy only permits:

- Solicitation for activities sponsored by MD Anderson or for which MD Anderson is a beneficiary; and
- Distribution of materials or information that are part of the business-related communications of MD Anderson.

These provisions were established to protect workforce members from unauthorized solicitations, receiving unauthorized material, and to ensure that the work environment is consistent with the Mission of MD Anderson.

For more information, see MD Anderson's Charitable Activities, Charitable Expenditures, and Solicitation Policy (#ADM0115).

### **Political Activities**

It is the policy of MD Anderson to recognize the right of MD Anderson workforce members to participate in political activities on their own time, as long as such political activities do not:

- Involve the use of state resources or the workforce member's official position,
- Interfere with the performance of the workforce member's duties and responsibilities related to The University of Texas System and MD Anderson, or
- Involve The University of Texas System or MD Anderson in politics.

### **Political Contributions**

MD Anderson workforce members may make political contributions from their personal funds.

Political contributions from any source of MD Anderson funds are strictly prohibited.

For more information regarding political activities and political contributions, see MD Anderson's:

- Political Activity Policy (#ADM0262).
- Memberships Policy (#ADM0134).

### Strategic Vision for Making Cancer History®

Every workforce member has an opportunity to contribute to MD Anderson's aim of Making Cancer History® by managing the substantial resources entrusted to us.

By safeguarding and enhancing our resources, we are able to provide research-driven patient care, seek new knowledge about cancer, educate others, and explore ways to prevent cancer.

**Patient Care:** 

Enhance the quality and value of our patient care throughout the cancer care cycle.

**Research:** Enhance existing research programs and develop priority programs for the future.

Education: Provide educational programs of the highest quality to fully address the needs of all learners.

**Prevention:** Accelerate the discovery and translation of new knowledge about cancer risk assessment and prevention in the laboratory, the clinic and the community.

 Our People: Enhance our most valuable asset, the people who work, volunteer and contribute to advancing our mission.

**Collaborations:** Enhance and disseminate our knowledge in all mission areas through collaborative and productive relationships locally, nationally and worldwide.

**Resources:** Safeguard and enhance our resources.



### Code of Conduct check: Focus on Making Cancer History®

Don't use any MD Anderson resources, including your time and your colleagues' time, in a wasteful manner, for personal benefit, to harm someone, for political activity or for illegal activity.

### **Questions and Answers**

Question: I sell cosmetics in my spare time. I process order requests using my computer at work.

Does this present any problems?

**Answer:** Yes, this activity is problematic. A state employee may not use state resources, which

include state time or property, to conduct a personal business. You also may not use state property during your lunch break or after work hours to conduct a personal business, see MD Anderson's Use of State-Owned Property, Equipment, Services, Funds, and Resources

Policy (#ADM0340).

Question: My daughter is selling Girl Scout Cookies, and my co-workers have expressed an interest in

purchasing a number of boxes. Is it acceptable to sell the cookies during my work hours on

behalf of my daughter and her Girl Scout Troop?

Answer: No. MD Anderson strives to protect employees and non-employees from unauthorized

solicitations. To that end, MD Anderson's <u>Charitable Activities</u>, <u>Charitable Expenditures</u>, <u>and Solicitation Policy (#ADM0115)</u> clearly prohibits the sale of products to raise funds for organizations or activities not authorized by MD Anderson (e.g., Girl Scout Cookies).

Question: May I use the copy machine to copy flyers for my child's birthday party?

Answer: No. Making copies of flyers for your child's birthday party is not considered an

incidental use.

Question: An employee I supervise wants to attend a three-day conference in Washington, D.C., that

includes a day of "lobbying." She will go to the U.S. Capitol and speak to legislators about

cancer rights. How do I manage this?

**Answer:** MD Anderson workforce members may participate in political activities on their own time.

However, MD Anderson employees may not use state time, money, equipment, or any resource for political purposes. Therefore, any time spent lobbying may not be paid for or reimbursed by MD Anderson. If the employee is attending the conference for work-related purposes, then two days may be treated as work days, but the lobbying day must be allocated as paid time off or annual leave. Likewise, MD Anderson cannot pay for any expenses related to political activities. Additionally, the employee may need to notify the Texas Office of State-Federal Relations (OSFR) in advance of traveling to the Washington, D.C., area. Remember, as state employees we owe a duty to the State of Texas. It makes no difference whether someone is lobbying for cancer rights or for a particular candidate, these activities cannot be related to his/her job at MD Anderson. For more information, see

MD Anderson's Political Activity Policy (#ADM0262).

### State Ethics Laws









As an institution of The University of Texas System, MD Anderson is considered a state institution of higher education. As such, our employees are subject to certain state ethics laws that regulate the behavior and actions of state employees.

### **Conflict of Interest**

Strict adherence to conflict of interest prohibitions allows MD Anderson to honor its Core Value of Integrity. A conflict of interest exists when the loyalty of an MD Anderson workforce member is divided between responsibilities to MD Anderson and responsibilities to an outside party. State laws, as well as institutional policies, govern conflict of interest issues. MD Anderson workforce members should review the appropriate policy in cases of possible conflicts of interest.

In general, employees should not:

- Accept outside employment, temporary or regular, that actually or potentially results in any conflict of interest with or interferes with the employee's responsibilities to MD Anderson;
- Accept or solicit any gift, favor, or service that might reasonably tend to, or is being offered with the intent to, influence the employee in the performance of his/her institutional duties;
- Accept outside employment or engage in a business or professional activity that might reasonably require or induce the employee to disclose confidential information acquired in the performance of his/her institutional duties;
- Accept outside employment or compensation that could reasonably impair the employee's independence of judgment in the performance of his/her institutional duties;

### Integrity

- Make personal investments that could reasonably create a substantial conflict between the employee's private interest and the interests of the institution; or
- Intentionally or knowingly solicit, accept, or agree to accept any benefit for having exercised the employee's official powers or performed the employee's official duties in favor of another.

For more information regarding conflict of interest issues, see MD Anderson's:

- Conflict of Interest and Conflict of Commitment Policy (#ADM0255)
- Conflict of Interest Policy for Faculty
   <u>Members, Trainees, Faculty Supervisors, Institutional Decision Makers, and Investigators of The University of Texas</u>
   <u>MD Anderson Cancer Center (#ACA0001)</u>

### **Bribery**

As state employees, MD Anderson employees may not intentionally or knowingly offer, confer, or agree to confer on another; or solicit, accept, or agree to accept from another:

- Any benefit no matter how large or small as consideration for the recipient's decision, recommendation, vote, or other exercise of discretion as a public servant.
- Any benefit as consideration for a violation of a duty imposed by law on a public servant.

For more information regarding bribery issues, see MD Anderson's:

- Ethics Policy (#ADM0337)
- Conflict of Interest and Conflict of Commitment Policy (#ADM0255)

### **Gifts to State Employees**

A gift of any value should never be accepted if the employee has any reason to believe it was given to influence the employee in the discharge of his or her official duties (e.g., discretionary decisions concerning expenditure or use of state assets). Unsolicited non-monetary gifts from patients, their friends, and/or family members are not prohibited so long as they are not given to influence care or secure preferential treatment. Cash gifts to faculty members from patients, their friends, and/or family members are governed by the Physicians Referral Service (PRS) Bylaws.

According to state law, non-cash gifts valued at less than \$50 may be accepted unless the employee has any reason to believe that the gift is being offered to influence the employee or the decision the employee makes. Cash or cash equivalents (e.g., gift certificates, gift cards) should not be accepted from any vendor or third party who is doing (or interested in doing) business with MD Anderson.

For more information regarding gifts, see the Gifts section in this publication and MD Anderson's <a href="https://example.com/Ethics-Policy">Ethics Policy (#ADM0337)</a>.

### Abuse of Position

An MD Anderson employee commits an offense if, with the intent to obtain a benefit or with the intent to harm or defraud another, the employee intentionally or knowingly: (a) violates a law relating to the employee's position; or (b) misuses state resources (e.g., MD Anderson property, services, personnel, or any other thing of value belonging to MD Anderson).

For more information, see MD Anderson's:

- Ethics Policy (#ADM0337)
- <u>Use of State-Owned Property, Equipment,</u> <u>Services, Funds, and Resources Policy</u> (#ADM0340)



**Endowments** 

MD Anderson workforce members are expected to abide by the institution's established Endowment Compliance Plan. At MD Anderson, the Associate Vice President and Controller is responsible for directing the Endowment Compliance education programs, which focus on adherence to The University of Texas System Policies and Standards - UTS138: Gift Acceptance Procedures (UTS138) associated with the establishment of endowments. The education programs also ensure that the terms of the Official Endowment Agreement are strictly followed.

The authority to accept donations to The University of Texas System is vested in the Board of Regents. Individual MD Anderson workforce members are not authorized to accept donations on behalf of the institution. When a workforce member has been approached about a proposed donation, the workforce member should notify the Office of the Chief Finanical Officer or the Development Office. The Chief Financial Officer will arrange for proper reporting to the Board of Regents, and the donor will be sent an acceptance

letter from the appropriate institutional official. All terms and restrictions placed on any gift or donation by a donor must be agreed to and accepted by the Board of Regents before the gift can be accepted.

For more information, see MD Anderson's Endowment Compliance Plan.

### Honoraria

An MD Anderson employee may not solicit, accept, or agree to accept an honorarium in consideration for services that the employee would not have been requested to provide but for the employee's official position or duties. A useful way for a public servant to analyze whether an acceptance of an honorarium is permissible is to ask, "Would my services be as useful or desirable if I did not hold a position with the government?" However, under certain circumstances, an MD Anderson employee may accept an honorarium given as compensation for providing a service for which the employee has specific expertise. If, however, funding is from a pharmaceutical company or health care vendor, additional laws and rules related to anti-kickback may apply. Honoraria/Fees for faculty members are governed by PRS Bylaws, MD Anderson's Faculty Extramural Leave Policy (#ACA0051) and MD Anderson's Conflict of Interest Policy for Faculty Members, Trainees, Faculty Supervisors, Institutional Decision Makers, and Investigators of The University of Texas MD Anderson Cancer Center (#ACA0001).

For more information regarding honorarium issues, see the Gifts – Patient Referrals to Other Entities section and MD Anderson's <u>Ethics Policy</u> (#ADM0337).

## **Questions and Answers**

**Question:** One of our department's existing vendors sent gift cards for every employee in our office.

Are we allowed to accept the gift card?

Answer: No. In general, non-cash gifts valued at less than \$50 may be accepted unless the

employee has any reason to believe that the gift is being offered to influence the employee or the decisions the employee makes. Cash or cash equivalents (e.g., gift certificates, gift cards) should not be accepted from any vendor or third party who is doing (or interested in

doing) business with MD Anderson.

Question: Sanya, a research nurse at MD Anderson, is responsible for coordinating, evaluating,

and following patient participation in a clinical trial of Drug X, funded by Drugs Unlimited. Because Sanya has many years of nursing experience with cancer patients, Drugs Unlimited wants to hire Sanya: (a) as a consultant for planning future clinical trials involving patients receiving chemotherapy; and (b) to audit ongoing Drug X clinical trials at two other sites. All the consulting work will be done outside of Sanya's normal work hours at MD Anderson, and Sanya thinks she has accrued just enough paid time off to perform the

audits. What should Sanya do?

Answer: Sanya should follow the steps outlined in MD Anderson's Conflict of Interest and Conflict of

Commitment Policy (#ADM0255) before she agrees to perform, or performs, any consulting

or audit work for Drugs Unlimited.

## Code of Conduct check: Be true to our mission

Avoid outside influences: Don't engage in activities or enter into contracts that could or could seem to interfere with your MD Anderson work, make you disclose confidential MD Anderson information or affect your independent judgment.

At MD Anderson, we are committed to creating a caring and healthy environment for everyone – including all workforce members. To that end, our workforce members are expected to treat each other in a fair and respectful manner – in accordance with our core values of Caring, Integrity and Discovery, and uphold all federal and state laws, rules, and guidelines.

## Behavior That Undermines a Culture of Safety

Safety, quality of patient care and research, as well as the retention of our most valuable resource – our people – are dependent on MD Anderson's ability to foster teamwork, maintain open lines of communication, and cultivate a positive, collaborative work environment.

Behavior that undermines a culture of safety is unprofessional and unacceptable at MD Anderson. Such behaviors create an unhealthy or even hostile work environment, as well as:

- · undermine team effectiveness;
- increase medical errors and/or preventable, adverse outcomes;
- · contribute to poor patient satisfaction;
- · add to the cost of care; and
- cause qualified employees to seek new positions in more professional environments.

Behavior that undermines a culture of safety sometimes goes unreported and therefore unaddressed. Workforce members may be hesitant to report such behaviors because they:

(a) are uncertain if the behavior would be considered disruptive behavior; (b) fear

# Caring

## Work Environment



#### What Behavior Undermines a Culture of Safety?

Behaviors that undermine a culture of safety include, but are not limited to:

- overt actions, such as verbal outbursts and physical threats;
- passive activities, such as not performing assigned tasks or quietly exhibiting uncooperative attitudes during routine activities;
- reluctance or refusal to answer questions, return phone calls or pages;
- · condescending language or voice intonation;
- · impatience with questions or discussions; and
- retaliation against those who report intimidating and/or disruptive behaviors.

#### **Non-Retaliation Policy**

MD Anderson workforce members are required to report misconduct, including instances of intimidating and/or disruptive behaviors.

MD Anderson's Non-Retaliation Policy (#ADM0254) prohibits any individual from retaliating or taking adverse action against a workforce member who has reported misconduct, or reported intimidating and/or disruptive behaviors. If a workforce member believes that he/she has been subjected to any retaliation related

with MD Anderson's Equal Employmen
Opportunity (EEO) team for investigation.

#### **How to Report**

MD Anderson does not tolerate intimidating or disruptive behaviors, and managers are expected to ensure that such behaviors are reported and addressed without delay.

Workforce members also have a duty to report intimidating and/or disruptive behaviors. Reports should be made through any of the following methods:

- Your immediate supervisor, who can enlist the help of leaders and Human Resources representatives to address the issue.
- Incident Reporting Tool, accessible from computer desktops or our intranet.
- 5-myHR (713-745-6947).
- All reports are treated confidentially and may be made on an anonymous basis.

For threats of violence, immediately contact The University of Texas Police at Houston (UTP-H) at 713-792-2890.

#### Sexual Harassment and Sexual Misconduct

MD Anderson is committed to the principle that our work environment should be free from inappropriate conduct of a sexual nature.

Sexual misconduct and sexual harassment are unprofessional behaviors. Any MD Anderson workforce member who engages in such behavior is subject to disciplinary action, up to and including termination of employment.

For more information, see MD Anderson's <u>Sexual Harassment and Sexual Misconduct Prevention</u>
Policy (#ADM0285).

#### **Corrective Action**

All workforce members are responsible for educating themselves with performance criteria for their particular jobs (e.g., rules, procedures, and standards of conduct established by the institution and their department) and maintaining standards of conduct suitable and acceptable for the work environment. A workforce member who does not fulfill the responsibilities set out by such performance criteria may be subject to discipline, up to and including termination of employment. Any sanctions will be applied in accordance with relevant MD Anderson personnel policies.

For more information, see MD Anderson's Corrective Action Policy (#ADM0256).

If you have any questions regarding the MD Anderson work environment, please contact your Human Resources (HR) Generalist at inside.mdanderson.org/human-resources/index. html.

#### **Equal Employment Opportunities**

- · race;
- · disability;
- · color;
- veteran status;
- · religion;
- genetic information; and

- sex;
- sexual orientation;
- gender identity/ expression;
- · national origin;
- age;

 any other basis protected by institutional policy or by federal, state, or local laws (unless such distinction is required by law). It is MD Anderson's policy to provide equal employment opportunity (EEO) without regard to:

Such EEO protections apply to all matters related to employee hiring or status–including but not limited to:

- advertising;
- · training;
- · recruitment;
- · transfer;
- · selection;
- · promotion;
- · employment;
- · demotion;
- · placement;
- realignment;
- · compensation;
- and/or
- · benefits;
- · termination.
- · upgrading;

Further, it is the policy of MD Anderson to provide a work environment free from verbal, physical, and/or visual forms of discrimination or harassment.

For more information, see MD Anderson's <u>Equal</u> <u>Employment Opportunity Policy (#ADM0284)</u>. In addition, to ensure compliance with the Equal Employment Opportunity Policy, MD Anderson has established the following specific policies:

- Affirmative Action Policy (#ADM0287)
- Accommodating Disabilities in the Workplace Policy (#ADM0286).
- <u>Sexual Harassment and Sexual Misconduct</u> Prevention Policy (#ADM0285)
- Nursing Peer Review Program Policy (CLN0632)

## Fitness for Duty and Drug Free Workplace

It is the policy of MD Anderson that all workforce members report to work in a condition to safely perform their duties. When at work, every workforce member must be free of illegal drugs or alcohol and able to safely and effectively perform the essential functions of his or her position.

MD Anderson prohibits the use of alcohol or a controlled substance—as well as its unlawful manufacture, sale, distribution, or possession—in or on premises or property owned or controlled by MD Anderson, regardless of whether such activity results in the imposition of a penalty under a criminal statute. Individuals who violate these policies are subject to appropriate disciplinary action, including, but not limited to, mandatory referral into the Employee assistance Program for treatment in an approved drug assistance or rehabilitation program and /or termination.

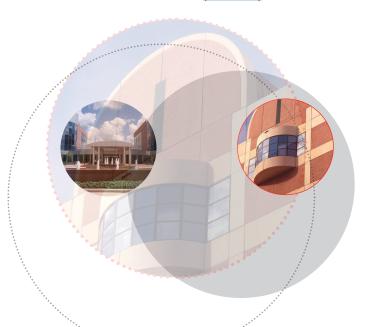
#### **Stop the Line for Patient Safety**

Any workforce member who observes or becomes aware of a potential risk to patient safety has the authority and responsibility to speak up and request the process be stopped in order to clarify the patient safety situation (*i.e.*, Stop The Line). If a workforce member believes that he/she has been subjected to any retaliation related to a Stop The Line request, that person should report such suspected retaliation so that it may be investigated in accordance with MD Anderson's Non-Retaliation Policy (#ADM0254). For more information regarding Stop The Line, including examples of what situations may prompt a Stop The Line request, see MD Anderson's Stop The Line for Patient Safety Policy (#CLN1185).

For more information, see MD Anderson's:

- Employee Assistance Program Policy (#ADM0275)
- <u>Drug Detection and Deterrence Policy</u> (#ADM0309)
- Practitioner Health and Impairment Policy (#CLN0619)
- Fitness for Duty Policy (#ADM0274)
- <u>Drug-Free Campus & Workplace Policy</u> (#ADM0278)
- Nursing Peer Review Program Policy (CLN0632)





## **Questions and Answers**

Question: A co-worker has vacation pictures on her desk that are somewhat provocative. If I am

uncomfortable with these pictures, can she be made to remove them?

Answer: Maybe. Consider bringing the matter to the employee's supervisor or contact your HR

Generalist at: inside.mdanderson.org/human-resources/index.html.

Question: My supervisor has repeatedly asked me out on dates. I am not interested in dating him and

this is making me very uncomfortable. What can I do?

**Answer:** Consider informing your supervisor that this behavior makes you uncomfortable. However,

if you prefer not to discuss the subject with your supervisor, contact your HR Generalist at:

inside.mdanderson.org/human-resources/index.html.

Question: I have repeatedly spoken with my supervisor about the rude and impatient way an

employee from another department speaks to me and others in my department. To date, I have seen no change in that individual's behavior. Where can I go to report this behavior

outside of my supervisor?

**Answer:** First speak with the other employee's supervisor about your concerns. If you are

uncomfortable going directly to another employee's supervisor, consider talking to your supervisor or HR Generalist to ask for assistance in bringing this issue to the attention of

others.



## Code of Conduct check: Be a good colleague

Act with honesty and good faith in all matters. Don't engage in discriminatory, harassing, retaliatory, inappropriate, intimidating or disruptive behaviors.

# Your Rights and Responsibilities

#### **Illegal/Unethical Activities**

MD Anderson is committed to maintaining an ethical culture that is consistent with its Mission, Vision, and core values. To that end, MD Anderson upholds a "zero tolerance" policy toward any illegal/unethical activity or knowing, intentional, or willing non-compliance. MD Anderson will not accept a workforce member's claim that improper conduct occurred for the benefit of MD Anderson. Any such conduct is not for the benefit of MD Anderson and is expressly prohibited.

Compliance issues can be complex and identifying a suspected violation is not always easy. Here is a checklist to help:

- Does the action comply with the Institutional Code of Conduct?
- Does the action violate any state or federal law?
- How would the action look to your family, friends, patients, and/or the community if published on the front page of the paper?

#### Compliance Concerns

It is every workforce member's responsibility to report a violation or a potential violation. Remaining silent and failing to report a violation or potential violation may subject a workforce member to disciplinary action.

To discuss or report compliance concerns, MD Anderson workforce members are encouraged to directly contact the Chief Compliance Officer via the page operator at 713-792-7090, or through the Institutional Compliance Office at 713-745-6636.

Additionally, MD Anderson has established a telephone hotline for workforce members to report suspected violations or questionable conduct:

#### The Compliance Hotline at 1-800-789-4448.

All discussions and reports are treated confidentially and may be made on an anonymous basis. Each report is reviewed, and the Chief Compliance Officer initiates any needed investigations, corrections, and/or follow-up.

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 at its website, www.sao.fraud.state.tx.us.

#### **Non-Retaliation**

MD Anderson encourages, and in some cases requires, its workforce members to report any perceived misconduct, including actual and/or potential violations. It is understandable that some workforce members may be hesitant to report any suspected violations out of fear of retaliation. MD Anderson has established a non-retaliation policy to encourage workforce members to report any perceived misconduct.

For more information, see MD Anderson's Non-Retaliation Policy (#ADM0254).



#### **Governmental Investigations**

MD Anderson cooperates with governmental investigations. To that end, the Institutional Compliance Office will assist all workforce members with taking the appropriate steps to cooperate with such governmental investigations. It is imperative that workforce members immediately — even after hours — notify the Chief Compliance Officer or the Institutional Compliance Office if approached by a person who has identified himself or herself as a governmental investigator.

## **Questions and Answers**

Question: How do I contact the Chief Compliance Officer?

**Answer:** By calling 713-745-6636 or via the page operator at 713-792-7090.

Question: How can I report a compliance concern?

**Answer:** You can:

· Talk to your supervisor.

- Call the Institutional Compliance Office at 713-745-6636.
- Page the Chief Compliance Officer at 713-792-7090.

• Call the Compliance Hotline at 1-800-789-4448.

Question: You receive a letter from the FBI that

demands access to MD Anderson patient records and confidential information. What should you do?

**Answer:** Immediately call the Chief

Compliance Officer and take no action until the Chief Compliance Officer or designee is able to assist.

#### Code of Conduct check: When in doubt, point it out

If you think or discover that someone isn't following our Code of Conduct, promptly notify the chief compliance and ethics officer or the Institutional Compliance Office. And always cooperate fully with all inquiries and investigations related to reported issues.

## Resources

### **Professional Standards**

#### **Accountants**

Texas State Board Of Public Accountancy: www.tsbpa.state.tx.us/

American Institute of Certified Public Accountants: www.aicpa.org

#### **Advanced Practice Nurses**

Texas Board of Nursing: www.bne.state.tx.us/

#### **Attorneys**

American Bar Association: www.abanet.org/

State Bar of Texas: www.texasbar.com/

#### **Auditors**

Texas State Auditor's Office: www.sao.state.tx.us/Audit/

#### **Dentists**

State of Texas Board of Dental Examiners: www.tsbde.state.tx.us/

#### **Medical Physicists**

American Association of Physicists in Medicine: www.aapm.org/

American College of Medical Physics: www.acmp.org/

American College of Radiology: www.acr.org

#### **Nurses**

American Nurses Association: www.nursingworld.org/

Texas Board of Nursing: www.bne.state.tx.us/

#### **Optometrists**

Texas Optometry Board: www.tob.state.tx.us/

#### **Pharmacists**

Texas State Board of Pharmacy: www.tsbp.state.tx.us/

#### **Physical and Occupational Therapists**

The Executive Council of Physical Therapy and Occupational Therapy Examiners: www.ecptote.state.tx.us/

#### Physician Assistants

American Academy of Physician Assistants: www.aapa.org

Texas Physician Assistant Board: www.tmb.state.tx.us/

Texas Academy of Physician Assistants: www.tapa.org/index.cfm

#### **Physicians**

American Medical Association: www.ama-assn.org/

Texas Medical Board: www.tmb.state.tx.us/

#### **Psychologists**

Texas State Board of Examiners of Psychologists: www.tsbep.state.tx.us/

#### Researchers

Office for Human Research Protections: www.hhs.gov/ohrp/

#### **Social Workers**

Texas State Board of Social Worker Examiners: www.dshs.state.tx.us/socialwork/

#### **Veterinarians**

Texas State Board of Veterinary Medical Examiners: www.tbyme.state.tx.us/

### Websites

#### The University of Texas System

The University of Texas System Board of Regents: www.utsystem.edu/bor/

The University of Texas System Office of General Counsel:

www.utsystem.edu/ogc/

#### **Federal Government Websites**

Centers for Medicare & Medicaid Services: www.cms.hhs.gov/

Office for Civil Rights – HIPAA: www.hhs.gov/ocr/privacy/

Office of Inspector General: www.oig.hhs.gov/

Novitas Solutions: www.novitas-solutions.com

U.S. Department of Health and Human Services: www.hhs.gov/

#### **Research-Related Websites**

Animal and Plant Health Inspection Service: www.aphis.usda.gov/programs/ag\_selectagent/

Animal Welfare Information Center: awic.nal.usda.gov/

Centers for Disease Control and Prevention: www.cdc.gov/

Food and Drug Administration: www.fda.gov/

National Cancer Institute: www.cancer.gov/

National Institutes of Health: www.nih.gov/

Office for Human Research Protections: www.hhs.gov/ohrp/

Office of Foreign Assets Control: www.ustreas.gov/offices/enforcement/ofac/

Office of Hazardous Materials Safety: hazmat.dot.gov/enforce/hmenforce.htm

Office of Laboratory Animal Welfare: grants.nih.gov/grants/olaw/olaw.htm#assur

Office of Research Integrity: ori.dhhs.gov/

#### **Texas Government Websites**

State of Texas Agencies: www.tsl.state.tx.us/landing/governments.html

Texas Department of Insurance: www.tdi.state.tx.us/

Texas Department of Licensing and Regulation: www.license.state.tx.us/

Texas Department of State Health Services: www.dshs.state.tx.us/

Texas Ethics Commission: www.ethics.state.tx.us/

Texas Health and Human Services Commission: www.hhsc.state.tx.us/

Texas Higher Education Coordinating Board: www.thecb.state.tx.us/

Texas Office of Attorney General: www.oag.state.tx.us/

## State and Federal Laws

## General Fraud & Abuse Compliance Laws - Federal

Conspiracy to Defraud the Government with Respect to Claims 18 U.S.C. § 286

False, Fictitious or Fraudulent Claims 18 U.S.C. § 287

False Statements Relating to Health Care Matters 18 U.S.C. § 1035

Health Care Fraud 18 U.S.C. § 1347

Criminal Penalties for Acts Involving Federal Health Care Programs (Including the Federal Anti-kickback Statute) 42 U.S.C. § 1320a-7b

Federal Stark Law 42 U.S.C. § 1395nn

Civil False Claims Act 31 U.S.C. § 3729-33

Civil Monetary Penalties 42 U.S.C. § 1320a-7a

## General Fraud & Abuse Compliance Laws - Texas

Texas Solicitation of Patients Act
Texas Occupations Code § 102.001 et seq.

Texas False Claims Act
Texas Human Resources Code § 36.002

Privacy and Confidentiality - Federal

HIPAA Privacy Rule 45 C.F.R. Part 160 and Part 164, Subparts A and E

HIPAA Security Rule 45 C.F.R. Part 160 and Part 164, Subparts A and C

#### **Privacy and Confidentiality - Texas**

Medical Records Privacy
Texas Health & Safety Code Chapter 181

Unauthorized Use of Identifying Information Business & Commerce Code, Chapter 521

Mental Health Records
Texas Health & Safety Code Chapter 611

Communicable Diseases
Texas Health & Safety Code Chapter 81

#### **Ethics Laws - Texas**

Political Activities by Certain Public Entities and Individuals

Texas Government Code Chapter 556

Standards of Conduct for State Officers or Employees Texas Government Code § 572.051

Requirement to Use State Property for State Purposes Texas Government Code § 2203.004

Texas Bribery Statute
Texas Penal Code § 36.02

Acceptance of Honorarium Texas Penal Code § 36.07

Gifts to Public Servant Texas Penal Code § 36.08(d)

Abuse of Official Capacity Texas Penal Code § 39.02

Misuse of Official Information Texas Penal Code § 39.06

## State and Federal Laws

#### **Research Laws**

Animal Welfare Act 7 U.S.C. §§ 1231 et. seq. 9 C.F.R. Parts 1 through 3

Financial Disclosure by Clinical Investigators 21 C.F.R. Part 54

Promoting Objectivity in Research for which PHS Funding is Sought 42 C.F.R. Part 50 Subpart F

Food, Drug and Cosmetic Act U.S.C. Title 21, Chapter 9

Investigational New Drug Application 21 C.F.R. Part 312

New Drug Applications 21 C.F.R. Part 314

Radioactive Drugs for Certain Research Uses 21 C.F.R. Part 361.1

Electronic Records; Electronic Signatures 21 C.F.R. Part 11

Good Laboratory Practice for Non-Clinical Laboratory Studies

21 C.F.R. Part 58

Investigational Device Exemptions 21 C.F.R. Part 812

Pre-market Approval of Medical Devices 21 C.F.R. Part 814

Protection of Human Subjects 21 C.F.R. Part 50 45 C.F.R. Part 46

Institutional Review Boards 21 C.F.R. Part 56

NIH Guidelines for Research Involving Recombinant DNA Molecules

www4.od.nih.gov/oba/rac/guidelines/guidelines.html

Public Health Service Policies on Research Misconduct 42 C.F.R. Part 93.103

Responsible Prospective Contractors 45 C.F.R. Part 94

#### **Select Agents**

Possession, Use, and Transfer of Biological Agents and Toxins 7 C.F.R. Part 331

Possession, Use, and Transfer of Biological Agents and Toxins 9 C.F.R. Part 121

Interstate Shipment of Etiologic Agents 42 C.F.R. Part 72

Select Agents and Toxins 42 C.F.R. Part 73

Civil Money Penalties, Assessments and Exclusions 42 C.F.R. Part 1003

#### **Time and Effort Reporting**

Cost Principles for Educational Institutions (OMB Circular A-21) 2 C.F.R. Part 220

Grants for Research Projects 42 C.F.R. Part 52

Uniform Administrative Requirements for Awards and Subawards 45 C.F.R. Part 74

Contract Cost Principles and Procedures 48 C.F.R. Part 31

#### **Export Controls**

Export Administration Regulations 15 C.F.R. Part 730

International in Arms Regulations 22 C.F.R. Part 120

Foreign Assets Control Regulations 31 C.F.R. Part 500

Foreign Trade Statistics Regulations 15 C.F.R. Part 30

## Institutional Code of Conduct

MD Anderson is committed to full compliance with all applicable laws, rules and guidelines.

To such end, we are all required to conduct ourselves in accordance with the ten principles of our Institutional Code of Conduct.

#### Know and follow the rules

Know and follow the letter and the spirit of applicable laws, rules and guidelines, as well as UT System and MD Anderson rules, policies, procedures and compliance plans.

#### Think and act ethically

Follow our ethical standards and those of your professional organizations. Before you say or do something, ask yourself: How would this look to our patients and our community? Would this harm our reputation?

#### Keep it confidential

Handle all MD Anderson information, especially patient information, in ways that meet applicable laws, rules, guidelines and document retention schedules. Treat our information the same way you treat yours.

#### Commit to research integrity

Perform all research efforts in ways consistent with applicable legal, ethical and professional requirements, as well as MD Anderson rules, policies and procedures.

#### **Avoid gifts**

In general, you can't accept or give gifts, favors, benefits, services or items of value — especially in return for preferential treatment or patient referrals.

#### **Bill accurately**

When you document and bill for the care you've provided, be accurate, be thorough, be honest — and be timely.

## Focus on Making Cancer History®

Don't use any MD Anderson resources, including your time and your colleagues' time, in a wasteful manner, for personal benefit, to harm someone, for political activity or for illegal activity.

#### Be true to our mission

Avoid outside influences: Don't engage in activities or enter into contracts that could or could seem to interfere with your MD Anderson work, make you disclose confidential MD Anderson information or affect your independent judgment.

#### Be a good colleague

Act with honesty and good faith in all matters. Don't engage in discriminatory, harassing, retaliatory, inappropriate, intimidating or disruptive behaviors.

#### When in doubt, point it out

If you think or discover that someone isn't following our Code of Conduct, promptly notify the chief compliance and ethics officer or the Institutional Compliance Office. And always cooperate fully with all inquiries and investigations related to reported issues.

#### Do the Right Thing: MD Anderson's Standards of Conduct

is a publication of MD Anderson's Institutional Compliance Office

Email: Institutional\_Compliance@mdanderson.org

**Telephone:** 713-745-6636

**Fax:** 713-563-4324

**Compliance Hotline:** 1-800-789-4448 **Online:** www.mdanderson.org/dotherightthing

#### **Mailing address:**

Institutional Compliance Office - Unit 1640
The University of Texas MD Anderson Cancer Center P.O. Box 301407
Houston, TX 77230-1407