

FY24 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, research, 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 understand that promoting research integrity, including appropriate use of all research funding and accurate documentation of all research work, is critical to ensuring our ongoing research efforts and fulfilling federal, state, and The University of Texas System (UT System) requirements
- We are intolerant of fraud, waste and abuse and other 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 facilitate programs to address key risk areas including international relationships, cybersecurity threats, and continually reassess the risk environment to proactively develop standards and processes that protect our resources.
- 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 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;
- Foster an environment of open communication by educating Workforce Members about their obligations to report compliance concerns;
- Protect 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; and
- Continually assess the effectiveness and quality of its 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 for the UT System (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 ten principles comprising [MD Anderson's 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 judgement.

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 Institutional Compliance. And always cooperate fully with all inquiries and investigations related to reported issues.

Executive Research Compliance Oversight

The purpose of the 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, and UT 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) as appropriate, whose membership is appointed by the Vice President, Chief Compliance and Ethics Officer (CCEO) 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](#). Dealings and minutes of all ERCC meetings are maintained in a confidential manner, provided to the EICC, and maintained by Institutional Compliance.

The ERCC is charged with the following tasks:

- Prepare and submit to the EICC and ERCC an annual report that summarizes the risk-based Institutional Compliance Work Plan.
- Validate the annual Compliance Risk Analysis related to research compliance matters.

The responsibility for implementing and managing the Institutional Compliance Program and the Research Compliance Plan is assigned to the CCEO, who functions within MD Anderson's organizational structure with a direct reporting relationship to the President and an administrative reporting relationship to the Senior Vice President, Regulatory Affairs. The CCEO, or designee, will, with assistance and guidance from the ERCC, perform the following activities:

- Develop or assist with developing risk management plans for risks areas identified through the annual Compliance Risk Analysis.
- 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 the action(s), 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 UT System Chief Compliance Officer, and any other appropriate authority.

The ERCC and Institutional Compliance 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 Science, Technology and Research Compliance Committee (Research Security Compliance Subcommittee) (STARCC), a subcommittee of the ERCC, is responsible for promoting the security of information, resources, and other products resulting from research efforts led or supported by MD Anderson. STARCC composition, functions, and responsibility information is described in its bylaws.

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 [Code of Conduct](#), [Standards of Conduct: Do the Right Thing](#), [institutional policies](#), and plans regarding compliance issues. Compliance with applicable laws, rules, guidelines, as well as institutional policies and plans is a condition of employment. Failure to comply may result in corrective action, up to and 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. Failure to complete the mandatory training as required by institutional policy and applicable legal and regulatory requirements may lead to corrective or disciplinary action.

Training courses are periodically evaluated and updated to ensure delivery of relevant information. Institutional Compliance 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 Institutional Compliance.

Ongoing Monitoring and Auditing

1.0 Monitoring Activities

- 1.1 The CCEO, 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 CCEO or designee shall monitor the progress of risk management plans.

2.0 Auditing Activities

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

Corrective Action and Disciplinary Action

MD Anderson upholds a "zero tolerance" policy toward any illegal activity or knowing, willing or intentional non-compliance with federal and state laws and regulations, and MD Anderson's policies. All actions taken will be in accordance with MD Anderson's [Hospital Compliance Plan](#).

Investigation and Remediation

Institutional Compliance investigations are conducted under, and therefore protected by, one or more of the following: Texas Rule of Evidence 503 (the lawyer-client privilege), Texas Education Code §51.971 (institutions of higher education conducting compliance program investigations), and/or Texas Health and Safety Code §161.032(b)(1), (c), and (e) (Medical Committees and compliance officer privileges).

The CCEO, 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 raised through MD Anderson's Compliance Hotline, direct contact, a third-party, or other source, and a preliminary assessment suggests that an investigation is warranted, the CCEO will initiate a confidential investigation to determine the facts and circumstances of the potential violation. Compliance investigations will involve only those individuals necessary to resolve a fact or issue. Barring exceptional circumstances, the CCEO does not apprise complainants or reporters of the status of investigations.

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

The CCEO promptly and fully investigates all reports professionally and without prejudice. Consultations follow with the appropriate division head(s), department chair(s), manager(s), and/or Workforce Member(s), as appropriate.

The CCEO ensures that all those interviewed as part of the investigative process are entitled to have a representative or advocate present during their interview. However, an interviewee's representative/advocate is not permitted to steer, coach, or rehabilitate the interviewee's responses or otherwise compromise the integrity of the interview. Any such attempts to compromise the integrity of the interview may be considered noncooperation. The interviewee will be provided with a copy of [MD Anderson's Non-Retaliation Policy \(MD Anderson Institutional Policy # ADM0254\)](#) and apprised of the ramifications of, as a consequence of the interview, engaging in conduct implicated by the Policy.

If an investigation indicates that corrective action is warranted, such action will be imposed in accordance with MD Anderson's written standards of corrective action and outlined in a corrective action plan. The corrective action plan to be implemented is developed after the outcome of each investigation. In determining the corrective action plan, MD Anderson should not take into consideration a Workforce Member's economic or reputation benefit to the institution. All corrective actions provided in the plan are disseminated to those responsible for completing such actions and must be undertaken and completed within their specified timeframes.

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 such misconduct, along with a description of the appropriate corrective action taken. If applicable, plans for repayment of federal funds will be included in the report.

Corrective action plans should also include determining whether the problem is systemic and implementing any necessary preventive measures.

Sanctioned Individuals

MD Anderson prohibits the employment of individuals who:

- have a criminal history related to federal health care program or state health care program; or
- have been disbarred, excluded, or otherwise determined ineligible for participation in federal health care programs as evidenced by appearance in one of the agencies listed in the Adverse Action Databases, as applicable. 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 Workforce Member knows or should have known of may subject a person to corrective 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 CCEO and the ERCC, Workforce Members contacting Institutional Compliance are assured non-retaliation in accordance with the [Non-Retaliation Policy \(MD Anderson Institutional Policy #ADM0254\)](#) and an atmosphere of confidentiality.

To report compliance concerns, Workforce Members and any other member of the MD Anderson community, including patients and their family members, may:

- Call the Compliance Hotline at: 1-800-789-4448;
- Call Institutional Compliance directly at: 713-745-6636; or
- Contact the CCEO via the Page Operator at: 713-792-7090.
- Email Institutional Compliance at Institutional_Compliance@mdanderson.org; or
- Submit an online report through the [Detecting and Addressing Compliance Concerns webpage](#).

Suspected fraud, waste, and abuse involving state resources may be reported to the State Auditor's Office's Hotline at 1-800-TX-AUDIT (1-800-892-8348). Additional information is provided on the [State Auditor's Office website](#).

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

- The Compliance Hotline number is included in employment materials, Code of Conduct badge cards, the Institutional Compliance Program intranet site and website, and MD Anderson's Standards of Conduct: Do the Right Thing and is displayed in poster form on MD Anderson bulletin boards.
- Telephone calls to the Compliance 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 Compliance Hotline is treated as privileged to the extent permitted by applicable law.
- Upon receiving information from the Compliance Hotline, the CCEO 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 CCEO or designee, will initiate any investigations, corrections and/or follow-up on an as-needed basis in accordance with provisions of this plan.
- The CCEO will provide routine reports and periodic updates as deemed necessary to the EICC and President.

Note that intentionally making false accusations is a serious violation of MD Anderson policy and will lead to corrective actions against the person making the accusation, up to and including termination of employment. Workforce Members may not use the Compliance Hotline to protect themselves from the outcome of their own violations or misconduct; however, self-reporting is strongly encouraged and may be considered a mitigating factor when determining the appropriate corrective actions.

In all reports of compliance concerns, the CCEO strictly complies with and enforces MD Anderson's [Non-Retaliation Policy \(MD Anderson Institutional Policy #ADM0254\)](#).

References

[Clinical Research Finance](#)

[Corrective Action Policy \(MD Anderson Institutional Policy #ADM0256\)](#)

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

[Hospital Compliance Plan](#)

[State Auditor's Office](#)

[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 \(MD Anderson Institutional Policy # ADM0254\)](#)

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

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

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

[MD Anderson's 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 \(UTS163\)](#)

[Texas Health and Safety Code § 161.031](#)

APPROVALS

Date	Approver
10-24-2023	Executive Institutional Compliance Committee
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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