MD Anderson’s Standards of Conduct:

Do the Right Thing

The University of Texas MD Anderson Cancer Center

Making Cancer History
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 a research compliance program that works in concert with our academic research endeavors. The goal of the program is to ensure that all research (including clinical, behavioral, and translational 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 and MD Anderson policies and procedures.
- 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 Documentation and Billing section.

Human Subjects Research

Human subjects research is research that involves a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual, or identifiable private information. Human subjects research includes research on disease mechanisms, therapeutic interventions, clinical trials, epidemiological and behavioral studies,
biomarker 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 an Institutional Review Board (IRB) 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.
- You will be in violation of both federal law and MD Anderson’s policies and procedures if you:
  - Conduct human subjects research without an IRB approved protocol.
  - Do not adhere to an IRB approved protocol.
  - Implement any change to your IRB approved protocol without IRB approval.
- Individuals should clearly understand everything that will happen to them, how their information will be used, and their financial responsibilities if 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.
- Be familiar with the requirements set forth in the MD Anderson Animal Care and Use Handbook and the National Research Council’s 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.

**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. Information on the IBC, and procedures related to approval of use of recombinant DNA, select agents and toxins, and/or biohazardous agents are available on the Office of Research Administration intranet page.

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.
**Effort Commitment/Effort Certification**

Expenditure of federal grant money is governed by federal cost principles. Thus, the use of grant funds for salaries, wages, and fringe benefits is allowable only if the payments conform to specific regulatory requirements.

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 Effort Certification Policy (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.

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

**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 define a Significant Financial Interest as anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights (e.g., patents, copyrights, and royalties from such rights).

An investigator who plans on participating in PHS funded research is required to disclose to MD Anderson his/her known Significant Financial Interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research for which PHS funding is sought; and (ii) in entities whose financial interests would reasonably appear to be affected by the research.

MD Anderson determines if the disclosed Significant Financial Interest constitutes a conflict of interest that must be managed, reduced, or eliminated. All financial disclosures must be updated during the period of the award, on an annual basis and as newly reportable financial interests are obtained. PHS funds may not be expended until an investigator’s conflict of interest has been managed, reduced, or eliminated.
**Export Controls**

The export (actual and deemed) of goods, software, technical data, and military items that are of U.S. origin is subject to compliance with federal export controls laws. The release of controlled technology to a foreign national in the U.S. through a demonstration or oral presentation is a deemed export. Actual and/or deemed exports of controlled technology require an export license.

The export of publicly available technology or technology that meets the fundamental research exception is exempt from the license requirement.

Workforce members should call the Office of Research Administration or the Institutional Compliance Office with questions related to export controls requirements and applicable institutional procedures.

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**Principle 4**

Conduct all research in a manner consistent with applicable legal, ethical, and professional requirements, as well as MD Anderson policies and procedures.