Policy Name: Research Misconduct: Allegations, Investigations and Reporting	
Policy Owner: Research Activities and Compliance Committee	**Effective Date:** 04/06/2022
Approved By: System Performance Alignment & Innovation (SPAN)	**Last Reviewed Date:** 05/15/2025
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1.0 Scope:

1.1 Applicable Entities:
This policy applies to:

- Texas Health Resources
- Texas Health Resources (Texas Health) member hospitals except those entities excluded below
- Texas Health Hospital Frisco
- Texas Health Physicians Group
- Texas Health Behavioral Health Virtual Visit
- Affiliated Individuals doing research on a Texas Health campus
- Excludes Texas Health Urgent Care and Texas Health joint venture entities including Texas Health Center for Diagnostics & Surgery (THCDS), Texas Health Flower Mound (THFM), Texas Heath Heart & Vascular (THHV), Texas Health Rockwall (THRW), and Texas Health Southlake (THSL)

1.2 Applicable Departments:
This policy applies to all departments.

1.3 Applicable Personnel:
Texas Health research investigators, research study staff and others engaged in research activities that are subject to Texas Health institutional oversight and oversight by a designated Texas Health Institutional Review Board (IRB) of Record.

2.0 Purpose:

2.1 To outline the policy and procedures to be taken by Texas Health regarding allegations, investigations, and reporting of research misconduct.

3.0 Policy Statements:

3.1 All persons involved in research have a responsibility to foster an environment which promotes intellectual honesty and integrity, and which does not tolerate misconduct in any research activities, handling of data or any aspect of the research endeavor.

3.2 Federal Funding Agency Requirements: Some federal funding agencies have their own policies regarding research misconduct and require notification to the

agency in the event of such an allegation or investigation. Where required, this notification will be made by the Institutional Official (IO) after consultation with Texas Health legal counsel. While federal funding agencies recognize that the primary responsibility for the prevention and detection of misconduct, and for the conduct of inquiries and investigations, rests with the institution, a number of agencies have retained the right to initiate their own investigations at any time. This policy is intended to comply with the provisions of 42 CFR Sections 93.100 through 93.319, when applicable.

3.3 Individual Reporting Responsibility: Concerns about potential research misconduct should be promptly communicated to the Research Compliance Officer (RCO), via the Texas Health System Compliance Helpline at 1-800-381-4728 or by email to SystemCompliance@texashealth.org.

Reporting concerns in good faith will not jeopardize anyone's employment. Texas Health prohibits retaliation of any kind against a person who, acting in good faith, reports or provides information about suspected or alleged misconduct.

3.4 Inquiry: An inquiry consists of preliminary information-gathering and preliminary fact-finding to determine whether an allegation or an apparent instance of misconduct has substance. The outcome of an inquiry is a determination as to whether or not an investigation will be conducted.

3.5 Investigation: An investigation is a formal examination and evaluation of relevant facts to determine whether or not misconduct has taken place.

4.0 Policy Guidance:

4.1 Procedure for Allegations or Concerns Involving Research:

4.1.1 Upon receipt of an allegation (from any source), the RCO will assess the information presented to determine: 1) whether it constitutes alleged research misconduct as defined by this policy, and 2) whether the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

a. If both of these criteria appear to be met, the RCO will notify the IO.

b. If the IO determines both criteria are met, an inquiry will be promptly initiated.

c. Upon initiation of an inquiry, the RCO will notify the Texas Health Chief Compliance Officer and Texas Health legal counsel who will participate as needed.

4.1.2 The inquiry process will be guided by the following:

a. Those conducting inquiries or investigations are promptly to take all reasonable and practical steps to obtain custody of research records and/or evidence needed to conduct the misconduct proceeding, inventory the records and evidence and safeguard them in an appropriate manner.

b. At the time of, or before the beginning or an inquiry, the accused individual (respondent) will be informed of the allegations and be invited to comment on them. The respondent will also be provided with a copy of the draft report of the inquiry and be given an opportunity to comment on the findings for the consideration of those conducting the inquiry. In so doing, best efforts will be made (where feasible) to protect the confidence of the individual(s) who brought forward the complaint.

c. Other relevant individuals, including the complainant(s), if known, should be interviewed.

d. The final report, including a recommendation as to whether or not a full investigation is warranted, will be submitted by the IO to the Research Activities and Compliance Committee (RACC) within 60 days of receipt of the allegation. If the timeframe is not possible in a particular case, the reasons are to be documented and the RACC so informed. The final report will include any comments provided by the respondent in response to the draft report.

e. The documentation should include sufficient detail to permit a later assessment of the determination of whether or not a full investigation was warranted. It should describe the information reviewed, include a summary of the interviews conducted, state conclusions reached, and indicate whether or not the IO believes an investigation is warranted.

f. The final report of the inquiry and a copy of the documentation will be transmitted to the RACC and maintained for seven years.

g. Unless the RACC has further concerns, an IO recommendation that an investigation is not warranted will be final.

4.1.3 Investigation Procedures:
If an inquiry leads to the conclusion that an investigation is warranted, it will be guided by the following considerations:

a. The formal investigation should begin within 30 days of the completion of the inquiry and after written notice to the respondent. The investigation to be completed and the final report sent to the RACC within 90 days (from start of an investigation). If an investigation cannot be completed within this time frame, the RACC should be notified. In such cases, it may be necessary for the IO to request an extension of time from federal funding agencies.

b. An investigation should normally include an examination of the relevant documentation, including but not limited to relevant research data and proposals, publications, correspondence, and memoranda of telephone calls.

c. Complainants, respondents, and witnesses who may have information related to the matter should be interviewed. Complete written summaries of each interview should be provided to the individual being questioned, and any comments should be appended to the summary, or reflected in a revised summary if the interviewer agrees.

d. All significant issues should be pursued until there is a reasonable conclusion that all necessary and appropriate information has been amassed.

e. A draft written report of findings shall be made available to the respondent with the opportunity to provide comments for the consideration of those conducting the investigation. Where identified and appropriate, complainants should also receive the portions of the draft report which concern the role or opinions they had in the investigation. Any comments on the draft from the respondent shall be appended to the final report.

f. In addition to the interview summaries and comments by the respondent and respondent and complainant(s) (if applicable) on the draft report, the final written report should include: a) a description of the policies and procedures followed, b) how and from whom relevant information was obtained, and c) the findings and basis for them.

g. If either the IO or the RACC considers that sanctions may be warranted, the IO shall refer the final report to the Institution Review Board (IRB) of record for a determination. The report should be sufficient for the IRB to determine whether disciplinary action is called for. If any sanctions result, the IO will be informed and he/she should append that information to the final report.

4.1.4 Internal Coordination:

a. The RCO and IO will coordinate with the Texas Health Chief Compliance Officer and Texas Health legal counsel to assure that all external notification requirements are met and to determine if any of the following emergency situations exist:

1) An immediate health hazard, including to human or animal research subjects.

2) An immediate need to protect federal or Texas Health funds or equipment.

3) An immediate need to protect the integrity of the research and/or the research misconduct proceeding.

4) An immediate need to protect the interests of those involved in the research misconduct proceeding.

5) The likelihood that an alleged incident will be reported publicly.

6) A reasonable indication of a possible criminal violation.

b. In emergency situations the IO is authorized to take all appropriate actions.

4.2 Notification to External Agencies

4.2.1 Texas Health will comply with the applicable requirements and regulations of its funding agencies and will cooperate with those agencies in regard to research misconduct.

4.2.2 Under circumstances not involving federal funding agencies, the IO (in consultation with Texas Health legal counsel) will make the decision whether information about the misconduct charges and their disposition will be disclosed publicly or to specific parties, including the research

sponsor. This decision will normally be made upon conclusion of the final report and review with the RACC.

a. However, if required by urgent circumstances, such a disclosure may be made at any time, by the IO in consultation with Texas Health legal counsel.

4.2.3 In accordance with requirements of federal funding agencies, in cases involving research funded by those agencies, the agency will be informed by the IO in the following situations:

a. Outcome of an Inquiry: Federal funding agencies will be notified of the outcome of an inquiry involving funds from their agency only if that outcome includes the recommendation to conduct a full investigation.

b. Commencement of an Investigation: Written notification will be provided to federal funding agencies upon determination that an investigation will be conducted. The notice will be provided on or before the commencement of the investigation and will include all information required by the agency. Generally, this notice will include at least the following: a) name(s) and position(s) of the respondent(s), b) general nature of the allegation(s), c) the agency support including any proposal or award numbers, d) the basis for the recommendation of an investigation, and e) any comments by the respondent. This information will be held in confidence to the extent permitted by law.

c. Written request for time extension: Although regulations generally permit 120 days for completion of the investigation and submission of the final report, the IO should consider whether it is advisable to request an extension of time from the agency when it appears the final report will require more than 90 days to complete. This allows 30 days for the disciplinary process, if deemed appropriate. The final report must contain a statement about the sanction (if any) imposed. An extension of time may be needed. If an extension is granted, the agency may require progress reports or the agency may undertake its own investigation prior to completion of the Texas Health investigation.

d. Interim reports: Federal agencies must be appraised during an investigation of facts that may affect current or potential funding of the individual under investigation or that may need to be disclosed

to ensure proper use of federal funds or protection of the public interest.

e. Early Termination: Federal funding agencies must be notified of the final outcome of an investigation involving their funded project(s) and provided with a complete copy of the final report.

f. Special emergency notifications: In addition, federal funding agencies will be informed at any stage of an inquiry or investigation if any of the following is discovered:

1) An immediate health hazard, including an immediate need to protect human or animal subjects.

2) An immediate need to protect federal or Texas Health funds or equipment.

3) An immediate need to protect the integrity of the research and/or the research misconduct proceeding.

4) A likelihood that an alleged incident is going to be reported publicly.

5) A reasonable indication of possible criminal activity.

4.3 Determination of Discipline

4.3.1 The determination as to whether discipline is to be imposed is governed by existing Texas Health policies.

a. In cases involving medical staff members, disciplinary sanctions may only be imposed through the medical staff disciplinary process.

b. The IO will refer cases of significant Texas Health employee misconduct to the Texas Health Chief Human Resources Officer.

4.3.2 Federal funding agencies have retained the right to impose additional sanctions, beyond those applied by Texas Health upon investigations or institutions. In addition, in cases where research misconduct is found, the IO may take all other appropriate actions (including correction of the public record) as deemed necessary and advisable to address the consequences of the research misconduct.

4.4 Cautions and Assistance

4.4.1 The gathering and assessing of information in cases of alleged research misconduct can be extremely difficult. It is essential to protect the professional reputations of those involved, as well as the interests of the public and of any who might be harmed by the alleged misconduct.

4.4.2 Texas Health may use the services of a consortium or person that Texas Health reasonably determines to be qualified by practice and experience to conduct research misconduct proceedings. A consortium or person acting on behalf of Texas Health must follow the requirement of this policy.

4.4.3 While conducting inquiries or investigations, the following provisions are applicable:

a. Expert assistance should be sought as necessary to conduct a thorough and authoritative evaluation of all evidence.

b. Precautions should be taken to avoid unresolved personal, professional, or financial conflicts of interest on the part of those involved in the inquiry or investigation.

c. The anonymity of respondents and, if they wish it, the confidentiality of complainants will be protected (where feasible), and care will be taken to protect the positions and reputations of those involved in the research (including research subjects) and in the research misconduct proceeding from harm (including retaliation). Except as required in the reporting provisions above, only those directly involved in an inquiry or investigation or with a need to know should be aware that the process is being conducted or have any access to information obtained during its course. Where appropriate, efforts will be made to restore the reputations of the respondent(s) when allegations are not confirmed.

5.0 Definitions:

5.1 Inquiry - An inquiry consists of preliminary information-gathering and preliminary fact-finding to determine whether an allegation or an apparent instance of misconduct has substance. The outcome of an inquiry is a determination as to whether or not an investigation will be conducted.

5.2 Investigation - An investigation is a formal examination and evaluation of relevant facts to determine whether or not misconduct has taken place.

5.3 Research Misconduct - Texas Health's definition of research misconduct is consistent with 42 CFR 93.103 and means "fabrication, falsification, or plagiarism in proposing, performing or reviewing research, or in reporting research results". Research misconduct does not include honest error or opinion.

5.3.1 Fabrication means making up data or results and recording or reporting them.

5.3.2 Falsification means 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.

5.3.3 Plagiarism means the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

6.0 Responsible Parties:

6.1 Texas Health Research Activities and Compliance Committee (RACC) has responsibility for the oversight and implementation of this policy.

6.2 Chief Compliance Officer

6.2.1 Responsible for oversight of the THR-wide Business Ethics and Compliance Program that includes human subject research compliance as one sub-component.

6.3 Research Compliance Officer

6.3.1 Oversees compliance of the human subject protection program which includes the implementation of policy, procedures, and personnel.

7.0 External References:

7.1 FDA regulations 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 50, Subpart D, 21 CFR Part 312, 21 CFR Part 600, and 21 CFR Part 812.

7.2 Department of Health and Human Services (DHHS) Regulations. 45 CFR Part 46, subpart A 45 CFR Part 46 Subpart A.

7.3 The DHHS human subject regulations (Subpart B); (Subpart C); and (Subpart D).

7.4 42 CFR 93.

8.0 Related Documentation and/or Attachments:

8.1 Research Engagement - THR System Policy

8.2 Human Research Protection Program - THR System Policy

8.3 Research Record Retention - THR System Policy

8.4 Research Compliance Program - THR System Policy

8.5 Human Research Protection Program - THR System Policy

9.0 Required Statements:

9.1 This policy represents the collaborative effort of the Texas Health system entities to determine and direct the recommended practice for the care anticipated under this policy and includes the input of clinical subject matter specialists.

As no policy or published procedure can anticipate every clinical and/or medical presentation, this policy is a guideline and is not intended as a substitute for the clinician's clinical judgment and/or experience.

9.2 Physicians on the medical staff of a Texas Health hospital practice independently and are not employees or agents of the hospital. Physicians in training in Graduate Medical Education programs are employees of the hospital/institution that hosts or sponsors their training program.