Leadership Policy: Misconduct in Research

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POLICY

Research misconduct is prohibited. Allegations of research misconduct shall be addressed in accordance with this policy and applicable regulations. The definition of misconduct may extend to other practices that deviate seriously from the commonly accepted standards or practices of the relevant research community.

This policy shall not supersede, supplant, or establish an alternate framework to the Public Health Service (PHS) regulation set forth in 42 CFR Part 93, nor any extant regulation governing research misconduct pertaining to non-PHS supported research. This policy does not abrogate PHS regulation. In the event of any conflict or inconsistency between the provisions of this document and 42 CFR Part 93, the PHS regulation shall prevail. The express intent of the policy is to enable Trinity Health Michigan (THM) to achieve and maintain full compliance with the requirements stipulated in federal regulations.

PURPOSE

The purpose of this policy is to ensure allegations of research misconduct are managed in a fair, accurate, objective, and consistent manner, regardless of the source of funding and/or support.

THM is committed to maintaining the highest standards of scientific rigor and integrity in all research endeavors. THM fosters an environment that champions responsible conduct, actively discourages research misconduct, and ensures prompt and thorough action on any allegations or evidence of potential research misconduct.

All institutional members of THM engaged in research are expected to conduct research to the highest standards of professional conduct; the maintenance of the highest ethical standards, and the validity and accuracy in the collection and reporting of data, are the fundamental principles of sound research practice. It is the responsibility of all institutional members of THM involved in proposing, reporting, supervising, managing, or supporting research related activities to be knowledgeable of and comply with THM Policies and Procedures that govern research.

THM Research Compliance Department (RCD) is responsible for ensuring that Research Misconduct policies and procedure for addressing allegations of research misconduct comply with applicable regulations. Such policies and procedures shall be established and maintained, distributed in an educational manner, and publicly accessible. THM and all institutional members are committed to adhering to these policies and procedures when responding to allegations of research misconduct.

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SCOPE

This policy applies to all institutional members at any affiliated locations of THM engaged in research. This includes, but is not limited to, principal investigators, sub-investigators, research nurses/coordinators, and support staff. Individuals in violation of this policy may be subject to imposition of corrective actions, including, but not limited to, termination of employment (employee) or expulsion (student).

This policy applies when the Research Integrity Officer (RIO) or Deciding Official (DO) receives a notification of an allegation of possible misconduct in scientific research.

This policy applies to allegations of research misconduct involving THM conducted or supported:

1. Applications or proposals for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training.
2. Biomedical or behavioral research.
3. Biomedical or behavioral research training programs.
4. Activities that are related to biomedical or behavioral research or research training, such as, but not limited to, the operation of tissue and data banks or the dissemination of research information.
5. Research records produced during research, research training, or activities related to that research or research training.
6. Research proposed, performed, reviewed, or reported, as well as any research record generated from that research, regardless of whether an application or proposal resulted in an awarded grant, contract, cooperation agreement, subaward, IRB approval or other form of THM support.

This policy applies only to research misconduct occurring within six (6) years of the date THM or any applicable regulatory authority receives an allegation of research misconduct, subject to the following exceptions:

1. The six-year time limitation does not apply if the Respondent continues or renews any incident of alleged research misconduct that occurred before the six-year period by republication of, or citation to the portion(s) of the research record alleged to have been fabricated, falsified, or plagiarized, for the potential benefit of the Respondent ("subsequent use exception"). For alleged research misconduct that appears subject to this subsequent use exception, but THM determines is not subject to the exception, the institution will document its determination that the subsequent use exception does not apply and will retain this documentation for the later of seven (7) years after completion of the institutional proceeding or the completion of any applicable federal proceeding.
2. The six-year time limitation does not apply if the Office of Research Integrity (ORI), Department of Health and Human Services (DHHS), or THM (in consultation with ORI) determined that the

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alleged research misconduct, if it occurred, would possibly have substantial adverse effect on the health or safety of the public.

In cases of research misconduct related to PHS supported activities, the final rule became effective January 1, 2025, and all regulatory requirements will be applicable on January 1, 2026, which will apply prospectively. For allegations received before January 1, 2026, THM follows 42 CFR part 93 as published in the 2005 edition of the Code of Federal Regulations, unless the Respondent and THM both elect in writing to follow the new final rule.

DEFINITION OF TERMS

Details provided in Appendix 1: Definition of Terms.

PROCEDURE

Roles, Rights, and Responsibilities

Details provided in Appendix 2: Roles, Rights, and Responsibilities.

Addressing Allegations of Research Misconduct

Assessment

An Assessment's purpose is to determine whether an allegation warrants an Inquiry. An Assessment is intended to be a review of readily accessible information relevant to the allegation.

Upon receiving an allegation of research misconduct, the RIO or another designated institutional official must promptly determine whether the allegation:

1. Falls within the definition of research misconduct as defined in this policy,
2. Is within the applicability criteria as detailed in the SCOPE section of this policy, and
3. Is sufficiently credible and specific to identify and sequester potential evidence.

If **all** three of these criteria are met, the RIO or another designated institutional official will promptly document the Assessment and initiate an Inquiry, including sequestering all research records and other evidence. Such documentation must be securely retained for seven (7) years following the completion of the misconduct proceedings.

If the RIO or another designated institutional official determines that the alleged misconduct does not meet all required criteria to proceed with an Inquiry, they are responsible for documenting why THM did not proceed to an Inquiry. Such documentation must be securely retained for seven (7) years to permit a later review by the Office of Research Integrity (ORI), or any other applicable regulatory authority, if requested.

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Inquiry

The purpose of an Inquiry is to conduct an initial review of the evidence to determine whether an allegation warrants a full Investigation; an Inquiry does not require a full review of all related evidence.

THM will complete the Inquiry within ninety (90) calendar days of its initiation. If circumstances necessitate a longer period, the reasons for exceeding this time limit must be thoroughly documented in the Inquiry report.

Notifying Regulatory Authorities

The RIO is responsible for identifying what regulatory authorities, if any, are applicable to any allegation of misconduct. The RIO will ensure that regulatory authorities are notified in a manner that is consistent regarding applicable regulatory requirements.

Sequestering Evidence and Notifying the Respondent

Before or at the time of notifying the Respondent(s), the RIO will take the following steps:

1. Secure the original or substantially equivalent copies of all research records and other evidence pertinent to the proceedings.
2. Create a comprehensive inventory of these materials.
3. Sequester the materials in a manner to prevent tampering or loss.
4. Retain all sequestered materials for seven (7) years.

THM's duty to obtain, inventory, and securely sequester evidence extends to any additional items that become known or relevant throughout the Inquiry or Investigation. The RIO has the authority to secure and/or copy data, research records, and other evidence related to the allegation(s) to fulfill obligations under federal, state, and/or local regulations, funder-specific requirements, and THM policy to thoroughly review and resolve allegations of research misconduct.

On or before the date on which the Respondent is notified, or the Inquiry begins, whichever is later, the RIO shall take all reasonable and practical steps to obtain custody of all the original research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner. If deemed appropriate, sequestration may be limited to copies of the data or evidence, so long as those copies have substantially equivalent evidentiary value. When appropriate, additional, or new evidence discovered after the initial sequestration should be sequestered as soon as practicable after it is identified. Failure to provide evidence at the time of sequestration may impact the credibility of such evidence.

At the time of, or before beginning an Inquiry, the RIO shall make a good faith effort to notify the presumed Respondent(s) in writing. This notification will inform them that:

1. An allegation(s) of research misconduct has been raised against them.
2. Relevant research records have been sequestered.

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3. An Inquiry will be conducted to determine whether to proceed with an Investigation.

If additional allegations are raised during the Inquiry, the RIO will promptly notify the Respondent(s) in writing. When appropriate, the RIO will provide the Respondent(s) with copies of, or reasonable supervised access to, the sequestered materials.

If additional Respondents are identified during the process, the RIO will provide written notification to these new Respondent(s). Any additional Respondents will be afforded the same rights and opportunities as the initial Respondent. Only allegations specific to a particular Respondent will be included in the notification provided to that Respondent.

Performing the Inquiry and Ensuring Neutrality

Upon determining an allegation of research misconduct warrants an Inquiry, the RIO can conduct an Inquiry, delegate this responsibility to an institutional official or convene an Inquiry Committee to determine whether there is sufficient substance to the allegation to warrant a formal Investigation. The RIO shall ensure that all members of an officially constituted Inquiry committee fully comprehend their assigned commission and obligations. Committee members are strictly required to maintain confidentiality of all parties involved, including Respondent(s), Complainant(s), and witness(es), throughout the entirety of the research misconduct proceedings. All such proceedings shall be conducted in strict adherence to this policy and applicable federal, state, and/or local regulations, funder-specific requirements, and THM policy.

Alternatively, the DO may appoint the RIO or another qualified institutional official to conduct the Inquiry. In such instances, the appointed official shall engage subject matter experts as deemed necessary to facilitate a comprehensive and accurate Inquiry, ensuring compliance with all applicable regulations.

The DO is responsible for ensuring that individuals responsible for carrying out the Inquiry proceedings do not have unresolved personal, professional or financial conflicts of interest with the Complainant(s), Respondent(s) or witness(es) involved with the allegation of misconduct.

Determining Whether an Investigation is Warranted

The designated authority, whether an Inquiry Committee, RIO, or another authorized institutional official, shall conduct a preliminary review of available evidence. During this fact-finding process, the Inquiry authority is authorized to interview the Respondent(s) and/or relevant witnesses to gather necessary information.

An Investigation into alleged research misconduct is warranted and shall be initiated if, and only if, **all** the following conditions are met:

1. There is a reasonable basis for concluding that the allegation falls within the definition of research misconduct, as defined within this policy.
2. Is within the applicability criteria as detailed in the SCOPE section of this policy, and

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3. Preliminary information-gathering and fact-finding from the Inquiry indicates that the allegation(s) may have substance.

The Inquiry authority shall not, at this stage, make a definitive determination whether research misconduct occurred, assess the intent, knowledge, or recklessness of the alleged misconduct, who was responsible, or to conduct exhaustive interviews and/or analysis.

Documenting the Inquiry

At the conclusion of the Inquiry, regardless of whether an Investigation is warranted, the Inquiry authority (RIO) will prepare a written Inquiry report. The contents of a complete Inquiry report will include:

1. The names, professional aliases, and positions of the Respondent, and Complainant(s).
2. A description of the research misconduct allegation(s).
3. Details about the pertinent agency support/funding (i.e., PHS, NSF), including any grant numbers, grant applications, contracts, and publications listing such support.
4. The composition of the Inquiry authority (i.e., Inquiry Committee, RIO, or designated institutional official), including name(s), position(s), and subject matter expertise.
5. An inventory of sequestered research records and other evidence and description of how sequestration was conducted.
6. Transcripts of any interviews with redactions to maintain confidentiality, if transcribed.
7. Inquiry timeline and procedural history.
8. Any scientific or forensic analysis conducted.
9. The basis for recommending that the allegation(s) warrant an Investigation.
10. The basis on which, if any, allegation(s) do not merit further Investigation.
11. Any comments on the Inquiry report by the Respondent or the Complainant(s).
12. Any institutional actions implemented, including internal communications or external communications with journals or funding agencies.
13. Documentation of potential evidence of honest error or difference of opinion.

Completing the Inquiry

The RIO shall provide the Respondent with a copy of the draft Inquiry report for review and comment. The RIO shall provide the Respondent with supervised access to evidence if requested and deemed to be appropriate. The Respondent shall be provided with an opportunity to review and comment on the Inquiry Report. The RIO may, but is not required to, provide relevant portions of the inquiry report to the Complainant(s) for comment.

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The Respondent and, if applicable, the Complainant(s) have ten (10) calendar days to provide written comments to the RIO for review and consideration by the Inquiry authority. All comments shall be added to the Inquiry report and may result in revisions to the Inquiry report as appropriate before finalizing and submitting the signed report to the RIO.

The RIO will notify the Respondent of the Inquiry's final determination and provide the Respondent with copies of the final Inquiry report, the applicable regulations, and these policies and procedures. The RIO may, but is not required to, notify the Complainant(s) whether the Inquiry found that an Investigation is warranted. If the institution provides notice to one Complainant in a case, it must provide notice, to the extent possible, to all Complainants in the case.

If an Investigation Is NOT Warranted

If the Inquiry authority determines that an Investigation is not warranted, the Inquiry authority must maintain sufficiently detailed documentation of the Inquiry to permit a later assessment by any applicable regulatory authority of the reasons why an Investigation was not conducted. These documents will be provided to authorized federal personnel upon request. Such records must be stored in a secure manner for at least seven (7) years after the termination of the Inquiry.

If an Investigation Is Warranted

If the Inquiry authority determines that an Investigation is warranted, the DO or designee must:

1. Notify the Respondent in writing within a reasonable amount of time after the decision to conduct an Investigation of the alleged misconduct, including any allegations of research misconduct not addressed during the Inquiry, and
2. Within thirty (30) calendar days of determining that an Investigation is warranted, provide any applicable regulatory authority (i.e., ORI, National Science Foundation (NSF)) with a copy of the Inquiry report.

For cases involving ORI jurisdiction, within thirty (30) calendar days of the determination that an Investigation is warranted, but not later than the date the Investigation begins, the RIO shall provide ORI notification of the determination and a copy of the Inquiry Report.

Investigation

The purpose of an Investigation is to formally develop a factual record, pursue leads, examine the evidence and record in depth, and recommend finding(s) to the DO, who will make the final adjudication, based on a preponderance of evidence, on whether research misconduct has been committed, by whom, and to what extent. As part of its Investigation, THM will pursue diligently any significant issues and relevant leads, including any evidence of additional instances of possible research misconduct that would justify broadening the scope beyond the initial allegations.

The Investigation proceedings shall be conducted in an efficient and timely manner. The Investigation should begin within thirty (30) calendar days after determining that an Investigation is warranted. As previously stated within this policy, within thirty (30) calendar days of the determination that an

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Investigation is warranted and when the Investigation is to be initiated, the DO will notify the applicable regulatory authority of the decision.

All Investigation procedures (e.g., the conduct of the Investigation, preparation of the draft Investigation report, providing the Investigation report to the Respondents for comment, documentation of the DO's adjudication of research misconduct, and transmission of the institutional record to any regulatory authority) must be completed within one hundred and eighty (180) calendar days. If the Investigation takes more than 180 calendar days to complete, THM will request an extension in writing to the applicable regulatory authority and document the reasons for exceeding the 180-calendar day period in the Investigation report. If there is no applicable regulatory authority, documentation within the Investigation report still applies.

Notifying the Respondent and Sequestering Evidence

The RIO is responsible for notifying the Respondent in writing of the allegation(s) within thirty (30) calendar days of determining that an Investigation is warranted and before the Investigation begins. If any additional Respondent(s) are identified during the Investigation, the institution will notify them of the allegation(s) and provide an opportunity to respond as consistent with this policy. If additional Respondents are identified during the Investigation, the RIO may choose to either conduct a separate Inquiry or add the new Respondent (s) to the ongoing Investigation.

The RIO is responsible for sequestering the original or substantially equivalent copies of all research records and other evidence, inventory these materials, sequestering them in a secure manner, and retaining them for seven (7) years after its proceedings or any regulatory authority proceeding, whichever is later.

Convening an Investigation Committee

The RIO is responsible for appointing an Investigation Committee to conduct a formal Investigation. The Investigation Committee will be composed of individuals who have appropriate scientific expertise and are free from any actual or perceived conflicts of interests. Investigation Committee membership will depend on the nature of the allegation(s) of research misconduct.

The RIO will function as an administrative non-voting member of the Investigation Committee.

The Respondent shall be notified of the Investigation Committee membership. The Respondent shall be afforded the opportunity to object the appointment of membership to the Investigation Committee based upon personal, professional, or financial conflict of interest, by submitting written objections to the RIO no more than ten (10) calendar days following notification regarding the committee membership. The DO, in conjunction with the RIO, makes the final determination as to whether a conflict exists.

After vetting the Investigation Committee members, the RIO is responsible for convening the Committee and ensuring that the members understand their responsibility to conduct the research misconduct proceedings in compliance with this policy and any applicable regulations. The Investigation Committee

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will conduct interviews, pursue leads, and examine all research records and other evidence relevant to reaching a decision on the merits of the allegation(s).

The RIO will use diligent efforts to ensure that the Investigation is thorough, sufficiently documented, and impartial and unbiased to the maximum extent practical. The RIO will notify the Respondent in writing of any additional allegation(s) raised against them during the Investigation.

Conducting Interviews

The Investigation Committee is responsible for interviewing each Respondent, Complainant(s), and any other available person who has been identified as having information regarding any relevant aspects of the Investigation, including witnesses identified by the Respondent. The Investigation Committee will number all relevant exhibits and refer to any exhibits shown to the interviewee during the interview by that number. The Investigation Committee will record and transcribe each interview during the Investigation and provide the transcript to the interviewee for correction. The transcript(s), along with any corrections, and exhibits will be included in the institutional record of the Investigation. The Respondent will not be present during the witnesses' interviews, but the RIO will provide the Respondent with a transcript of each interview, with redactions as appropriate to maintain confidentiality.

Documenting the Investigation

The Investigation Committee is responsible for preparing a written report of the results of the Investigation with a conclusion as to whether misconduct occurred. To make a finding of research misconduct, the Investigation Committee must find by a preponderance of the evidence that:

1. Research misconduct, as defined in this Policy and any applicable regulatory authority, occurred
2. The research misconduct is a significant departure from the accepted practices of the relevant research community; and
3. The Respondent committed the research misconduct recklessly, knowingly, or intentionally.

The RIO will advise the Investigation Committee of any additional applicable regulatory standards for making a finding of research misconduct.

The Investigation report per each Respondent will include:

1. Description of the nature of the allegation(s) of research misconduct, including any additional allegation(s) addressed during the research misconduct proceeding.
2. Description and documentation of the pertinent agency support/funding (e.g., ORI, NSF), including any grant applications, contracts, and publications listing such support. This documentation includes known applications or proposals for support that the Respondent has pending.
3. Description of the specific allegation(s) of research misconduct for consideration in the Investigation of the Respondent.

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4. Composition of the Investigation Committee, including name(s), position(s), and subject matter expertise.
5. Inventory of sequestered research records and other evidence, except records THM did not consider or rely on. This inventory will include manuscripts and funding proposals that were considered or relied on during the Investigation. The inventory will also include a description of how any sequestration was conducted during the Investigation.
6. Transcripts of all interviews conducted.
7. Identification of the specific published papers, manuscripts submitted but not accepted for publication (including online publication), any federal agency funding applications, progress reports, presentations, posters, or other research records that contain the allegedly falsified, fabricated, or plagiarized material.
8. A list of any current support or known applications or proposals for support that the Respondent has pending with any federal agency.
9. Any scientific or forensic analyses conducted.
10. Any comments made by the Respondent and Complainant(s) on the draft Investigation report and the Investigation Committee's consideration of those comments.
11. A statement for each separate allegation of whether the Investigation Committee recommends a finding of research misconduct.
    a. If the Investigation Committee recommends a finding of research misconduct for an allegation, the Investigation report must include the following findings for each allegation:
        i. Identification of the individual(s) who committed the research misconduct
        ii. Whether the misconduct was falsification, fabrication, and/or plagiarism, as defined within this policy.
        iii. Whether the misconduct was committed intentionally, knowingly, or recklessly.
        iv. Identification of any significant departure from the accepted practices of the relevant research community.
        v. The allegation was proven by a preponderance of the evidence.
        vi. Summary of the facts and analysis supporting the conclusion and considering the merits of any explanation by the Respondent.
        vii. Identification of the specific agency support/funding.
        viii. Whether any publications need correction or retraction.

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b. If the Investigation Committee does not recommend a finding of research misconduct for an allegation, the Investigation report will provide a detailed rationale for its conclusion.

Completing the Investigation

The RIO will provide the Respondent with a copy of the draft Investigation report and, concurrently, a copy of, or supervised access to, the research records and other evidence that the Investigation Committee considered or relied on. The Respondent is responsible for submitting any comments on the draft Investigation report to the RIO, in writing, within fifteen (15) calendar days of receiving the report.

If THM chooses to share a copy of the draft Investigation report or relevant portions of it with the Complainant(s) for comment, the Complainant(s) is responsible for submitting any comments on the draft Investigation report to the RIO, in writing, within fifteen (15) calendar days of receiving the report. If one Complainant, in a case, is provided with an opportunity to review and comment on the draft Investigation report, it must provide such an opportunity, to the extent possible, to all Complainants in the case.

The Investigation Committee is responsible for reviewing any written comments received within the above-described timeline. All comments will be added to the final version of the Investigation report and may include the Investigation Committee's considerations related to the comments.

Deciding Official's Adjudication of the Research Misconduct

Once the Investigation report has been finalized the RIO will provide the Investigation report to the DO for adjudication. The DO is responsible for reviewing the Investigation report and making a final written adjudication of whether THM found research misconduct and, if so, who committed the misconduct.

The DO is responsible for reviewing the Investigation report and making a final written adjudication of whether THM found research misconduct and, if so, who committed the misconduct. The DO must additionally include a description of the relevant institutional actions taken or to be taken. If research misconduct is determined to have occurred, the appropriate institutional management including legal counsel may be notified for review of the report for legal sufficiency.

Notification of Adjudication and Appeal Process

Following adjudication of the research misconduct, the DO is responsible for informing the Respondent(s), in writing, and informing the Respondent of the determinations rendered and if applicable, the corrective action(s) necessary. A copy of the DO's adjudication and the Investigation report may be provided to the Respondent. The Respondent then has fifteen (15) calendar days to provide a written appeal to the RIO. The Respondent is responsible for providing a comprehensive, factual appeal including all necessary evidence to substantiate their claim/position. If no appeal is made within the fifteen (15) calendar day timeline, the DO's initial adjudication is final.

If the Respondent appeals the adjudication of research misconduct, the allegation decision, the DO is responsible for reviewing all appeal information and documentation. The DO must document a

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secondary adjudication determination in consideration with all appeal information and documentation. The second adjudication by the DO is the final adjudication by THM and is to be disseminated in the same manner as the initial adjudication.

If the appeal process results in the Investigation taking more than 180 calendar days to complete, THM will request an extension in writing to the applicable supporting federal agency and document the reasons for exceeding the 180-calendar day period in the Investigation report. If there is no applicable regulatory authority, documentation within the Investigation report still applies.

Creating and Transmitting the Institutional Record

After the DO has made a final adjudication of research misconduct findings, the RIO will add the DO's written adjudication to the Investigation report and organize the institutional record in a logical manner. The institutional record consists of the records that were compiled or generated during the research misconduct proceeding, except the records the institution did not rely on. These records include, but are not limited to, documentation of the Assessment, a single index listing of all research records and evidence, the Inquiry report and Investigation report, and all records considered or relied on during the Investigation. The institutional record also includes the DO's final adjudication and any information the Respondent provided throughout the research misconduct proceedings. The institutional record must also include a general description of the records that were sequestered by not considered or relied on.

If the Respondent filed an appeal, the complete record of any institutional appeal also becomes part of the institutional record. If an appeal is submitted, THM will wait until the appeal is concluded to transmit the institutional record to any applicable regulatory authority. After the DO's final adjudication, and any institutional appeal is complete, THM must transmit the institutional record to any applicable regulatory authority.

Other Procedures and Special Circumstances

Multiple Institutions and Multiple Respondents

When allegations of research misconduct involve multiple institutions, THM will collaborate with the other institutions to determine if a joint research misconduct proceeding is appropriate. If a joint proceeding is initiated, THM will collaborate with all institutions to designate a leading institution. The lead institution will be responsible for gathering all pertinent research records and evidence, including witness testimony, from all involved institutions. Committee members for a joint proceeding may be drawn from each of the participating institutions, by mutual agreement. The decision regarding whether to proceed with further Inquiry or Investigation, the final adjudication of research misconduct, and the subsequent institutional actions may be made jointly by the involved institutions or delegated to the lead institutions per the mutual agreement. All delegation of responsibilities must be documented.

If the alleged research misconduct involves multiple Respondents, THM may either initiate a separate Inquiry for each new Respondent or incorporate them into the ongoing proceedings. In all cases, additional Respondents must receive proper notice of the allegations and be afforded an opportunity to respond to them.

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Respondent(s) Admission(s)

THM will promptly notify any applicable regulatory authority in advance if at any point during the research misconduct proceedings (including the Assessment, Inquiry, Investigation or appeal stage) it plans to close a research misconduct case because the Respondent has admitted to committing research misconduct or a settlement with the Respondent has been reached. Should a Respondent make an admission, the RIO, in consultation with the DO and other appropriate officials, shall promptly consult with any appropriate regulatory authority to determine the next steps that should be taken. The admission must state the specific fabrication, falsification, or plagiarism that occurred, which research records were affected, and that it constituted a significant departure from accepted practices of the relevant research community; the Respondent must sign the written admission. If resolving an allegation due to Respondent admission, the RIO must ensure this action would not prejudice or interfere with the review of another allegation against that Respondent or against a different Respondent. The RIO must formulate a written statement confirming the Respondent's culpability and explaining how THM determined that the Respondent's admission fully addressed the scope of the misconduct. In the event the affected research includes funding/support by a federal agency, such an agency must accept the admission statement and process before the research misconduct case is permitted to be closed locally.

Other Special Circumstance

At any time during the research misconduct proceedings, THM will immediately notify the appropriate federal, state, or local regulatory authorities if any of the following circumstances arise:

1. Health or safety of the public is at risk, including an immediate need to protect human subjects.
2. Federal resources or interests are threatened (e.g., HHS, DoD).
3. Research activities should be suspended.
4. There is a reasonable indication of possible violations of civil or criminal law.
5. Federal action is required to protect the interest of those involved in the research misconduct proceeding.
6. Applicable Federal Agencies (e.g., ORI, NSF) may need to take appropriate steps to safeguard evidence and protect the rights of those involved.

Records Retention & Confidentiality

THM will maintain the institutional record and all sequestered evidence, including physical objects (regardless of whether the evidence is part of the institutional record) in a confidential and secure manner to the extent possible.

To the maximum extent possible, the RIO and all participants in the process will endeavor to protect the confidentiality of Respondents and Complainants, and of research subjects identifiable from research records or evidence, by limiting disclosure of information related to the research misconduct proceedings to those who need to know in order to carry out a thorough, competent, objective, and fair research misconduct proceeding or as required by law. At the RIO's discretion, written confidentiality

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agreements or other mechanisms may be used when appropriate to maintain the confidentiality required by this Policy and any applicable federal, state, and/or local regulations and/or any other funder-specific requirements.

The goal of maintaining confidentiality should not prohibit officials from consulting, on a confidential basis and to the extent necessary, with other offices or individuals and/or persons outside THM with relevant experience or expertise to thoroughly investigate the allegations. The RIO, in consultation with other officials and offices as appropriate, shall be the official responsible for determining when a release of information to affiliated individuals is necessary or appropriate. The DO, in consultation with the RIO and other officials and offices as appropriate, shall be the official responsible for determining when a release of information outside of the ministry and/or Region is necessary or appropriate.

All records/information collected during a research misconduct proceeding will be filed and retained in a confidential and secure manner for seven (7) years after the completion of the proceeding or the completion of any regulatory authority proceeding, whichever is later, unless custody has been transferred to such regulatory authority. Such applicable regulatory authority should advise THM, in writing, that the records no longer need to be retained locally.

The RIO is also responsible for providing any information, documentation, research records, evidence, or clarification requested by authorized federal officials to carry out their review of an allegation of research misconduct or of the handling of such an allegation.

REFERENCES

Federal Register, Part III Department of Health and Human Services, 42 CFR Part 93, Public Health Service Policies on Research Misconduct; Final Rule, Tuesday, September 17th, 2024. Date accessed: November 20, 2024 Federal Register: Public Health Service Policies on Research Misconduct

U.S. Department of Health and Human Services, The Office of Research Integrity. Date accessed: July 28, 2025. ORI - The Office of Research Integrity

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Accepted practices of the relevant research community. Practices established by 42 CFR Part 93 and by the Public Health Services funding components, as well as commonly accepted professional codes or norms within the overarching community of researchers and institutions that apply for and receive Public Health Services awards.

Administrative record. Comprises: the institutional record; any information provided by the Respondent(s) to the Office of Research Integrity (ORI), DHHS, including but not limited to the transcript of any virtual or in-person meetings under Section 403(b) of 42 CFR Part 93 between the Respondent(s) and ORI, and correspondence between the Respondent and ORI; any additional information generated or obtained by ORI. Any analysis or additional information generated or obtained by ORI will also be made available to the Respondent.

Allegation. Any oral or written disclosure of possible research misconduct through any means of communication and brought directly to the attention of the Research Integrity Officer.

Assessment. A consideration of whether an allegation of research misconduct appears to fall within the definition of research misconduct and whether it is sufficiently credible and specific such that potential evidence of research misconduct may be identified. The Assessment only involves the review of readily accessible information relevant to the allegation.

Complainant. An individual who in good faith makes an allegation of research misconduct.

Deciding Official (DO). The institutional signatory official who makes the final determinations regarding allegations of research misconduct and institutional recommendations and/or corrective actions at Inquiry and Investigation. The same individual cannot serve as the Deciding Official and the Research Integrity Officer. Within Trinity Health Michigan Region, the Deciding Official is the Institutional Signatory Official.

Evidence. Anything offered or obtained during a research misconduct proceeding that tends to prove or disprove the existence of an alleged fact. Evidence includes documents, whether in hard copy or electronic form, information, tangible items, and testimony.

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.

Good faith – Complainant/Witness. Good faith as applied to a Complainant or witness means having a reasonable belief in the truth of one's allegation or testimony, based on the information known to the Complainant or witness at the time. Al allegation or cooperation with a research misconduct proceeding

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is not in good faith if made with knowledge of reckless disregard for information that would negate the allegation or testimony.

Good faith – Institutional/Committee Member. Good faith as applied to an institutional or committee member means cooperating with the research misconduct proceeding by impartially carrying out the duties assigned for the purpose of helping an institution meet its responsibilities under applicable federal regulations. An institutional or committee member does not act in good faith if their acts or omissions during the research misconduct proceedings are dishonest or influenced by personal, professional, or financial conflicts of interest with those involved in the research misconduct proceeding.

Inquiry. Preliminary information gathering and preliminary fact finding to determine whether an allegation or apparent research misconduct warrants an Investigation.

Institutional member. An individual(s) who is employed by, is an agent of, or is affiliated by contract or agreement with an institution. Institutional members may include, but are not limited to, officials, physicians, tenured and untenured faculty, teaching and supporting staff, researchers, research coordinators, technicians, postdoctoral and other fellows, students, volunteers, subject matter experts, consultants, or attorneys, or employees or agents of contractors, subcontractors, or sub-awardees.

Institutional record. Comprises: (a) The records that the institution compiled or generated during the research misconduct proceeding, except records the institution did not consider or rely on. These records include but are not limited to (1) documentation of the Assessment as required; (2) if an Inquiry in conducted, the Inquiry report and all records (other than drafts of the report) considered or relied on during the Inquiry, including, but not limited to, research records and the transcripts of any transcribed interviews conducted during the Inquiry, information the Respondent provided to the institution, and the documentation of any decision not to investigated as required; (3) if an Investigation is conducted, the Investigation report and all records (other than drafts of the report) considered or relied on during the Investigation, including, but not limited to, research records, the transcripts, of each interview conducted, and information the Respondent provided to the institution; (4) decision(s) by the Institutional Deciding Official, such as the written decision to adjudicate the research misconduct as required; (5) the complete record of any institutional appeal as required; (b) a single index listing all the research records and evidence that the institution compiled during the research misconduct proceeding, except records the institution did not consider or rely on; and (c) a general description of the records that were sequestered but not considered or relied on.

Intentionally. To act with the aim of carrying out the act.

Investigation. The formal development of a factual record and the examination and evaluation of relevant facts to determine whether research misconduct has taken place and if research misconduct is believed to have taken place, to assess its extent and determine appropriate action.

Knowingly. To act with awareness of the act.

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Person. Any individual, corporation, partnership, institution, association, unit of government, or other legal entity, however organized.

Plagiarism. The appropriation of another person's ideas, processes, results, or words without giving appropriate credit. (a) Plagiarism includes the unattributed verbatim or nearly verbatim copying of sentences and paragraphs from another's work that materially misleads the reader regarding the contributions of the author. **It does not include the limited use of identical or nearly identical phrases that describe a common methodology**. (b) Plagiarism does not include self-plagiarism or authorship or credit disputes, including disputes among former collaborators who participated jointly in the development of conduct of a research project. Self-plagiarism and authorship disputes do not meet the definition of research misconduct.

Preponderance of evidence. Proof by evidence that, compared with evidence opposing it, leads to the conclusion that the fact at issue is more likely true than not.

Recklessly. To propose, perform, or review research, or report research results, with indifference to a known risk of fabrication, falsification, or plagiarism.

Research. A systematic Investigation, study, evaluation, demonstration, or experiment designed to develop or contribute to generalizable knowledge. This applies to all scholarly study, including but not limited to all fields of science.

Research Integrity Officer (RIO). The institutional official responsible for administering the institution's written policies and procedures and for addressing allegations of research misconduct in compliance with all Trinity Health Michigan research misconduct policies and procedures. Within Trinity Health Michigan the RIO shall be appointed by the Chief Clinical Officer to assume responsibilities assigned to the Research Integrity Officer under this Policy and applicable regulations.

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

Research misconduct proceeding. Any actions related to alleged research misconduct taken under applicable regulations or this policy, including allegation Assessments, Inquiries, Investigations, federal and institutional oversight reviews, and appeals as applicable.

Research record. The record of data or results that embody the facts resulting from scientific Inquiry. Data or results may be in physical or electronic form. Examples of items, materials or information that may be considered part of the research record include, but are not limited to, research proposals, raw data, processed data, clinical research records, laboratory records, study records, laboratory notebooks, progress reports, manuscripts, abstracts, theses, records of oral presentations, online content, lab meetings, and journal articles.

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Respondent. The individual against whom an allegation of research misconduct is directed or who is subject of a research misconduct proceeding.

Retaliation. Adverse actions taken against a Complainant, witness, or committee member by an institution or one of its members in response to a good faith allegation or research misconduct or good faith cooperation with a research misconduct proceeding.

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APPENDIX 2: ROLES, RIGHTS, AND RESPONSIBILITIES

Trinity Health Michigan Region's General Responsibilities

To the maximum extent practicable, THM shall limit the disclosure of identities for Respondents, Complainants, and witnesses during research misconduct proceedings to individuals with a need to know. The institution will ensure that all institutional members are informed of this policy, and this policy is publicly available. This limitation on disclosure shall not apply after THM's final determination of research misconduct findings. THM commits to responding to each allegation of research misconduct in accordance with applicable regulations, ensure a thorough, competent, objective, and fair process.

THM shall undertake all reasonable and practical measures to secure the cooperation of Respondents and other institutional members throughout research misconduct proceedings. This includes, but is not limited to, ensuring the provision of information, research records, and other relevant evidence. THM further agrees to cooperate fully with any applicable regulatory authority during any research misconduct proceeding or compliance review. This cooperation includes addressing any deficiencies or additional allegations identified in the institutional record as directed, and assisting in the administration and enforcement of any administrative actions imposed upon institutional members by applicable regulatory authorities.

THM reserves the right to take appropriate steps to manage published data or acknowledge the potential unreliability of data, as deemed necessary.

Trinity Health Michigan Region's Responsibilities During and After a Research Misconduct Proceeding

Except as otherwise mandated by applicable law, THM shall maintain the confidentiality of all records or evidence. Disclosure of such information will be strictly limited to individuals with a legitimate need to know for the purpose of conducting a research misconduct proceeding. Individuals who may be identified as having a need to know include, but are not limited to, Institutional Review Boards, journals, editors, publishers, co-authors, and collaborating institutions.

Prior to, or concurrent with notifying the Respondent of the allegation(s), and as additional relevant items are identified, THM shall promptly take all reasonable and practical steps to obtain and securely sequester all research records and other evidence. THM is responsible for ensuring that the institutional record encompasses all requisite elements, specifically: Research records compiled and considered during the proceedings; Assessment documentation; Inquiry and Investigation reports.

Upon conclusion of the Inquiry, THM shall provide any applicable regulatory authority (e.g., ORI, NSF) with the complete Inquiry report, which will then be incorporated into the institutional record. THM shall maintain the institutional record, along with all sequestered research records and other evidence, in a secure manner for a period of seven (7) years following the completion of the institution and/or regulatory authority proceedings. THM shall provide information pertinent to alleged research misconduct related proceedings to any applicable regulatory authority upon request. This includes the transfer of custody provision of copies of the institutional record, any component thereof, and any sequestered evidence, irrespective of whether such evidence is formally included in the institutional

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record. Furthermore, THM shall promptly notify applicable regulatory authority of any special circumstances that may arise during the proceedings.

During the conduct of research misconduct proceedings, the disclosure of the identities of Respondents, Complainants, and witnesses shall be restricted to individuals determined by THM to have a need to know.

Trinity Health Michigan Region's Responsibilities to Complainant(s)

THM is committed to ensuring confidentiality for all Complainants involved in a research misconduct proceeding. Proactive measures shall be taken to prevent any potential, perceived, or actual personal professional, or financial conflicts of interest among individuals responsible for any aspect of the research misconduct proceeding.

All reasonable and practical steps shall be taken to protect the positions and reputations of Complainants, and to shield them from retaliation by Respondents or other institutional members. Should THM decide to inform a Complainant of the Inquiry results, to the extent possible, all Complainants involved in that research misconduct proceeding shall additionally be notified.

Trinity Health Michigan Region's Responsibilities to Respondent(s)

THM shall afford confidentiality to all Respondents in a research misconduct proceeding. A good-faith effort shall be made to notify the Respondent(s) in writing of the specific allegation(s) made against them. All necessary precautions to ensure that individuals responsible for conducting any component of the research misconduct proceeding do not possess unresolved personal, professional, or financial conflicts of interest with the Respondent(s) will be made. THM is responsible for providing the Respondent(s) with copies of, or supervised access to, all sequestered research records.

THM shall notify the Respondent(s) regarding whether the Inquiry has determined that an Investigation is warranted. Furthermore, the Respondent shall be awarded the opportunity to review and comment on the draft Inquiry report and ensure that their comments are appended to the final Inquiry report. Should an Investigation be initiated, THM must provide written notice to the Respondent(s) of any additional allegations not previously addressed by the Inquiry report. The Respondent(s) shall also be afforded an opportunity to review all the witness transcripts, with redactions as appropriate to maintain confidentiality. The Respondent(s) shall additionally be provided with an opportunity to read and comment on the draft Investigation report and any information or allegation subsequently added to the institutional record. Consideration shall be given to all admissible and credible evidence of honest error or difference of opinion presented by the Respondent(s).

THM shall bear the burden of proof, demonstrating research misconduct by a preponderance of the evidence, for any finding of research misconduct. All reasonable and practical efforts shall be made, upon request and as appropriate, to protect or restore the reputation of any Respondent(s) against whom no finding of research misconduct is made.

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Trinity Health Michigan's Responsibilities to Committee Members

THM will ensure that any committee, consortium, or individual acting on its behalf in conducting research misconduct proceedings does so in full compliance with this policy and applicable regulations. All reasonable and practical steps will be taken to protect the positions and reputations of good-faith committee members involved in such proceedings; this includes safeguarding committee members from retaliation.

Trinity Health's Responsibilities to the Witness(es)

Confidentiality shall be extended to all witnesses involved in a research misconduct proceeding. Robust precautions shall be implemented to ensure that individuals tasked with executing any portion of the research misconduct proceedings do not possess unresolved personal, professional, or financial conflicts of interest with the witness(es). All reasonable and practical steps will be taken to protect the positions and reputations of witnesses and to safeguard these individuals from retaliation.

Research Integrity Officer

The Research Integrity Officer (RIO) serves as the designated institutional official responsible for administering THM's written policies and procedures concerning allegations of research misconduct. To ensure impartiality, the RIO will not simultaneously serve as the Deciding Official (DO).

Within THM the RIO shall be appointed in writing by the Chief Clinical Officer. The RIO is responsible for the overall management of the research misconduct proceeding as detailed within this policy. When found to be appropriate (e.g., conflict of interest) the responsibilities of the RIO may be delegated, in writing, to another institutional official, and, if needed, this individual may utilize one or more subject matter experts to assist them.

Upon receipt of an allegation of research misconduct, the RIO or another designated institutional official will promptly assess the allegation as addressed in this policy. The RIO shall function as the point of contact for all research misconduct proceedings to internal and external stakeholders.

Complainant

The Complainant is the individual who in good faith makes an allegation of research misconduct. Allegations of research misconduct may be brough directly to the attention of THM's RIO through any means of communication.

Respondent

The Respondent is the individual whom an allegation of research misconduct has been made or who is the subject of a research misconduct proceeding. The Respondent bears the burden of going forward with and proving, by a preponderance of evidence, any affirmative defense raised. The Respondent's destruction of research records documenting the questioned research is evidence of research misconduct where a preponderance of evidence establishes that the Respondent intentionally or knowingly destroyed records after being informed of the research misconduct allegations. A Respondent's failure to provide research records documenting the questioned research serves as

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evidence of research misconduct if the Respondent claims to possess the records but refuses to provide them.

The Respondent is not permitted to be presented during witness interviews. Additionally, the Respondent will have opportunities to (a) view and comment on the Inquiry report, (b) view and comment on the Investigation report, and (c) submit any comments on the draft Investigation report to THM within thirty (30) calendar days of receiving it.

If admission to research misconduct occurs, the Respondent will sign a written statement specifying the affected research records and confirming the misconduct was falsification, fabrication, and/or plagiarism; committed intentionally, knowingly, or recklessly; and a significant departure from accepted practices of the relevant research community.

Committee and Consortium Members

Committee members (and consortium members where applicable) are experts who act in good faith to cooperate with the research misconduct proceedings by impartially performing their assigned duties for the purpose of helping THM meet its responsibilities under applicable research misconduct regulations and this policy. Committee members must demonstrate relevant scientific expertise and be free from any actual or perceived conflicts of interest with parties involved.

All research misconduct proceedings conducted by committee/consortium members or their designees on behalf of THM will comply with this policy. Their responsibilities include:

1. Assessing the need for an Investigation and formalizing this determination in an Inquiry report
2. Conducting recorded interviews throughout the Investigation with the Respondent(s), Complainant(s), and any other reasonably identified individual with relevant information, including Respondent-identified witnesses.
3. Reaching a determination on whether research misconduct occurred. This finding, along with the rationale, will be documented in the Investigation report.
4. Considering and documenting in the Investigation report all comments received from Respondents and/or Complainants regarding the Inquiry and Investigation reports.

In cases involving multiple Respondents, a single committee or consortium may conduct the Investigation. However, each Respondent will receive a distinct Investigation report and a separate research misconduct determination. Committee and consortium members are eligible to serve across multiple Investigations and may participate in both the Inquiry and Investigation stages of a single case.

Institutional Members and Witnesses

THM institutional members who have reason to believe that an individual performing research conducted or supported by THM has engaged in scientific misconduct has a responsibility to report pertinent facts in accordance with this policy. The individual may discuss the situation with the RIO or may report the facts through other established reporting procedures, such as Trinity Health's Integrity & Compliance Line. If the circumstances described do not meet research misconduct, as defined within

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this policy, the RIO may refer the individual or allegation to other offices or officials with responsibility for resolving the problem. The following acts are generally considered research misconduct; however, research misconduct is not limited to these acts:

1. Fabrication of recording or reporting of data or results or professional credentials (fraud).
2. Falsely claiming someone else's written words or ideas as one's own (plagiarism).
3. Altering and/or fabrication of dates, results, or individual medical records.
4. Exploiting privileged access to obtain and use the work of others in a manner inconsistent with scholarly practice.
5. Deliberate destruction (partial or whole) of one's own research data or records to avoid the detection of wrong-doing or the deliberate destruction of someone else's data or records.
6. Material failure to comply with relevant federal regulation applicable to the conduct and reporting of research.
7. Misleading publications by failing to appropriately reference authors or other collaborators of the published literature.
8. Condoning or not reporting the performance by another staff member of any acts noted above.
9. Falsely claiming authorship of someone that is not involved in the research project either as an investigator on a grant application or as an author on a submitted manuscript to be considered for publication.

Note: Research misconduct does not include honest error or differences of opinion.

Institutional Members considered to be witnesses must cooperate with research misconduct proceedings in good faith and have a reasonable belief in the truth of their testimony, based on the information known to them at the time. Failure to cooperate or to provide relevant evidence will not prevent the process defined in this Policy from proceeding and may lead to other disciplinary actions.

The following acts are generally not considered falsification or fabrication of the research record as described above and would not be considered scientific misconduct but may be reportable to the appropriate regulatory authority such as the Food and Drug Administration (FDA), the Office of Civil Rights (OCR), and/or the Office for Human Research Protections (OHRP).

1. Failing to report an adverse event with a participant to the sponsor or the IRB.
2. Deviating from the approved protocol (i.e., entering an ineligible subject in a trial, or administering an off-protocol drug).
3. Breaching human subject confidentiality and privacy.

<u>Deciding Official (DO)</u>

The Deciding Official (DO) holds sole authority for issuing final adjudications regarding research misconduct. The DO is precluded from concurrently fulfilling the role of the RIO. Within THM, the DO is

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the Institutional Signatory Official, or when applicable, as designated in writing on the ORI Assurance for each ministry. The DO is responsible for fostering a research environment that promotes research integrity and the responsible conduct of research, discourages research misconduct, and deals promptly with allegations or evidence of possible research misconduct. The DO may delegate any responsibilities detailed within this policy, in writing, to ensure a timely, fair, and thorough research misconduct proceeding, at their discretion.

The DO's research misconduct adjudication shall be articulated in a comprehensive written decision that includes:

1. A conclusive finding on the occurrence of research misconduct
2. Identification of the specific type of research misconduct, if substantiated
3. Attribution of responsibility for the misconduct, and
4. An itemized account of all institutional actions implemented or projected in response.

This formal written decision is to be integrated into the institution's official records.