

Research Compliance Plan

Mission Statement

The mission of The University of Texas MD Anderson Cancer Center (MD Anderson) 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. To fulfill this mission:

- We are committed to meeting the highest standards of medical and business ethics.
- We recognize that, regardless of payor source, appropriate, medically necessary services must be delivered in the most efficient manner and meet all applicable local, state and federal guidelines and regulations.
- We are intolerant of fraud, waste and abuse and violations of such guidelines and regulations.
- We are committed to providing education, monitoring and oversight to ensure that faculty, employees, volunteers, trainees, contractors and other persons whose conduct, in the performance of work for MD Anderson, is under the direct control of MD Anderson, whether or not they are paid by MD Anderson, (collectively referred to as Workforce Members) are fully informed and committed to these standards.
- We promote an open work environment so that all individuals associated with MD Anderson feel free to communicate openly on such issues.

The mission of MD Anderson's Institutional Compliance Program is to support MD Anderson's Mission, Vision, and Core Values and to help 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 will also continually assess the effectiveness and quality of the program to ensure that all MD Anderson business is conducted with integrity and in compliance with the law.

Code of Conduct

MD Anderson requires all Administration, Medical Staff, employees, and other Workforce Members to follow the [Standards of Conduct](#) adopted by the Board of Regents.

MD Anderson is committed to full compliance with all applicable laws, rules, and guidelines. To such end and in order to uphold MD Anderson's core value of integrity, our Workforce Members are required to conduct themselves in accordance with the following principles of the Institutional Code of Conduct:

Principle One: 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.

Principle Two: 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?

Principle Three: 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.

Principle Four: Commit to research integrity

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

Principle Five: 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.

Principle Six: Bill accurately

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

Principle Seven: 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.

Principle Eight: 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 judgement.

Principle Nine: Be a good colleague

Act with honesty and good faith in all matters and refrain from engaging in discriminatory, harassing, retaliatory, inappropriate, intimidating, or disruptive behaviors.

Principle Ten: 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.

Compliance Oversight

The purpose of MD Anderson's Research Compliance Plan is to assure that MD Anderson complies with federal and state laws, regulations and guidelines, The University of Texas rules and guidelines, U.T. System and MD Anderson policies, applicable to the conduct of research (collectively Research Compliance Requirements).

Responsibility for oversight of the Research Compliance Plan rests with the multi-disciplinary Executive Research Compliance Committee (ERCC) and its subcommittee(s), whose membership is appointed by the Vice President, Chief Compliance and Ethics Officer (CCO) and annually approved by the Executive Institutional Compliance Committee (EICC). All members of the ERCC must sign a statement assuring total confidentiality in all dealings of the ERCC. The ERCC is a Medical Committee within the meaning of [Texas Health and Safety Code § 161.031](#). Minutes of all ERCC meetings are maintained in a confidential manner and are provided to the EICC. Minutes are maintained in the Institutional Compliance Office.

The ERCC is charged with the following tasks:

- Prepare and submit to the EICC an annual work plan that outlines the major activities and initiatives of the ERCC for the upcoming fiscal year.
- Prepare and submit to the EICC an annual report that summarizes the ERCC's progress regarding each work plan objective contained in the ERCC's annual work plan for the preceding fiscal year.
- Validate the annual Compliance Risk Analysis related to research compliance matters.

The responsibility for implementing and managing the Institutional Compliance Program and Research Compliance Plan is assigned to the CCO, who functions within MD Anderson's organizational structure. The CCO, or designee, will, with assistance of the ERCC, perform the following activities:

- Develop or assist with developing response plans for certain risks identified through the annual Compliance Risk Assessment.
- Review laws, regulations, statutes, policies, and guidelines related to research compliance.
- Serve as a resource across MD Anderson on substantive research compliance questions and issues.
- Assist with developing training materials and monitoring training programs, as needed.
- Mandate the completion of training programs regarding specific research compliance topics.
- Communicate regularly with the EICC on new and emerging issues related to research compliance.
- Review, revise, recommend, and formulate appropriate policies and procedures and related materials to guide the Research Compliance Plan.
- Develop and monitor methodologies and systems to optimize the implementation of the Research Compliance Plan.
- Recommend and monitor the development and implementation of necessary changes in practice and procedure in identified specific research compliance risk areas to improve compliance with the Research Compliance Requirements.
- Develop and implement an effective audit and monitoring program concerning research compliance.
- Respond to, conduct, and coordinate the investigation of alleged non-compliance with Research Compliance Requirements.
- Take all actions, including recommending corrective and/or disciplinary action, necessary to ensure MD Anderson's full compliance with the Research Compliance Requirements; and
- As needed, complete and submit a report of findings regarding research compliance to the EICC, the President, The University of Texas System Chief Compliance Officer, and any other appropriate authority.

The ERCC and the Institutional Compliance Office (ICO) will seek guidance and input from various departments and committees that manage research support related operations in accordance with the Research Compliance Requirements, and from the institutional Research Integrity Officer.

The Clinical Research Billing Compliance Subcommittee (CRBCS), a subcommittee of the Executive Billing Compliance Committee (EBCC) and the ERCC, is responsible for oversight of clinical research billing compliance. CRBCS composition, functions, and responsibility information is described in the Billing Compliance Plan.

Education

Compliance with all applicable laws and regulations is one of MD Anderson's priorities. Workforce Members at MD Anderson must be knowledgeable about MD Anderson's Institutional Code of Conduct and policies and plans regarding institutional compliance. Compliance with applicable laws, rules, guidelines, as well as institutional policies and plans is a condition of employment. Failure to comply may result in disciplinary action, including termination. All Workforce Members engaged in research must be knowledgeable about all applicable Research Compliance Requirements. The institutional operational units responsible for the various research areas will develop and implement training programs, as appropriate. Mandatory training must be completed in accordance with requirements established by the applicable MD Anderson operational unit, the ERCC, or the EICC prior to commencement of research or within established timeframes.

Training courses are periodically evaluated and updated to ensure delivery of relevant information. The ICO will conduct, as needed, additional training and education regarding new and emerging compliance issues and trends. A variety of teaching materials, tools, and methods are used to facilitate understanding of the subject matter. Tracking of attendance/training completion will be maintained by the operational units conducting the training programs. Additional training will be provided as requested by the operational units or as recommended by the ICO.

Failure to complete the mandatory training as required by institutional policy and applicable legal and regulatory requirements may lead to disciplinary action.

Ongoing Monitoring and Auditing

1.0 Monitoring Activities

1.1 The CCO, or designee, shall meet periodically with designated departmental representatives to stay abreast of current and/or new matters related to research compliance.

1.2 The CCO, or designee, shall monitor the progress of risk management plans.

2.0 Auditing Activities

The CCO, or designee, shall perform periodic audits or similar assurance activities regarding research compliance.

Corrective and/or Disciplinary Action

MD Anderson upholds a "zero tolerance" policy towards any illegal activity or knowing, intentional or willing non-compliance. Any employee knowingly, willingly, and/or intentionally in violation of the federal and state laws, regulations, Regents' Rules and Regulations and/or institutional policies is subject to disciplinary actions, up to and including termination. All actions taken will be in accordance with MD Anderson's [Hospital Compliance Plan](#).

Investigation and Remediation

The CCO, with support from legal counsel and the EICC, addresses any violation of the laws, regulations, and MD Anderson's policies and standards applicable to governmental compliance. Whenever a compliance issue has been identified through the hotline, direct contact, a third-party, or other source, the CCO will initiate a confidential investigation to determine the facts and circumstances of the potential violation. The CCO does not apprise complainants or reporters of the status of investigations, barring exceptional circumstances.

The CCO may accept a previously conducted investigation if such investigation was conducted with knowledge and approval of the CCO. Compliance investigations will be performed with the assistance of legal counsel, as needed, and will be reported confidentially to the EICC, and ERCC as appropriate. If the CCO believes the integrity of the investigation is at stake, the appropriate employee(s) may be removed from duty until the investigation is completed. The CCO ensures that steps are taken to prevent destruction of documents or other evidence.

The CCO promptly and fully investigates all reports professionally and without prejudice. Consultations follow with the appropriate division head(s), manager, and/or employee, as appropriate. The corrective action plan to be implemented is determined after the outcome of each investigation. In determining the corrective action plan, MD Anderson should not take into consideration a Workforce Member's economic benefit to MD Anderson. All corrective action taken will be in accordance with MD Anderson's [Hospital Compliance Plan](#). If the investigation indicates that disciplinary action is warranted, such action will be imposed in accordance with MD Anderson's written standards of disciplinary action.

Any misconduct that violates civil or criminal law, or rules and regulations may be reported, to the governing body after receipt of the credible evidence of misconduct, along with a description of the appropriate disciplinary action taken. If applicable, plans for repayment of funds will be included in the report.

Sanctioned Individuals

MD Anderson prohibits the employment of or contracting with individuals or entities who: (a) have a criminal history related to health care; or (b) have been disbarred, excluded, or otherwise determined ineligible for participation by certain federal or state agencies ("Adverse Action Databases"). Sanction Checks are handled in accordance with the MD Anderson [Hospital Compliance Plan](#).

Reporting Compliance Concerns

Remaining silent and failing to report any violation or potential violation that a person knows or should have known of, may subject a person to disciplinary action up to and including termination. 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.

To encourage open communication in all dealings with the CCO and the EICC, Workforce Members contacting the Institutional Compliance Office are assured non-retaliation in accordance with the [Non-Retaliation Policy \(UTMDACC Institutional Policy # ADM0254\)](#) and an atmosphere of confidentiality.

To report compliance concerns, Workforce Members may:

- Call the Compliance Hotline at: 1-800-789-4448;
- Contact the Institutional Compliance Office directly at: 713-745-6636; or
- Contact the CCO via the Page Operator at: 713-792-7090.
- 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, <http://sao.fraud.state.tx.us>.

MD Anderson has established the Compliance Hotline listed above, for Workforce Members to report all suspected violations or questionable conduct. The hotline includes the following features:

- The hotline number is included in employment materials, employee badge cards, Institutional Compliance Program website, MD Anderson's Standards of Conduct: Do the Right Thing, and it displayed in poster form on MD Anderson bulletin boards;
- Telephone calls to the hotline are treated anonymously upon request, and confidentially to the extent possible;
- The caller is not recorded, traced or identified, and the caller is not required to furnish his/her name;
- Information provided to the hotline is treated as privileged to the extent permitted by applicable law;
- The CCO strictly complies with and enforces MD Anderson's [Non-Retaliation Policy \(UTMDACC Institutional Policy # ADM0254\)](#).

Intentionally making false accusations is a serious violation of MD Anderson policy and will lead to disciplinary actions against the person making the accusation, up to and including termination of employment;

Employees may not use the hotlines to protect themselves from the outcome of their own violations or misconduct, nor will the discipline be increased or decreased for an employee who reported his or her own violation;

Upon receiving information from the hotline, the CCO will communicate and disseminate all compliance complaints to the triage team and assign to the appropriate party for investigation;

Each report will be reviewed, and the CCO or designee, will initiate any investigations, corrections and/or follow-up on an as-needed basis in accordance with provisions of this plan; and

The CCO will provide routine reports and periodic updates as deemed necessary to the EICC and President.

References

[Clinical Research Finance.](#)

[Department of Environmental Health and Safety \(EH&S\).](#)

[Hospital Compliance Plan.](#)

[http://sao.fraud.state.tx.us.](http://sao.fraud.state.tx.us)

[Institutional Animal Care and Use Committee \(IACUC\).](#)

[Institutional Biosafety Committee \(IBC\).](#)

[Institutional Conflict of Interest Committee \(COIC\).](#)

[Institutional Review Board \(IRB\).](#)

[Human Embryonic and Induced Pluripotent Stem Cell Oversight Committee \(HEIPSCO\)](#)

[Radiation Safety Committee \(RSC\)](#)

[Research Integrity](#)

[Non-Retaliation Policy \(UTMDACC Institutional Policy # ADM0254\).](#)

[Office of Clinical Research \(OCR\).](#)

[Office of Research Administration \(ORA\).](#)

[Office of Sponsored Programs \(OSP\).](#)

[Standards of Conduct.](#)

[The University of Texas System Regents' Rules and Regulations Series 30103: Standards of Conduct.](#)

[The University of Texas System Policies & Standards - UTS163: Guidance on Effort Reporting Policies \(UTS163\).](#)

APPROVALS

| Date | Approver |
|------------|--|
| 10-27-2020 | Executive Institutional Compliance Committee |
| 02-07-2020 | Vice President & Chief Compliance and Ethics Officer |
| 10-22-2019 | Executive Institutional Compliance Committee |
| 10-17-2018 | Executive Institutional Compliance Committee |
| 11-06-2017 | Executive Institutional Compliance Committee |
| 11-20-2014 | Executive Institutional Compliance Committee |
| 09-11-2013 | Executive Institutional Compliance Committee |
| 10-09-2012 | Executive Institutional Compliance Committee |
| 09-07-2011 | Executive Institutional Compliance Committee |
| 11-30-2010 | Executive Institutional Compliance Committee |

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