THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center
Making Cancer History®

UTMDACC INSTITUTIONAL POLICY # ACA0013

RESEARCH MISCONDUCT POLICY

PURPOSE

The purpose of this policy is to establish and communicate Research Misconduct guidelines for individuals involved in research activities at The University of Texas MD Anderson Cancer Center (MD Anderson). This policy is meant to carry out the institution's responsibilities under Public Health Service (PHS) Policies on Research Misconduct, 42 CFR Part 93.

POLICY STATEMENT

It is the policy of MD Anderson to foster a research environment that:

- Promotes the responsible conduct of research, research training, and activities related to that research or research training;
- Discourages Research Misconduct; and
- Deals promptly with Allegations or evidence of possible Research Misconduct.

Research Misconduct is an offense that not only damages the reputation of the entire academic community, but also can result in civil and criminal penalties against involved faculty, trainees/students, and other members of MD Anderson's workforce. MD Anderson and its faculty, trainees/students, and other members of MD Anderson's workforce have an Affirmative Duty to protect research funds from misuse and to assure the integrity of all research. Faculty, trainees/students, and other members of MD Anderson's workforce are responsible for responding to and reporting Allegations of Research Misconduct.

SCOPE

This policy applies to:

- All faculty, trainees/students, and other members of MD Anderson's workforce; and
- Activities that involve proposing, performing, or reviewing and/or reporting biomedical or behavioral research and biomedical or behavioral training.

Compliance with this policy is the responsibility of all faculty, trainees/students, and other members of MD Anderson's workforce.

DEFINITIONS

Affirmative Duty: A legal obligation to act in a specific, proactive manner.

Allegation: Disclosure of possible Research Misconduct through any means of communication. The disclosure may be a written or oral statement or other communication to an MD Anderson or United States Department of Health and Human Services (HHS) official.

Committee Member: Faculty, trainees/students, or other members of MD Anderson's workforce involved in a Research Misconduct Proceeding who:

- Shall not have any unresolved personal, professional, or financial conflict of interest with respect to the matter or any individual involved in the matter;
- Shall be unbiased; and
- Shall have the appropriate expertise (including scientific) to evaluate the evidence and issues related to the Allegations and to conduct the Investigation.

Complainant: Person who in Good Faith makes an Allegation of Research Misconduct.

Finding of Research Misconduct: Requires that:

- There be a significant departure from accepted practices of the relevant research community;
- The Research Misconduct be committed intentionally, knowingly, or recklessly; and
- The Allegation must be proved by a Preponderance of the Evidence.

Good Faith: For a Complainant or a witness, having a belief in the truth of one's Allegation or testimony that a reasonable person in the Complainant's or witness' position could have based on the information known to the Complainant or witness at the time.

For a Committee Member, cooperating with the Research Misconduct Proceeding by carrying out the duties assigned impartially to help MD Anderson meet its responsibilities pursuant to this policy and the law.

Initial Inquiry Report: A written report that includes:

- The name and position of the Respondent;
- A description of the Allegations of Research Misconduct;
- The PHS or other support, including, for example, grant numbers, grant applications, contracts, and publications listing PHS or other support; and
- The basis for recommending that the alleged actions warrant an Investigation.

Inquiry: The preliminary information gathering and fact-finding in response to an Allegation to determine whether or not a formal Investigation is required.

Investigation: Formal development of a factual record and the examination of that record leading to a decision not to make a Finding of Research Misconduct or to make a recommendation for a Finding of Research Misconduct including a recommendation for other appropriate action(s).

Office of Research Integrity (ORI): The office to which the HHS Secretary has delegated responsibility for addressing research integrity and misconduct issues related to PHS' supported activities.

Preponderance of the Evidence: Proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not.

Public Health Services (PHS): The unit within the HHS that includes the Office of Public Health and Science and the following Operating Divisions: Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and the Substance Abuse and Mental Health Services Administration, and the offices of the Regional Health Administrators.

Research Misconduct: Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or in reporting research results. Research Misconduct does not include honest error or differences of opinion.

- **Fabrication:** Making up data or results and recording or reporting them.
- **Falsification:** Manipulating research materials, equipment or processes, or changing or omitting data or results such that the research is not accurately represented in the Research Record.
- **Plagiarism:** The appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

Research Misconduct Proceedings: Any actions related to alleged Research Misconduct taken by MD Anderson under this policy, including but not limited to, Allegation assessments, Inquiries, and Investigations.

Research Record: Record of data or results that embody the facts resulting from scientific inquiry, including but not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and any documents and materials provided to the HHS or an institutional official by a Respondent in the course of a Research Misconduct Proceeding. A Research Record includes, but is not limited to, grant or contract applications, whether funded or unfunded; grant or contract progress reports or other reports; laboratory notebooks; notes; correspondence; videos; photographs; X-ray film; slides; biological materials; computer files, diskettes, or hard drives, and printouts; instrument files and printouts; manuscripts and publications; equipment use logs; laboratory procurement records; animal facility records; human and animal subject protocols; human research subject consent forms; human research subject medical charts; and human research subject files; or any other written or non-written account or object that reasonably may be expected to provide evidence or information regarding the proposed, conducted, or reported research that constitutes the subject of an Allegation of Research Misconduct.

Respondent: Person against whom an Allegation of Research Misconduct is directed, or who is the subject of a Research Misconduct Proceeding.

PROCEDURE

1.0 Confidentiality, Impartiality, and Non-Retaliation

1.1 Any Inquiry or Investigation of Allegations of Research Misconduct must proceed promptly, confidentially to the extent allowed by law, and with due regard for the reputation and rights of all individuals involved. MD Anderson will take all reasonable steps to assure that affected individuals will receive confidential treatment to the maximum extent allowed by law. All MD Anderson faculty, trainees/students, and other members of MD Anderson's workforce are expected to act in Good Faith, cooperate in any Allegation assessment, Inquiry or Investigation, and to treat the matter with confidentiality.

1.2 MD Anderson will undertake diligent efforts to protect or restore the positions and reputations of all:

A. Good Faith Complainants,

B. Witnesses,

C. Committee Members, and

D. Respondents against whom no Finding of Research Misconduct is made.

1.3 MD Anderson will also protect Good Faith Complainants, witnesses, and Committee Members from retaliation by Respondent(s) or other faculty, trainees/student(s), or other member(s) of MD Anderson's workforce.

1.4 Complainants or witnesses determined to be acting in bad faith may be sanctioned in accord with the institution's disciplinary policies.

1.5 Legal advice will be sought from institutional counsel and University of Texas System General Counsel as appropriate.

2.0 Evidentiary Standards

All Finding(s) of Research Misconduct made pursuant to this policy will apply the following evidentiary standards:

2.1 Finding of Research Misconduct must be proved by a Preponderance of the Evidence.

2.2 MD Anderson has the burden of proof for making a Finding of Research Misconduct.

2.3 The destruction, absence of, or a Respondent's failure to provide Research Records adequately documenting the questioned research shall be evidence of Research Misconduct where the institution establishes that the Respondent:

A. Intentionally, knowingly, or recklessly had Research Records and destroyed them;

B. Had the opportunity to maintain the Research Records and failed to produce them in a timely manner; and

C. Engaged in conduct that constitutes a significant departure from the accepted practices of the relevant research community.

2.4 The Respondent has the burden of going forward with and proving by a Preponderance of the Evidence any and all affirmative defenses, such as honest error or difference of opinion, raised.

2.5 The Respondent has the burden of going forward with and proving by a Preponderance of the Evidence any mitigating factors that are relevant to a decision to impose administrative actions following a Research Misconduct Proceeding.

3.0 Allegations

3.1 Allegations of Research Misconduct, including any new Allegations related to a Respondent and the Respondent's ongoing Research Misconduct Proceeding should be brought to the attention of the appropriate Department Chair, Division Head, Vice President, Chief Academic Officer, the Institutional Research Integrity Officer, or the Chief Compliance Officer. If such Allegations involve a Department Chair, Division Head or Vice President, the Allegations should be brought to the attention of the Chief Academic Officer or the Chief Compliance Officer.

3.2 The recipient of the Allegations will bring such Allegations to the attention of the Chief Academic Officer and the Institutional Research Integrity Officer.

3.3 Upon receiving an Allegation of Research Misconduct, the Chief Academic Officer and the Institutional Research Integrity Officer will immediately assess the Allegation to determine if an Inquiry is warranted based on whether or not the Allegation:

A. Falls within the definition of Research Misconduct; and

B. Is sufficiently credible and specific so that potential evidence of Research Misconduct may be identified.

3.4 If the Chief Academic Officer and the Institutional Research Integrity Officer determine that the Allegation(s) received warrant an Inquiry, the Chief Academic Officer will send a written notice of such Allegations to the attention of:

A. Individual(s) accused of Research Misconduct;

B. Any researcher(s) affected by the Allegation(s);

C. Relevant Department Chair(s); and

D. Relevant Division Heads.

3.5 If the Institutional Research Integrity Officer as well as the Chief Academic Officer determine that an Allegation was not made in Good Faith, the Chief Academic Officer, in conjunction with the President of MD Anderson, will determine whether any administrative action should be taken against the Complainant.

3.6 Upon a finding that Inquiry into the Allegation is warranted, the institution shall make good faith effort to provide notice to the Respondent. Such notice shall include:

A. Information on the nature of the Allegation;

B. A copy of the PHS Policies on Research Misconduct; and

C. A copy of this policy.

4.0 Inquiry

4.1 If additional Respondents are identified during the Inquiry, MD Anderson will make a Good Faith effort to notify them within a reasonable amount of time.

4.2 If an Inquiry is warranted, the Chief Academic Officer, in consultation with the Institutional Research Integrity Officer, will appoint an inquiry committee consisting of at least three Committee Members to evaluate the evidence and issues related to the Inquiry (Inquiry

Committee). The Committee Members, with due regard for the reputations of all parties involved, will immediately initiate the Inquiry process and document the decision.

4.3 The purpose of the Inquiry is to conduct an initial review of the evidence to determine whether to conduct an Investigation; and thus an Inquiry does not require the full review of all the evidence related to the Allegation.

4.4 The Institutional Research Integrity Officer shall obtain relevant Research Records necessary to determine whether an Investigation is warranted. Such Research Records shall be maintained in accordance with the Records and Documentation Section below.

4.5 The Committee Members shall conduct the Inquiry to determine whether an Investigation is warranted, using the following criteria:

A. There is a reasonable basis for concluding that the Allegation falls within the definition of Research Misconduct.

B. Preliminary information-gathering and preliminary fact-finding from the Inquiry indicates that the Allegation may have substance.

4.6 The Committee Members should complete the initial review of the evidence and the Inquiry within 60 calendar days from initiating the Inquiry. If circumstances clearly warrant a longer period, the Inquiry record must include documentation of the reasons for exceeding the 60 calendar-day period.

4.7 Upon the completion of the Inquiry, the institution shall provide notice to the Respondent. Such notice shall include:

A. A determination as to whether the Inquiry found that an Investigation is warranted;

B. A copy of the PHS Policies on Research Misconduct;

C. A copy of this policy; and

D. A copy of the Initial Inquiry Report.

4.8 If the Respondent wishes to provide written comments to the Initial Inquiry Report, such written comments must be provided to the President of MD Anderson through the Office of Research Administration and/or the Institutional Research Integrity Officer no later than 10 calendar days from the date the Respondent received the report.

4.9 At a minimum, the final written Inquiry report shall include the following:

A. The name and position of the Respondent;

B. A description of the Allegations of Research Misconduct;

C. The PHS or other support, including, for example, grant numbers, grant applications, contracts, and publications listing PHS support;

D. If an Investigation is warranted, the basis for recommending that the alleged actions warrant an Investigation; and

E. Any comments on the report provided by the Respondent or the Complainant.

4.10 With respect to PHS supported research, in the event that the institution determines that an Investigation is warranted, the Institutional Research Integrity Officer shall provide ORI with the written finding of the Inquiry, and a copy of the final written Inquiry Report. In addition, the Institutional Research Integrity Officer will notify the ORI Director of the decision to begin an Investigation on or before the date the Investigation begins.

4.11 Upon the request of ORI, the institution will also provide the following additional information:

A. A copy of this policy;

B. The Research Records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and

C. The charges for the Investigation to consider.

4.12 In the event that the institution determines that an Investigation is not warranted, the institution shall keep sufficiently detailed documentation of the Inquiry to permit a later assessment by ORI of the reasons why the institution decided not to conduct an Investigation. Such documentation shall be maintained in accordance with Section 6.0, Records and Documentation Section, and provided to the ORI upon its request.

5.0 Investigation

5.1 Under no circumstance may an Investigation begin, until the institution has provided the Respondent with written notification of the Allegation(s) of Research Misconduct. Such notification shall be provided within a reasonable amount of time after determining that an Investigation is warranted. The Investigation must begin within 30 days from the date the Inquiry Committee determines that an Investigation is warranted.

5.2 As they become known or relevant, any additional Research Records that were not obtained during the Inquiry will be obtained by the institution. In addition, the institution will ensure that such additional Research Records are maintained in accordance with Section 6.0, Records and Documentation Section.

5.3 Investigation Committee Membership:

A. If an Investigation is warranted, the Chief Academic Officer, the Institutional Research Integrity Officer, and the Chair of the Faculty Senate will appoint a committee of at least three 3 Committee Members to evaluate the evidence and issues related to the Investigation (Investigation Committee). These Committee Members may be the same individuals who conducted the Inquiry.

B. The Respondent shall be given the opportunity to provide a list of individuals who may be inappropriate to serve as a Committee Member on the basis of personal, professional, or financial conflicts of interest.

5.4 The Committee Members shall:

A. Use diligent efforts to ensure that the Investigation is thorough as well as sufficiently documented, and that it includes examination of all Research Records and evidence relevant to reaching a decision on the merits of the Allegations.

B. Take reasonable steps to ensure an impartial and unbiased Investigation to the maximum extent practicable.

C. Interview the Respondent, Complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspect of the Investigation, including witnesses identified by the Respondent. Such interviews shall be recorded or transcribed. The interviewee will be provided with an opportunity to review and correct the recording or transcript. MD Anderson will include the recording or transcript in the record of the Investigation.

D. Diligently pursue all significant issues and leads discovered that are determined relevant to the Investigation, including any evidence of additional instances of possible Research Misconduct.

E. Diligently continue the Investigation to completion.

5.5 Investigation Time Limit:

All aspects of an Investigation must be completed within 120 calendar days from the initiation of the Investigation, including:

A. Conducting the Investigation;

B. Preparing the report of findings;

C. Providing the draft Investigation Report to the Respondent for comment; and

D. With respect to PHS funded research, sending the final written Investigation Report to ORI.

5.6 If all aspects of the Investigation with respect to PHS funded research, will not be completed within 120 calendar days from the initiation of the Investigation, the Institutional Research Integrity Officer shall submit a written extension request to ORI.

Note: If ORI grants the extension, MD Anderson may be required to file periodic progress reports.

5.7 Draft Investigation Report:

The institution shall prepare a draft written Investigation Report that:

A. Describes the nature of the Allegation(s) of Research Misconduct.

B. Describes and documents the PHS or other support, including, for example, any grant numbers, grant applications, contracts, and publications listing PHS or other support.

C. Describes the specific Allegation(s) of Research Misconduct for consideration in the Investigation.

D. Includes a copy of this policy.

E. Identifies and summarizes the Research Records and evidence reviewed, and identifies any evidence taken into custody but not reviewed.

F. Describes any relevant records and evidence not taken into custody along with an explanation of why such records and evidence were not taken into custody;

G. Provides a finding as to whether Research Misconduct did or did not occur for each separate Allegation of Research Misconduct identified during the Investigation. If Research Misconduct did occur, the Investigation Report shall also:

- Identify whether the Research Misconduct was Falsification, Fabrication, or Plagiarism, and if it was intentional, knowing, or in reckless disregard;
- Summarize the facts and the analysis which support the conclusion and consider the merits of any reasonable explanation by the Respondent;
- Identify the specific PHS or other support;
- Identify whether any publications need correction or retraction;
- Identify the person(s) responsible for the Research Misconduct; and
- List any current support or known applications or proposals for support that the Respondent has pending with non-PHS Federal agencies or other entities.

5.8 MD Anderson will give the Respondent a copy of the draft written Investigation Report and a copy of, or supervised access to, the evidence on which the report is based.

5.9 Response Period:

A. The Respondent will have no more than 30 calendar days from receipt of the draft written Investigation Report to review and provide written comments to the President of MD Anderson through the Office of Research Administration and/or the Institutional Research Integrity Officer.

B. MD Anderson shall consider and include in the final Investigation Report any written comments made by the Respondent, which were received within the above-established thirty (30) calendar day response period.

C. After completing the Investigation with respect to PHS funded research, MD Anderson will provide ORI with:

- A copy of the final Investigation Report, including copies of all attachments.
- A statement of the final institutional action that identifies whether or not the institution found Research Misconduct, and if so, who committed the Research Misconduct.
- A statement by the institution regarding whether or not it accepts the Investigation's findings.
- A description of any pending or completed institutional administrative actions against the Respondent.

5.10 With respect to PHS funded research, MD Anderson will notify ORI in advance in the event that MD Anderson plans to close a Research Misconduct Proceeding at the Inquiry or Investigation stage:

A. On the basis that the Respondent has admitted guilt;

B. On the basis that a settlement with the Respondent has been reached; or

C. For any other reason, except that the closing of a case at the Inquiry stage on the basis that an Investigation is not warranted.

5.11 The institution shall notify the funding source of any Finding of Research Misconduct or of the termination of any Investigation as described in Section 5.10.

6.0 Records And Documentation

6.1 Maintenance of Research Records during Research Misconduct Proceedings:

On or before the date on which the Respondent is notified of the Allegation(s) or the Inquiry begins, whichever is earlier, MD Anderson will:

A. Obtain custody of all the Research Records and evidence needed to conduct the Research Misconduct Proceedings;

B. Inventory the records and evidence; and

C. Sequester the records and evidence in a secure manner.

6.2 If Research Records or evidence encompass scientific instruments shared by a number of users, or human research subject records, human research subject medical charts, human research subject consent forms, human research subject research files, MD Anderson may limit custody to copies of the data or evidence on such instruments or the human research subject records and other human research subject-related documents, so long as those copies are substantially equivalent to the evidentiary value of the instruments, documents or data. The institution will as prescribed by law, maintain confidentiality and restrict access to records or evidence from which research subjects might be identified, to those who have a need to know to carry out a Research Misconduct Proceeding.

6.3 Institutional Access:

Research Records produced under PHS or other grants and cooperative agreements are the property of the institution, and faculty, trainees/students, and other members of MD Anderson's workforce cannot interfere with the institution's right of access to them. Under contracts, certain Research Records may belong to PHS or other sponsor, but MD Anderson will be provided access to such records in the custody of PHS or other sponsor for purposes of reviewing Allegations.

6.4 Original Records:

The documents and materials to be sequestered will include all of the original items (or copies if originals cannot be located) that may be relevant to the Allegation(s). These include, but are not limited to Research Records.

6.5 Maintenance of Research Misconduct Proceedings Records:

MD Anderson will maintain and, with respect to PHS funded research shall, provide to ORI upon request all relevant Research Records and records of the Institution's Research Misconduct Proceeding, including results of all interviews and the transcripts or recordings of such interviews.

6.6 Such records of Research Misconduct Proceedings include:

A. The records that the institution secures for the Research Misconduct Proceeding except to the extent that MD Anderson subsequently determines and documents that those

records are not relevant to the Research Misconduct Proceeding or that the records duplicate other records that are being retained;

B. The documentation of the determination of irrelevant or duplicate records;

C. The Inquiry Report and final documents (not drafts) produced in the course of preparing that report, including the documentation of any decision not to investigate; and

D. The Investigation Report and all records (other than drafts of the report) in support of that report, including the recordings or transcriptions of each interview.

6.7 MD Anderson shall maintain records of Research Misconduct Proceedings in a secure manner for seven years after completion of the Research Misconduct Proceeding or the completion of any PHS proceeding involving the Research Misconduct Allegation**,** whichever is later.

6.8 Inventory of the Records:

A dated receipt should be signed by the Institutional Research Integrity Officer or his/her designee and the person from whom an item is collected, and a copy of the receipt should be given to the person from whom the record is taken. If it is not possible to prepare a complete inventory list at the time of collection, one should be prepared as soon as possible, and then a copy should be given to the person from whom the items were collected.

6.9 Security and Chain of Custody:

The Institutional Research Integrity Officer, with the assistance of The University of Texas Police Department, will lock all Research Records and other materials related to the Allegation or Research Misconduct Proceeding in a secure place. The persons from whom items are collected may be provided with a copy of any item if requested and deemed appropriate by the Institutional Research Integrity Officer. Where feasible, that person will have access to his or her own original items under the direct and continuous supervision of an institutional official. Reasonable efforts will be made to ensure that a proper chain of custody is maintained and that the originals are kept intact and unmodified. Any questions about maintaining the chain of custody of records that arise are to be referred to the Legal Services Department.

6.10 Addressing Allegations related to Public Health Service Projects:

A. In the event that Allegations of misconduct in research are made with regard to an application for or a grant of funds for research, research training, a research related activity, or a cooperative agreement under the Public Health Service Act appropriate interim administrative actions will be taken to protect federal funds. In addition, the additional actions listed below must be taken.

B. MD Anderson will immediately notify ORI, if at any time during a Research Misconduct Proceeding the institution has reason to believe that any of the following conditions exist:

- Health or safety of the public is at risk, including an immediate need to protect human or animal subjects.
- HHS resources or interests are threatened.
- Research activities should be suspended.
- There is reasonable indication of possible violations of civil or criminal law.

- Federal action is required to protect the interests of those involved in the Research Misconduct Proceeding.
- The institution believes the Research Misconduct Proceeding may be made public prematurely so that HHS may take appropriate steps to safeguard evidence and protect the rights of those involved.
- The research community or public should be informed.

7.0 Institutional Response to a Finding of Research Misconduct

The President of MD Anderson will make the institution's final determination of the consequences of a Finding of Research Misconduct.

7.1 The Final Investigation Report is provided to the President of MD Anderson;

7.2 All other relevant materials are provided to the President of MD Anderson;

7.3 The final report may be returned to the committee for further fact-finding and/or analyses;

7.4 Notice of the final institutional decision and any action taken shall be provided to the Respondent and any funding agencies;

7.5 Notice of the final decision, and any action taken, may also be provided, as appropriate to journals, professional societies, licensing boards, collaborators in the activity and/or other relevant parties.

7.6 Penalties can be up to and including loss of employment.

ATTACHMENTS / LINKS

None.

RELATED POLICIES

Principles for Ethical Scientific Research Policy (UTMDACC Institutional Policy # ACA0014).

JOINT COMMISSION STANDARDS / NATIONAL PATIENT SAFETY GOALS

None.

OTHER RELATED ACCREDITATION / REGULATORY STANDARDS

42 CFR Part 93 - Public Health Service Policies on Research Misconduct.

REFERENCES

None.

POLICY APPROVAL

Approved With Revisions Date: 12/18/2017
Approved Without Revisions Date:
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Version: 27.0

RESPONSIBLE DEPARTMENT(S)

Office of Research Administration & Operations