



MIDWESTERN UNIVERSITY STANDARD POLICY

Title: Authorship of Publications		
Issue Date: 8/14/2024	Supersedes: 03/11/2016, 08/17/2018, 9/15/2020, 8/5/2021, 8/2/2022, 7/1/2023	Pages: 1
Division: University	Campus: Downers Grove and Glendale	
Approved by: Kathleen H. Goepfing, Ph.D., President and CEO		

PURPOSE

This policy establishes Midwestern University's authorship standards for faculty, students, and trainees.

POLICY

1. All authors must follow the International Committee of Medical Journal Editors ("ICMJE") standards for authorship and contributorship, which states that authorship should be based on the following four criteria:

- "Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting of the work or reviewing it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved."¹

2. Ghostwriting and honorary authorship are strictly prohibited.

- Ghostwriting refers to the act of one person writing in the name of another person or group, but the former receives no credit for authorship.
- Honorary authorship refers to the act of assigning authorship to an individual who should not have been included as an author because the individual made no or made insufficient contribution to qualify as an author.

3. If artificial intelligence-assisted technologies, e.g., chatbots, image creators, were used in the production of submitted work, authors must disclose to the publisher (1) the AI tool name, version number or type, and manufacturer, and (2) what the AI tool was used to do and specify the content that was created using the AI tool.

When an AI tool is used, the author(s) is/are responsible for the accuracy, integrity, and originality of their submitted work. The author(s) must carefully review and edit all content produced by AI tools to ensure the content is accurate, complete, and unbiased and that no plagiarism of text or images produced by AI is included within the publication.²

AI tools cannot be listed as an author or co-author.

References:

1. International Committee of Medical Journal Editors. Recommendation for the conduct, reporting, editing, and publication of scholarly work in medical journals (updated May 2023). 2023. Available from: <https://www.icmje.org/icmje-recommendations.pdf>. Accessed 6/25/2024).
2. Bell S. The write algorithm: promoting responsible artificial intelligence usage and accountability in medical writing. BMC Medicine 2023;21:334. Doi.org/10.1186/s12916-023003039-7.

MIDWESTERN UNIVERSITY

STANDARD POLICY

DIVISION: All University Colleges

AREA: Administrative

SUBJECT: Misconduct	POLICY NO. 0012		
APPROVED BY: Joshua Baker, M.S., O.D. Interim President & CEO President and Chief Executive Officer 	ISSUE DATE 06/23/2025	SUPERSEDES 1/02, 1/23	PAGES 1 of 17

PURPOSE: Midwestern University, as an institution of higher education, is dedicated to learning and research and the truthful presentation of scholarly information to its students and the academic community at-large. In this regard, intellectual honesty and cultivation of a work environment free from unlawful harassment and discrimination, including sexual harassment (“Unlawful Acts”) is of paramount importance as faculty members conduct their scholarly activities and maintain research integrity. Breaches and violations must be dealt with promptly and fairly to preserve the integrity of the research community, increase transparency, and promote accountability.

POLICY: This policy and procedures apply to all individuals at Midwestern University engaged in any research, research-training or research-related grant or cooperative agreement regardless of the source of funding. This policy applies to any person paid by, under the control of, or affiliated with Midwestern University, such as scientists, trainees, technicians and other staff members, students, fellows, guest researchers, or collaborators at Midwestern University.

The policy and associated procedures will normally be followed when an allegation of possible misconduct in science is received by an institutional official. Particular circumstances in an individual case may dictate variation from the normal procedure deemed in the best interests of Midwestern University and PHS. Any change from normal procedures also must ensure fair treatment to the subject of the inquiry or investigation. Any significant variation should be approved in advance by the Assistant Vice President of Research of Midwestern University. Allegations of unlawful harassment (including sexual harassment), discrimination, and retaliation (“Unlawful Acts”) will be dealt with in accordance with the University’s policies and procedures concerning Unlawful Act in the employment context. As such, those policies and procedures apply as a parallel structure to matters concerning misconduct and will largely govern the approach to addressing Unlawful Acts. Given the unique circumstances presented by research activity, the Research

Integrity
Definitions Officer shall be involved in any matter concerning Unlawful Acts to maintain research integrity.

- A. *Allegation* means a disclosure of possible research misconduct, regardless of the method of communication made to an institutional official.
- B. *Assessment* means a preliminary review of an allegation of research misconduct to determine whether it warrants further investigation. The assessment only involves the review of readily accessible information pertaining to the allegation.
- C. *Conflict of interest* means the real or apparent interference of one person's interests with the interests of another person, where potential bias may occur due to prior or existing personal or professional relationships.
- D. *Deciding Official* means the institutional official who makes final determinations on allegations of scientific misconduct and any responsive institutional actions. The Deciding Official at Northwestern University is the President and CEO. The Research Integrity Officer is the Assistant Vice President of Research.
- E. *Good faith allegation* means an allegation made with the honest belief that scientific misconduct may have occurred. An allegation is not in good faith if it is made with reckless disregard for or willful ignorance of facts that would disprove the allegation.
- F. *Inquiry* means gathering information and initial fact-finding to determine whether an allegation or apparent instance of scientific misconduct warrants an investigation.¹
- G. *Intentionally* means to act with the aim of carrying out the act.
- H. *Investigation* means the formal examination and evaluation of all relevant facts to determine if misconduct has occurred, and, if so, to determine the responsible person and the seriousness of the misconduct.²
- I. *Knowingly* means to act with awareness of the act.
- J. *ORI* means the Office of Research Integrity, the office within the U.S. Department of Health and Human Services (DHHS) that is responsible for the scientific misconduct and research integrity activities of the U.S. Public Health Service.

- K. *PHS* means the U.S. Public Health Service, an operating component of the DHHS.
- L. *PHS regulation* means the Public Health Service regulation establishing standards for institutional inquiries and investigations into allegations of scientific misconduct, which is set forth at 42 C.F.R. Part 50, Subpart A, entitled "Responsibility of PHS Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science."
- M. *PHS support* means PHS grants, contracts, or cooperative agreements or applications thereof.
- N. *Plagiarism* means the appropriation of another person's ideas, processes, results, or words without giving appropriate credit, but excludes self-plagiarism and authorship or credit disputes.
- O. *Recklessly* means to act (propose, perform or review research) with indifference to a known risk of fabrication, falsification, or plagiarism.
- P. *Research Integrity Officer* means the institutional official responsible for assessing allegations of scientific misconduct and determining when such allegations warrant inquiries and for overseeing inquiries and investigations. The Research Integrity Officer at MWU is the Assistant Vice President of Research.
- Q. *Research record* means any data, document, computer file, computer diskette, 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 scientific misconduct. A research record includes, but is not limited to, grant or contract applications, whether funded or unfunded; grant or contract progress and other reports; laboratory notebooks; notes; correspondence; videos; photographs; X-ray film; slides; biological materials; computer files and printouts; manuscripts and publications; equipment use logs; laboratory procurement records; animal facility records; human and animal subject protocols; consent forms; medical charts; and patient research files.
- R. *Respondent* means the person against whom an allegation of scientific misconduct is directed or the person whose actions are the subject of the inquiry or investigation. There can be more than one respondent in any inquiry or investigation.
- S. *Retaliation* means any action that adversely affects the employment or other

institutional status of an individual that is taken by an institution or an employee because the individual has in good faith, made an allegation of scientific misconduct or of inadequate institutional response thereto or has cooperated in good faith with an investigation of such allegation.

- T. *Scientific misconduct or misconduct in science* means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.³
- U. *Unlawful Act* means unlawful discrimination, harassment, or retaliation as used in the University's policies and procedures concerning equal employment opportunity, the NIH Grants Policy Statement concerning behavioral codes of conduct for NIH award recipients, and the December 2019 final report from the Advisory Committee to the NIH Director entitled "ACD Working Group on Changing the Culture to End Sexual Harassment."
- V. *Whistleblower* means a person who makes an allegation of scientific misconduct.

Rights and Responsibilities

A. Research Integrity Officer

The Assistant Vice President of Research will serve as the Research Integrity Officer who will have primary responsibility for implementation of the procedures set forth in this document. The Assistant Vice President of research is an institutional official who is well qualified to handle the procedural requirements involved and is sensitive to the varied demands made on those who conduct research, those who are accused of misconduct, and those who report apparent misconduct in good faith.

The Assistant Vice President of Research will appoint the inquiry and investigation committees and ensure that necessary and appropriate expertise is secured to carry out a thorough and authoritative evaluation of the relevant evidence in an inquiry or investigation. The Assistant Vice President of Research will attempt to ensure that confidentiality is maintained.

The Assistant Vice President of Research will assist inquiry and investigation committees and all institutional personnel in complying with these procedures and with applicable standards imposed by government or external funding sources. The Assistant Vice President of Research is also responsible for maintaining files of all documents and evidence and for the confidentiality and the security of the files.

The Assistant Vice President of Research will report to ORI as required by regulation and keep ORI apprised of any developments during the course of the inquiry or investigation that may affect current or potential DHHS funding for the individual(s) under investigation or that PHS needs to know to ensure appropriate use of Federal funds and otherwise protect the public interest.⁴

B. Whistleblower

The whistleblower will have an opportunity to testify before the inquiry and investigation committees, to review portions of the inquiry and investigation reports pertinent to his/her allegations or testimony, to be informed of the results of the inquiry and investigation, and to be protected from retaliation. Also, if the Assistant Vice President of Research has determined that the whistleblower may be able to provide pertinent information on any portions of the draft report, these portions will be given to the whistleblower for comment.

The whistleblower is responsible for making allegations in good faith,

maintaining confidentiality, and cooperating with an inquiry or investigation.

C. Respondent

The respondent will be informed of the allegations when an inquiry is opened and notified in writing of the final determinations and resulting actions. The respondent will also have the opportunity to be interviewed by and present evidence to the inquiry and investigation committees, to review the draft inquiry and investigation reports, and to have the advice of counsel.

The respondent is responsible for maintaining confidentiality and cooperating with the conduct of an inquiry or investigation. If the respondent is not found guilty of scientific misconduct, he or she has the right to receive institutional assistance in restoring his or her reputation.⁵

D. Deciding Official

The President and CEO will receive the inquiry and/or investigation report and any written comments made by the respondent or the whistleblower on the draft report. The President and CEO will consult with the Assistant Vice President of Research or other appropriate officials and will determine whether to conduct an investigation, whether misconduct occurred, whether to impose sanctions, or whether to take other appropriate administrative actions [see section X].

General Policies and Principles

A. Responsibility to Report Misconduct

All employees or individuals associated with Midwestern University should report observed, suspected, or apparent misconduct in science to the Assistant Vice President of Research. If an individual is unsure whether a suspected incident falls within the definition of scientific misconduct, he or she may call the Assistant Vice President of Research to discuss the suspected misconduct informally. If the circumstances described by the individual do not meet the definition of scientific misconduct, the Assistant Vice President of Research will refer the individual or allegation to other offices or officials with responsibility for resolving the problem.

At any time, an employee may have confidential discussions and consultations about concerns of possible misconduct with the Assistant Vice President of Research and will be counseled about appropriate procedures for reporting allegations.

B. Protecting the Whistleblower

The Assistant Vice President of Research will monitor the treatment of individuals who bring allegations of misconduct or of inadequate institutional response thereto, and those who cooperate in inquiries or investigations. The Assistant Vice President of Research will ensure that these persons will not be retaliated against in the terms and conditions of their employment or other status at the institution and will review instances of alleged retaliation for appropriate action.

Employees should immediately report any alleged or apparent retaliation to the Assistant Vice President of Research.

Also, Midwestern University will protect the privacy of those who report misconduct in good faith⁶ to the maximum extent possible. For example, if the whistleblower requests anonymity, Midwestern University will make an effort to honor the request during the allegation assessment or inquiry within applicable policies and regulations and state and local laws, if any. The whistleblower will be advised that if the matter is referred to an investigation committee and the whistleblower's testimony is required, anonymity may no longer be guaranteed. Midwestern University will undertake diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations.⁷

C. Protecting the Respondent

Inquiries and investigations will be conducted in a manner that will ensure fair treatment to the respondent(s) in the inquiry or investigation and confidentiality to the extent possible without compromising public health and safety or thoroughly carrying out the inquiry or investigation.⁸

An employee accused of scientific misconduct may consult with legal counsel or a non-lawyer personal adviser (who is not a principal or witness in the case) to seek advice and may bring the counsel or personal adviser to interviews or meetings on the case.

D. Cooperation with Inquiries and Investigations

Midwestern University employees will cooperate with the Assistant Vice President of Research and other institutional officials in the review of allegations and the conduct of inquiries and investigations. MWU employees have an obligation to provide relevant evidence to the Assistant Vice President of Research or other MWU officials on misconduct allegations.

E. Preliminary Assessment of Allegations

Upon receiving an allegation of scientific misconduct, the Assistant Vice

President of Research will immediately assess the allegation to determine whether there is sufficient evidence to warrant an inquiry, whether PHS support or PHS applications for funding are involved, and whether the allegation falls under the PHS definition of scientific misconduct.

Conducting the Inquiry

A. Initiation and Purpose of the Inquiry

Following the preliminary assessment, if the Assistant Vice President of Research determines that the allegation provides sufficient information to allow specific follow-up, involves PHS support, and falls under the PHS definition of scientific misconduct, he or she will immediately initiate the inquiry process. In initiating the inquiry, the Assistant Vice President of Research should identify clearly the original allegation and any related issues that should be evaluated. The purpose of the inquiry is to make a preliminary evaluation of the available evidence and testimony of the respondent, whistleblower, and key witnesses to determine whether there is sufficient evidence of possible scientific misconduct to warrant an investigation. The purpose of the inquiry is **not** to reach a final conclusion about whether misconduct definitely occurred or who was responsible. The findings of the inquiry must be set forth in an inquiry report.

B. Sequestration of the Research Records

After determining that an allegation falls within the definition of misconduct in science and involves PHS funding, the Assistant Vice President of Research must ensure that all original research records and materials relevant to the allegation are immediately secured. The Assistant Vice President of Research may consult with ORI for advice and assistance in this regard.

C. Appointment of the Inquiry Committee

The Assistant Vice President of Research, in consultation with other MWU officials, as appropriate, will appoint an inquiry committee and committee chair within 14 days of the initiation of the inquiry. The inquiry committee should consist of individuals who do not have real or apparent conflicts of interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry. These individuals may be scientists, subject matter experts, administrators, lawyers, or other qualified persons, and they may be from inside or outside Midwestern University.

The Assistant Vice President of Research will notify the respondent of the proposed committee membership in 14 days. If the respondent submits a written objection to any appointed member of the inquiry committee or expert based on bias or conflict of interest within 5 days, the Assistant Vice President of Research will determine whether to replace the challenged member or expert with a qualified substitute.

D. Charge to the Committee and the First Meeting.

The Assistant Vice President of Research will prepare a charge for the inquiry committee that describes the allegations and any related issues identified during the allegation assessment and states that the purpose of the inquiry is to make a preliminary evaluation of the evidence and testimony of the respondent, whistleblower, and key witnesses to determine whether there is sufficient evidence of possible scientific misconduct to warrant an investigation as required by the PHS regulation. The purpose is not to determine whether scientific misconduct definitely occurred or who was responsible.

At the committee's first meeting, the Assistant Vice President of Research will review the charge with the committee, discuss the allegations, any related issues, and the appropriate procedures for conducting the inquiry, assist the committee with organizing plans for the inquiry, and answer any questions raised by the committee. The Assistant Vice President of Research and

MWU counsel will be present or available throughout the inquiry to advise the committee as needed.

E. Inquiry Process

The inquiry committee will normally interview the whistleblower, the respondent, and key witnesses as well as examining relevant research records and materials.

Then the inquiry committee will evaluate the evidence and testimony obtained during the inquiry. After consultation with the Assistant Vice President of Research and MWU counsel, the committee members will decide whether there is sufficient evidence of possible scientific misconduct to recommend further investigation. The scope of the inquiry does not include deciding whether misconduct occurred or conducting exhaustive interviews and analyses.

The Inquiry Report

A. Elements of the Inquiry Report

A written inquiry report must be prepared that states the name and title of the committee members and experts, if any; the allegations; the PHS support; a summary of the inquiry process used; a list of the research records reviewed; summaries of any interviews; a description of the evidence in sufficient detail to demonstrate whether an investigation is warranted or not; and the committee's determination as to whether an investigation is recommended and whether any other actions should be taken if an investigation is not recommended. Midwestern University counsel will review the report for legal sufficiency.

B. Comments on the Draft Report by the Respondent and the Whistleblower

The Assistant Vice President of Research will provide the respondent with a copy of the draft inquiry report (including all interview transcripts) for comment and rebuttal and will provide the whistleblower, if he or she is identifiable, with portions of the draft inquiry report that address the whistleblower's role and opinions in the investigation. [MWU may provide the whistleblower with a summary of the inquiry findings for comment instead of portions of the draft report.]

1. Confidentiality

The Assistant Vice President of Research may establish reasonable conditions for review to protect the confidentiality of the draft report.

2. Receipt of Comments

Within 14 calendar days of their receipt of the draft report, the whistleblower and respondent will provide their comments, if any, to the inquiry committee. Any comments that the whistleblower or respondent submits on the draft report will become part of the final inquiry report and record.⁹ Based on the comments, the inquiry committee may revise the report as appropriate.

C. Inquiry Decision and Notification

1. Decision by Deciding Official

The Assistant Vice President of Research will transmit the final report and any comments to the President and CEO, who will make the determination of whether findings from the inquiry provide sufficient evidence of possible scientific misconduct to justify conducting an investigation. The inquiry is completed when the President and CEO makes this determination, which will be made within 90 days of the first meeting of the inquiry committee. Any

extension of this period will be based on good cause and recorded in the inquiry file.

2. Notification

The Assistant Vice President of Research will notify both the respondent and the whistleblower in writing of the President and CEO's decision of whether to proceed to an investigation and will remind them of their obligation to cooperate in the event an investigation is opened. The Assistant Vice President of Research will also notify all appropriate institutional officials of the President and CEO's decision.

D. Time Limit for Completing the Inquiry Report

The inquiry committee will normally complete the inquiry and submit its report in writing to the Assistant Vice President of Research no more than 90 calendar days following its first meeting,¹⁰ unless the Assistant Vice President of Research approves an extension for good cause. If the Assistant Vice President of Research approves an extension, the reason for the extension will be entered into the records of the case and the report.¹¹ The respondent also will be notified of the extension.

Conducting the Investigation

A. Purpose of the Investigation

The purpose of the investigation is to explore in detail the allegations, to examine the evidence in depth, and to determine specifically whether misconduct has been committed, by whom, and to what extent. The investigation will also determine whether there are additional instances of possible misconduct that would justify broadening the scope beyond the initial allegations. This is particularly important where the alleged misconduct involves clinical trials or potential harm to human subjects or the general public or if it affects research that forms the basis for public policy, clinical practice, or public health practice. The findings of the investigation will be set forth in an investigation report.

B. Sequestration of the Research Records

The Assistant Vice President of Research will immediately sequester any additional pertinent research records that were not previously sequestered during the inquiry. This sequestration should occur before or at the time the respondent is notified that an investigation has begun. The need for additional sequestration of records may occur for any number of reasons,

including MWU's decision to investigate additional allegations not considered during the inquiry stage or the identification of records during the inquiry process that had not been previously secured. The procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry.

C. Appointment of the Investigation Committee

The Assistant Vice President of Research, in consultation with other institutional officials as appropriate, will appoint an investigation committee and the committee chair within 14 days of the notification to the respondent that an investigation is planned or as soon thereafter as practicable. The investigation committee should consist of at least three individuals who do not have real or apparent conflicts of interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegations, interview the principals and key witnesses, and conduct the investigation.¹² These individuals may be scientists, administrators, subject matter experts, lawyers, or other qualified persons, and they may be from inside or outside Midwestern University. Individuals appointed to the investigation committee may also have served on the inquiry committee.

The Assistant Vice President of Research will notify the respondent of the proposed committee membership within 5 days. If the respondent submits a written objection to any appointed member of the investigation committee or expert, the Assistant Vice President of Research will determine whether to replace the challenged member or expert with a qualified substitute.

D. Charge to the Committee and the First Meeting

1. Charge to the Committee

The Assistant Vice President of Research will define the subject matter of the investigation in a written charge to the committee that describes the allegations and related issues identified during the inquiry, defines scientific misconduct, and identifies the name of the respondent.

The charge will state that the committee is to evaluate the evidence and testimony of the respondent, whistleblower, and key witnesses to determine whether, based on a preponderance of the evidence, scientific misconduct occurred and, if so, to what extent, who was responsible, and its seriousness.

During the investigation, if additional information becomes available that substantially changes the subject matter of the investigation or

would suggest additional respondents, the committee will notify the Assistant Vice President of Research, who will determine whether it is necessary to notify the respondent of the new subject matter or to provide notice to additional respondents.

2. The First Meeting

The Assistant Vice President of Research, with the assistance of MWU counsel, will convene the first meeting of the investigation committee to review the charge, the inquiry report, and the prescribed procedures and standards for the conduct of the investigation, including the necessity for confidentiality and for developing a specific investigation plan. The investigation committee will be provided with a copy of these instructions and, where PHS funding is involved, the PHS regulation.

E. Investigation Process

The investigation committee will be appointed and the process initiated within 30 days of the completion of the inquiry if findings from that inquiry provide a sufficient basis for conducting an investigation.¹³

The investigation will normally involve examination of all documentation including, but not necessarily limited to, relevant research records, computer files, proposals, manuscripts, publications, correspondence, memoranda, and notes of telephone calls.¹⁴ Whenever possible, the committee should interview the whistleblower(s), the respondents(s), and other individuals who might have information regarding aspects of the allegations.¹⁵ Interviews of the respondent should be tape recorded or transcribed. All other interviews should be transcribed, recorded, or summarized. Summaries or transcripts of the interviews should be prepared, provided to the interviewed party for comment or revision, and included as part of the investigatory file.¹⁶

The Investigation Report

A. Elements of the Investigation Report

The final report submitted to ORI must describe the policies and procedures under which the investigation was conducted, describe how and from whom information relevant to the investigation was obtained, state the findings, and explain the basis for the findings. The report will include the actual text or an accurate summary of the views of any individual(s) found to have engaged in misconduct as well as a description of any sanctions imposed and administrative actions taken by Midwestern University.¹⁷

B. Comments on the Draft Report

1. Respondent

The Assistant Vice President of Research will provide the respondent with a copy of the draft investigation report for comment and rebuttal. The respondent will be allowed 30 days to review and comment on the draft report. The respondent's comments will be attached to the final report. The findings of the final report should take into account the respondent's comments in addition to all the other evidence.

2. Whistleblower

The Assistant Vice President of Research will provide the whistleblower, if he or she is identifiable, with those portions of the draft investigation report that address the whistleblower's role and opinions in the investigation. The report should be modified, as appropriate, based on the whistleblower's comments.

3. Midwestern University Counsel

The draft investigation report will be transmitted to Midwestern University counsel for a review of its legal sufficiency. Comments should be incorporated into the report as appropriate.

4. Confidentiality

In distributing the draft report, or portions thereof, to the respondent and whistleblower, the Assistant Vice President of Research will inform the recipient of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure

such confidentiality. For example, the Assistant Vice President of Research may request the recipient to sign a confidentiality statement or to come to his or her office to review the report.

C. **Midwestern University Review and Decision**

Based on a preponderance of the evidence, the President and CEO will make the final determination whether to accept the investigation report, its findings, and the recommended institutional actions. If this determination varies from that of the investigation committee, the President and CEO will explain in detail the basis for rendering a decision different from that of the investigation committee in Midwestern University's letter transmitting the report to ORI. The President and CEO's explanation should be consistent with the PHS definition of scientific misconduct, the institution's policies and procedures, and the evidence reviewed and analyzed by the investigation committee. The President and CEO may also return the report to the investigation committee with a request for further fact-finding or analysis. The President and CEO's determination, together with the investigation committee's report, constitutes the final investigation report for purposes of ORI review. When a final decision on the case has been reached, the Assistant Vice President of Research will notify both the respondent and the whistleblower in writing. In addition, the President and CEO will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the respondent in the work, or other relevant parties should be notified of the outcome of the case. The Assistant Vice President of Research is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

D. **Transmittal of the Final Investigation Report to ORI**

After comments have been received and the necessary changes have been made to the draft report, the investigation committee should transmit the final report with attachments, including the respondent's and whistleblower's comments, to the President and CEO, through the Assistant Vice President of Research.

E. **Time Limit for Completing the Investigation Report**

An investigation should ordinarily be completed within 180 days of its initiation,¹⁸ with the initiation being defined as the first meeting of the investigation committee. This includes conducting the investigation, preparing the report of findings, making the draft report available to the subject of the investigation for comment, submitting the report to the President and CEO for approval, and submitting the report to the ORI.¹⁹

Requirements for Reporting to ORI

- A. Midwestern University's decision to initiate an investigation must be reported in writing to the Director, ORI, on or before the date the investigation begins.²⁰ At a minimum, the notification should include the name of the person(s) against whom the allegations have been made, the general nature of the allegation as it relates to the PHS definition of scientific misconduct, and the PHS applications or grant number(s) involved.²¹ ORI must also be notified of the final outcome of the investigation and must be provided with a copy of the investigation report.²² Any significant variations from the provisions of Midwestern University's policies and procedures should be explained in any reports submitted to ORI.
- B. If Midwestern University plans to terminate an inquiry or investigation for any reason without completing all relevant requirements of the PHS regulation, The Assistant Vice President of Research will submit a report of the planned termination to ORI, including a description of the reasons for the proposed termination.²³
- C. If Midwestern University determines that it will not be able to complete the investigation in 180 days, the Assistant Vice President of Research will submit to ORI a written request for an extension that explains the delay, reports on the progress to date, estimates the date of completion of the report, and describes other necessary steps to be taken. If the request is granted, the Assistant Vice President of Research will file periodic progress reports as requested by the ORI.²⁴
- D. When PHS funding or applications for funding are involved and an admission of scientific misconduct is made, the Assistant Vice President of Research will contact ORI for consultation and advice. Normally, the individual making the admission will be asked to sign a statement attesting to the occurrence and extent of misconduct. When the case involves PHS funds, MWU cannot accept an admission of scientific misconduct as a basis for closing a case or not undertaking an investigation without prior approval from ORI.²⁵
- E. The Assistant Vice President of Research will notify ORI at any stage of the inquiry or investigation if:
 - 1. there is an immediate health hazard involved;²⁶
 - 2. there is an immediate need to protect Federal funds or equipment;²⁷
 - 3. there is an immediate need to protect the interests of the person(s) making the allegations or of the individual(s) who is the subject of the

- allegations as well as his/her co-investigators and associates, if any;²⁸
4. it is probable that the alleged incident is going to be reported publicly;²⁹
or
 5. the allegation involves a public health sensitive issue, *e.g.*, a clinical trial; or
 6. there is a reasonable indication of possible criminal violation. In this instance, Midwestern University must inform ORI within 24 hours of obtaining that information.³⁰

Institutional Administrative Actions

Midwestern University will take appropriate administrative actions against individuals when an allegation of misconduct has been substantiated.³¹

If the President and CEO determines that the alleged misconduct is substantiated by the findings, he or she will decide on the appropriate actions to be taken, after consultation with the Assistant Vice President of Research. The actions may include:

- withdrawal or correction of all pending or published abstracts and papers emanating from the research where scientific misconduct was found.
- removal of the responsible person from the particular project.

Behavioral Misconduct

- The University prohibits Unlawful Acts. The policies and procedures outlined above shall apply to any allegations of Unlawful Acts as a parallel structure to the University's policies and procedures concerning Unlawful Acts in the equal employment opportunity context (generally "EEO Policies"). Should any of these policies and procedures conflict with the University's EEO Policies, the EEO Policies will prevail insofar as to govern the process of investigation of such matters. The University will apply this misconduct policy to the fullest extent possible, including maintaining participation of the Research Integrity Officer. Nothing about the incorporation of the EEO Policies shall limit the ability of the Research Integrity Officer to take any and all actions needed to achieve research integrity, as determined by the Research Integrity Officer. Such action includes, but is not limited to, taking adverse action against a Principal Investigator or other key personnel that has committed Unlawful Acts and reporting those individuals to the NIH. Individuals who feel they have been a victim of Unlawful Acts are encouraged to bring their concerns to the

Research Integrity Officer, the University's Human Resources department, or the NIH.

- i. 42 C.F.R. ' 50.102.
- ii. 42 C.F.R. ' 50.102.
- iii. 42 C.F.R. ' 50.102.
- iv. 42 C.F.R. ' 50.103(d)(12).
- v. 42 C.F.R. ' 50.103(d)(13).
- vi. 42 C.F.R. ' 50.103(d)(2).
- vii. 42 C.F.R. ' 50.103(d)(13).
- viii. 42 C.F.R. ' 50.103(d)(3).
- ix. 42 C.F.R. ' 50.103(d)(1).
- x. 42 C.F.R. ' 50.103(d)(1).
- xi. 42 C.F.R. ' 50.103(d)(1).
- xii. 42 C.F.R. ' 50.103(d)(8).
- xiii. 42 C.F.R. ' 50.103(d)(7).
- xiv. 42 C.F.R. ' 50.103(d)(7).
- xv. 42 C.F.R. ' 50.103(d)(7).
- xvi. 42 C.F.R. ' 50.103(d)(7).
- xvii. 42 C.F.R. ' 50.104(a)(4); 42 C.F.R. ' 50.103(d)(15).
- xviii. 42 C.F.R. ' 50.104(a) (2).
- xix. 42 C.F.R. ' 50.104(a)(2).
- xx. 42 C.F.R. ' 50.104(a)(1).
- xxi. 42 C.F.R. ' 50.104(a)(1).

- xxii. 42 C.F.R. ' 50.103(d)(15).
- xxiii. 42 C.F.R. ' 50.104(a)(3).
- xxiv. 42 C.F.R. ' 50.104(a)(5).
- xxv. 42 C.F.R. ' 50.104(a)(3).
- xxvi. 42 C.F.R. ' 50.104(b)(1).
- xxvii. 42 C.F.R. ' 50.104(b)(2).
- xxviii. 42 C.F.R. ' 50.104(b)(3).
- xxix. 42 C.F.R. ' 50.104(b)(4).
- xxx. 42 C.F.R. ' 50.104(b)(5).
- xxxi. 42 C.F.R. ' 50.103(d)(14).

MIDWESTERN UNIVERSITY

STANDARD POLICY

DIVISION: All University Colleges

AREA: Administrative

SUBJECT: Biosafety	POLICY NO. 0010		
APPROVED BY: Joshua Baker, M.S., O.D. Interim President & Chief Executive Officer 	ISSUE DATE 06/27/2025	SUPERSEDES 12/98	PAGES 1-6

PURPOSE: To establish the means of ensuring compliance with the Occupational Safety and Health Administration (OSHA), the National Institutes of Health (NIH), and other external agencies' safety standards regarding the use of biological, chemical, physical and DNA hazards, and to provide guidelines on the safe waste disposal of such hazards.

POLICY: Midwestern University (MWU) is committed to ensuring, as thoroughly as possible, that all research laboratory personnel have safe working conditions, and that the uncontrolled release of hazardous biological agents, chemicals, and recombinant DNA into the environment is strictly prohibited. The personal safety and health of all research laboratory personnel and any other individuals who are required to enter a research area at MWU are of utmost importance and will take precedence over all other activities. MWU aims to fully comply with all external agencies' regulations, standards, and guidelines regarding occupational health, safety, and waste disposal related to its laboratories and research facilities. The university will provide the essential education, training, and protective equipment necessary for all laboratory personnel to guard against health hazards associated with biological, chemical, and physical agents found in MWU laboratories and research facilities. A University Biosafety Committee has been established at the Downers Grove and Glendale campuses of MWU to implement this policy.

Biosafety Program

The Midwestern University Biosafety Committee has the following responsibilities regarding the MWU Biosafety Program:

1. Committee Charge
 - a. Ensure all activities involving biohazardous materials, hazardous chemicals, and physical substances comply with federal, state, and local regulations and relevant university policies.

- b. Support and guide the MWU research community in implementing effective biological, chemical, and physical safety practices for all activities involving hazardous materials.
 - c. Minimize the risk of possible biohazard, chemical, and physical hazards to the MWU research community, the public, and the environment.
- 2. The University Biosafety Committee holds the authority over all research labs and other research areas in all colleges and programs at MWU. This authority applies to:
 - a. Evaluate and authorize practices and procedures concerning research and activities that involve biohazardous materials, hazardous chemicals, and hazardous physical agents.
 - b. Conduct regular and as needed inspections for all research laboratory facilities that use biohazardous materials, hazardous chemicals, physical substances, and other related materials.
 - c. Implement necessary measures, such as suspending or terminating research, in situations that pose a risk to life or health and in cases of serious, repeated, or ongoing non-compliance with regulations and safety guidelines.
- 3. The Chemical Hygiene Officer (designated as the Chair of the biosafety committee) is responsible for implementing the Chemical Hygiene Plan outlined in 29 CFR 1910.
- 4. Committee Responsibilities
 - a. To develop and implement policies, procedures, and guidelines related to biohazardous materials, hazardous chemicals, and hazardous physical agents (e.g., reviewing and updating the Lab Safety Manual and the Chemical Hygiene Plan as described in 29 CFR 1910, among others) for university laboratory activities.
 - b. To review and monitor all research, teaching, and activities conducted in MWU research laboratories that involve biological toxins, and recombinant DNA (subject to review and approval by the Institutional Biosafety Committee [IBC]) alongside biohazardous materials, hazardous chemicals, and hazardous physical agents. This also includes the annual registration requirement for laboratories containing biological materials, hazardous chemicals, and hazardous physical agents.
 - c. To assist the MWU research community in fulfilling their responsibilities for risk assessment, developing policies and procedures, training staff, reporting incidents, safe waste disposal, ensuring appropriate safety apparel and equipment, and maintaining facilities and equipment.
 - d. To meet regularly to discuss pertinent laboratory health and safety issues.
 - e. To develop, implement, and update a laboratory safety manual and chemical hygiene plan, which will be issued to all faculty, other university employees and laboratory personnel engaged in research conducted on campus.

- f. To provide training for laboratory personnel in safe laboratory practices and the safe handling of hazardous chemicals, hazardous biological agents, and hazardous physical agents. Training for all laboratory personnel and any individuals who enter a lab will be provided upon hiring, covering both general (also known as right-to-know) and lab-specific information, and will be updated regularly thereafter. Specific shipping training will be provided, if necessary. All training must be documented.
- g. To make routine and as needed inspections of laboratories and research work areas to ensure that safe practices are being followed, that hazardous chemicals, biological, and physical agents are used properly, and that safety apparel and equipment are usable and/or functional. To provide documented training of personnel on proper storage, use and disposal of PPE.
- h. To review laboratory activities and research operations to determine which jobs and procedures need to be revised to incorporate safety and chemical hygiene measures for the protection of all individuals associated with that laboratory and to require BSC-approved documentation of such activities (i.e., SOPs).
- i. To ensure the presence of appropriate door signage for all laboratories and other research areas.
- j. To ensure that faculty are maintaining an up-to-date list reviewed annually of hazardous materials (chemical and/or biological) used and/or stored in laboratories for use in research conducted on campus. For chemicals, an up-to-date inventory of Safety Data Sheets (SDS) must be maintained. Appropriate, safe storage of chemicals is required as determined by the BSC.
- k. To ensure that proper reporting practices are used for all on-site laboratory-related accidents, injuries, and illnesses.
- l. To ensure that hazardous materials (chemical, biological, sharps, etc.) are disposed of in an appropriate manner.
- m. To review all lab-related Incident/Injury Reports in a timely manner and when appropriate, take the required action to minimize recurrences.

Responsibilities

1. Chief Executive Officer
 - a. Provide and ensure a safe working environment for laboratory personnel. This responsibility includes oversight of the development and implementation of a laboratory safety and chemical hygiene plan, and oversight of programs to see that the plan has continuing management support and adequate resources to be effective.
2. Administration:

- a. Provide management support for the University Biosafety Committee and all actions adopted by the committee to ensure compliance with the OSHA Laboratory Standard, NIH and other external agencies.
 - b. Document training of employees and other laboratory personnel in workplace safety and health issues.
 - c. Monitor procurement, use, and disposal of hazardous chemicals, biological and physical agents.
 - d. Periodically audit the laboratory safety and chemical hygiene plan.
3. Office of Research and Sponsored Programs (ORSP)
- a. Involved in annual lab inspections.
 - b. Involved in access approval to buildings and research laboratories.
 - c. Provide training and administrative support for MSDSonline.
 - d. Documentation of annual lab registration.
 - e. Annual lab training for MWU non-research personnel (ITS, Campus Facilities, Safety & Security, cleaning crew), communication and documentation.
 - f. Certification of proper glove use (PPE training).
 - g. Provide administrative support for CITI training modules (BBP, shipping training, etc.).
4. College Deans
- a. Ensure that laboratory managers (department chairs and faculty) develop, implement, review, and update safety and chemical hygiene practices as well as the use of adequate procedures and protective equipment.
 - b. Notify the University Biosafety Committee Officer (BSO) immediately upon discovering any violations of university, local, state, or national environmental health and occupational safety rules or regulations. This also includes interactions with local, state, and federal regulatory agencies.
5. Faculty and Principal Investigators (PIs)
- a. Maintain an up-to-date list of hazardous materials used or stored. A review of the entire inventory should be conducted annually.
 - b. Maintain an up-to-date inventory of Safety Data Sheets (SDS) online.

- c. Review lab activities and research operations and update of laboratory personnel job descriptions and laboratory procedures (SOPs) to incorporate appropriate safety and health measures.
- d. Monitor laboratory personnel to ensure compliance with the Chemical Hygiene Plan (CHP).
- e. Follow standard procedures and use prescribed protective equipment.
- f. Maintain precautionary labels on all physical hazards and all containers of hazardous chemicals and biologicals.
- g. Know the location and use of emergency equipment.
- h. Know and participate in the practice of emergency procedures.
- i. Maintain and request repairs for any malfunctioning laboratory ventilation or safety equipment, as well as any equipment necessary for safe operations.
- j. Inform department chair when faculty, staff or students experience symptoms or signs of possible exposure to hazardous chemicals, biological and physical agents.
- k. Notify the University Biosafety Committee Officer (BSO) immediately upon discovering any violations of university, local, state, or national environmental health and occupational safety rules or regulations. This also includes interactions with local, state, and federal regulatory agencies.
- l. Participate in biosafety and other laboratory safety training to ensure compliance with relevant training requirements.

6. Laboratory Personnel

- a. Participate in the review and risk assessment of lab activities and research operations and update of job descriptions and laboratory procedures (SOPs) to incorporate appropriate safety and health measures.
- b. Know how to access the Lab Safety Manual, Chemical Hygiene Plan, and other relevant safety-related documents, as well as understanding the requirements and procedures outlined within them.
- c. Follow standard procedures and use prescribed protective equipment to perform their duties in a safe manner to minimize exposure.
- d. Maintain precautionary labels on all physical hazards and containers of hazardous chemicals and biological substances.

- e. Know location and use of SDSs, emergency equipment (spill kits, first aid kits, emergency shower and eyewash stand), and participate in the practice of emergency procedures.
- f. Inform the supervisor of any malfunctioning laboratory ventilation or other safety equipment, and of any precautions, labels or equipment needed for working safely.
- g. Inform supervisor if laboratory personnel experience symptoms or signs of possible overexposure to hazardous chemicals.
- h. Participate in biosafety and other laboratory safety training to ensure compliance with relevant training requirements.
- i. Notify the PI, Department Chair and University Biosafety Committee Officer (BSO) upon discovering any violations of university, local, state, or national environmental health and occupational safety rules or regulations. This also includes interactions with local, state, and federal regulatory agencies.

APPENDIX 1

The University Biosafety Committee

This university committee is composed of at least five (5) members, one of whom is appointed as chairperson by the president with the advice of the University Faculty Senate. The committee includes one member of the technical staff. All members are appointed by the president upon the recommendation of the University Faculty Senate via the committee on committees. The Associate Director, Office of Research and Sponsored Programs is an *ex-officio* non-voting member of this committee on each campus. Manager of Occupational Safety and Health serves as the *ex-officio* member on the AZ campus. This committee is responsible for overseeing all lab safety issues on campus related to research and teaching activities of the faculty at Northwestern University. In addition to assisting the University administration in developing appropriate policies and procedures, the committee will develop guidelines and oversee the use of potentially hazardous biological (including recombinant DNA), chemical, and physical agents used in teaching and research programs on campus. The committee will assess the hazards, determine the safeguards needed for their control, evaluate procedures for waste disposal, conduct inspection of research facilities and areas, ensure all individuals involved in research comply with all appropriate policies and procedures, and assure that all faculty, students, and support staff are provided appropriate training necessary to work with these potentially hazardous agents.

MIDWESTERN UNIVERSITY

STANDARD POLICY

DIVISION: All University Colleges

AREA: Administrative

SUBJECT: Radiation Safety	POLICY NO. 0011		
APPROVED BY: Administrative Team	ISSUE DATE 12/98	SUPERSEDES	PAGES 1 of 9

PURPOSE: To comply with all applicable federal and state laws, rules, and regulations concerning radioactive material purchases, usage, waste, disposal and radiation safety on campus related to research and teaching activities of faculty at MWU.

POLICY: It is the policy of MWU to assure as completely as possible, that all laboratory personnel at MWU have safe and healthful working conditions and to forbid the uncontrolled releases of radioactive materials into the environment. The personal safety and health of all laboratory personnel at MWU is of primary importance and will be given priority over all other activities. It is the intent of MWU to fully comply with all applicable state and federal laws, rules, and regulations concerning radioactive material purchases, usage, waste disposal, and radiation safety (including monitoring radiation exposure) on campus related to research and teaching activities of faculty at MWU. MWU will provide the necessary education, training, and protective equipment needed by all laboratory personnel for protection against excessive exposure to radiation and/or radioactive materials. MWU will assess the hazards to non-users of radioactive materials on campus and provide the necessary monitoring, protection, and training to minimize risks. A Radiation Safety Committee has been formed at the Downers Grove and Glendale campuses of MWU to implement this policy.

Radiation Safety Committee:

The Midwestern University Radiation Safety Committee with the expertise of the campus Radiation Safety Officer (RSO) has the following responsibilities:

1. To establish procedures and criteria for making safety evaluations of proposed uses of radioactive material. The procedures and criteria will include: 1) Consideration of the adequacy of facilities and equipment; 2) Need for special requirements such as bioassay, physical exams, and other special monitoring procedures; 3) Operating, handling and emergency procedures; 4) The extent of experience and training necessary for proposed users of greater than exempt quantities of material.

MIDWESTERN UNIVERSITY

STANDARD POLICY

DIVISION: All University Colleges

AREA: Administrative

SUBJECT: Radiation Safety	POLICY NO. 0011		
APPROVED BY: Administrative Team	ISSUE DATE 12/98	SUPERSEDES	PAGES 2 of 9

2. To establish the criteria to determine which category of workers will receive training and the extent of training provided to each category of worker.
3. Establish the methods employed for maintaining records of the Radiation Safety Committee's proceedings and safety evaluations of proposed uses of radioactive material. These records must include the date, attending and absent members, summary of deliberations and discussions, recommended actions and results of votes and documentation of reviews conducted pursuant to the procedures and criteria identified in (1) above.
4. Establish the scope of an annual review of the safety program.
5. The monitoring of the institution's As Low As is Reasonably Achievable (ALARA) Program on a quarterly basis. These reviews must include a review of the exposure records of all personnel working in the vicinity of radioactive materials, determining the exposure to members of the public through release of radioactive materials, and all unusual events and incidents involving radioactive materials with respect to cause and subsequent actions.
6. Establishing exposure levels consistent with any federal, state or municipal law which, when exceeded, will prompt an investigation.
7. Establish the scope of biennial reviews of previous evaluations of authorized users, approved projects, etc. made pursuant to the procedures and criteria of (1) above.

To provide all authorized users and laboratory personnel working in the labs of authorized users with the MWU Radiation Safety manual and other timely information. This manual contains protocols and procedures for the use of radioactive materials to assure compliance with all applicable federal and state laws, rules, and regulations.

MIDWESTERN UNIVERSITY

STANDARD POLICY

DIVISION: All University Colleges

AREA: Administrative

SUBJECT: Radiation Safety	POLICY NO. 0011		
APPROVED BY: Administrative Team	ISSUE DATE 12/98	SUPERSEDES	PAGES 3 of 9

The University administration and the RSC has transferred all responsibilities and duties specified in item above (1 through 7) to the RSO.

Responsibilities:

Chief executive officer:

1. Provide a safe and healthful working environment for laboratory personnel. This responsibility includes oversight of MWU compliance with the terms of the Radiation Materials License and assurance that the Radiation Safety Committee and the Radiation Safety Officer have the resources to comply with the conditions of the license.

Administration:

1. Provide management support for the Radiation Safety Committee and all actions adopted by the committee to implement compliance with all applicable federal and state laws, rules and regulations.
2. Document radiation safety training of appropriate personnel (authorized users, faculty, staff and laboratory personnel).

College deans:

1. Ensure that authorized users (Department Chairs, faculty) and laboratory personnel working in the labs of authorized users adhere to all applicable federal and state law, and MWU requirements concerning radioactive material purchases, usage and disposal and radiation safety on campus related to research and teaching activities of faculty at MWU.

MIDWESTERN UNIVERSITY

STANDARD POLICY

DIVISION: All University Colleges

AREA: Administrative

SUBJECT: Radiation Safety	POLICY NO. 0011		
APPROVED BY: Administrative Team	ISSUE DATE 12/98	SUPERSEDES	PAGES 4 of 9

Department chairs:

1. Ensure that authorized users (faculty) and laboratory personnel working in the labs of authorized users adhere to all applicable federal and state laws and MWU requirements concerning radioactive material purchases, usage and disposal and radiation safety on campus related to research and teaching activities of faculty at MWU.

Authorized users (faculty):

1. Adhere to all applicable federal and state laws and MWU requirements concerning radioactive material purchases, usage and disposal and radiation safety on campus related to the authorized user's research and teaching activities at MWU.
2. Ensure that laboratory personnel working in the lab of the authorized users adhere to all applicable federal and state laws and MWU requirements concerning radioactive material purchases, usage and disposal and radiation safety on campus related to the authorized user's research and teaching activities at MWU.

Laboratory personnel:

1. Adhere to all applicable federal and state laws and MWU requirements concerning radioactive material purchases, usage and disposal and radiation safety on campus related to the authorized user's research and teaching activities at MWU.

Radiation Safety Officer (RSO):

The RSO is responsible for the daily implementation of an effective radiation safety program by ensuring that all activities involving radionuclides and/or radiation are conducted in accordance with the campus license provisions and regulatory requirement.

MIDWESTERN UNIVERSITY

STANDARD POLICY

DIVISION: All University Colleges

AREA: Administrative

SUBJECT: Radiation Safety	POLICY NO. 0011		
APPROVED BY: Administrative Team	ISSUE DATE 12/98	SUPERSEDES	PAGES 5 of 9

1. Providing surveillance over all activities involving radioactive materials through quarterly audits/spot checks including radiation monitoring, and special surveys of all areas in which radioactive material is used and/or stored to determine compliance with rules, regulations, license conditions and approvals made by the RSC.
2. Monitoring and maintaining positive control of administrative systems associated with the receipt, use, storage, transfer and/or disposal of radioactive material.
3. Providing or arranging for professional advice on all aspects of radiation protection to personnel at all levels of responsibility.
4. Distributing and processing personnel monitoring equipment, determining the need for, and evaluation of bioassay, if applicable, and notifying individuals and their supervisors of exposure approaching maximum permissible amounts and recommending appropriate remedial action.
5. Conducting training programs and otherwise instructing personnel in the proper procedures for the use of radioactive materials prior to use, at annual intervals (refresher training) and as 11. Implementing written policy, procedures, and corrective actions needed as a result of investigations and maintaining records associated with the above duties and responsibilities.
6. Supervising and coordinating the radioactive waste disposal program, including effluent monitoring.
7. Performing or arranging for calibrations of instruments used to conduct required radiation surveys.
8. Terminating activities found to be a threat to health or property.
9. Supervising decontamination and recovery operations.

MIDWESTERN UNIVERSITY

STANDARD POLICY

DIVISION: All University Colleges

AREA: Administrative

SUBJECT: Radiation Safety	POLICY NO. 0011		
APPROVED BY: Administrative Team	ISSUE DATE 12/98	SUPERSEDES	PAGES 6 of 9

10. Conducting investigations of: 1) Deviations from ALARA practices noted in quarterly reviews of dosimetry records; 2) Unauthorized uses, transfers, disposal and other deviations from approved practices; and 3) Accidents, spills, losses, thefts and unusual events.
11. Implementing written policy, procedures, and corrective actions needed as a result of investigations and maintaining records associated with the above duties and responsibilities.
12. Serve as liaison with state or federal regulatory agencies.
13. Assure that radioactive material possessed by the licensee conforms to the material authorized by the license.
14. Assure that only individuals authorized by the license use the radioactive material.
15. Assure that personnel monitoring devices are used where indicated, exchanged at required intervals, and that records are kept of the results of such monitoring.
16. Assure that required signs and notices are properly posted.
17. Investigate each known or suspected case of excessive or abnormal exposure to determine the cause and take steps to prevent its recurrence.
18. Be available to give assistance in case of emergency (e.g., damage, fire, theft, etc.).
19. Assure that the proper authorities (i.e., state, local police, U.S. Department of Transportation, etc.) are notified promptly in case of accident, damage, theft or loss of radioactive material.
20. Assure that the terms and conditions of the license (such as personnel exposure, leak tests, accountability, etc.) are maintained and reviewed for compliance with applicable regulations and license conditions.

MIDWESTERN UNIVERSITY

STANDARD POLICY

DIVISION: All University Colleges

AREA: Administrative

SUBJECT: Radiation Safety	POLICY NO. 0011		
APPROVED BY: Administrative Team	ISSUE DATE 12/98	SUPERSEDES	PAGES 7 of 9

21. Maintain records of all individuals designated by the Radiation Safety Officer to perform duties or meet regulatory requirements which would otherwise be required as a duty or responsibility of the RSO. These records will include:
 - a) The name of the designated individual.
 - b) A list of all duties the designee is authorized to perform.
 - c) The date upon which the designation becomes effective.
22. Serve as a permanent member of the Radiation Safety Committee and distribute minutes of the meeting.

MIDWESTERN UNIVERSITY

STANDARD POLICY

DIVISION: All University Colleges

AREA: Administrative

SUBJECT: Radiation Safety	POLICY NO.		
APPROVED BY: Administrative Team	ISSUE DATE 12/98	SUPERSEDES	PAGES 8 of 9

A P P E N D I X I

The Radiation Safety committee:

This institutional committee is composed of at least seven (7) members including the MWU Radiation Safety Officer (RSO) and one voting member of the technical staff. The committee chairperson is appointed by the president with the advice of the University Faculty Senate. All members are appointed by the president upon the recommendation of the University Faculty Senate. The Director, ORSP is an *ex officio* non-voting member of this committee on one campus, and her/his assistant(s) serve as an *ex officio* member on the other campus(es). The chairperson of this committee must be a faculty member and an authorized user. All other MWU faculty and staff committee members must be authorized users or supervised users. This committee is responsible for overseeing all radionuclide/radioisotope purchases, usage, storage and disposal issues as well as radiation safety issues (including monitoring radiation exposure) on campus related to research and teaching activities of MWU faculty. The committee monitors and assures compliance of the university community with all applicable federal and state laws, rules and regulations concerning radionuclide/radioisotope purchases, usage and disposal and radiation safety. Within the framework of all applicable federal and state laws, rules and regulations, the committee will assist the University administration in developing appropriate policies and procedures concerning radioactive materials in research or teaching programs. The committee oversees all radionuclide material purchases, assesses hazards, determines the safeguards needed for their purchase and control, evaluates procedures for waste disposal, conducts inspections of research facilities and areas where radioactive materials are used or stored, ensures that all individuals involved in research involving radioactive material or radiation comply with all appropriate policies and procedures, and assures that all faculty, students, and support staff are provided with appropriate training necessary to work with these substances. The committee also assesses the hazards to non-users of radioactive materials and provides these individuals with the necessary monitoring, protection and training.

MIDWESTERN UNIVERSITY

STANDARD POLICY

DIVISION: All University Colleges

AREA: Administrative

SUBJECT: Radiation Safety	POLICY NO. 0011		
APPROVED BY: Administrative Team	ISSUE DATE 12/98	SUPERSEDES	PAGES 9 of 9

It is the policy of Midwestern University that research activities or programs utilizing radioactive materials conducted under the auspices of MWU shall be suspended or terminated by the responsible investigator or upon direction of the MWU Radiation Safety Officer (RSO) or chairperson of the radiation safety committee when a *bona fide* question is raised concerning known or suspected risks to the principal research investigator, their associate(s), the University or general community.

MIDWESTERN UNIVERSITY
STANDARD POLICY

DIVISION: All University Colleges

CAMPUS: Downers Grove and Glendale

SUBJECT: Animal Research	POLICY NO. 0006		
APPROVED BY:  Kathleen H. Goeppinger, Ph.D. President and CEO	ISSUE DATE 4/1/25	SUPERSEDES 12/98	PAGES 7

PURPOSE: This policy describes institutional measures designed to ensure appropriate care and use of animals in research, training, and testing at Midwestern University (MWU).

POLICY: It is the policy of MWU that no activity involving animals shall be conducted in association with research, training, or testing under the auspices of MWU until approved by the Institutional Animal Care and Use Committee (IACUC).

(1) This review is required of all activities involving MWU-owned animals without qualification as to source of funds.

(2) Review is also required of any activity involving animals carried out under the sponsorship of an institution other than MWU.

The procurement, retention, or use of live animals by any member of MWU must be approved by the IACUC and be in accordance with procedures stated in the *Public Health Service Policy on Humane Care and Use of Laboratory Animals* (hereinafter referred to as the *PHS Policy*) and the *Guide for the Care and Use of Agricultural Animals in Research and Teaching* (hereinafter referred to as the *Ag Guide*).

All members using animals shall be responsible for ensuring that animal use and care both comply with all stated regulations and requirements and conform to an acceptable humane ethic. Students and staff using animals

shall be supervised by a faculty member who shall be accountable for any actions of these individuals. Personnel involved in the care and use of animals are required to complete all training as deemed appropriate by the IACUC and respective Animal Facility.

- (1) When animals are used for testing, training, or research, such work shall be under the direct supervision of an experienced faculty member. The rules for the care of animals used for testing and training must be the same as for animals used for research.
- (2) Appropriate anesthetics must be used to eliminate sensibility to pain during operative or painful procedures.
- (3) Where recovery from anesthesia is necessary during the study, acceptable techniques to minimize pain must be followed.
- (4) Curarizing agents are not anesthetics.
- (5) For studies that do not require recovery from anesthesia, animals must be euthanized in a humane manner at the conclusion of the experiment following the guidelines established by the American Veterinary Medical Association (AVMA) Panel on Euthanasia (<https://olaw.nih.gov/policies-laws/avma-guidelines-2020.htm>).

Information Required in Applications and Proposals for IACUC Review

- (1) All APPLICATIONS FOR USE OF ANIMALS must include the following information:
 - (a) Identification of the species and number of animals to be used.
 - (b) Rationale for using animals, appropriateness of the species chosen, and number of each species/strain to be used.
 - (c) A complete description of the proposed procedures to be applied to animals.

- (d) A description of procedures designed to ensure that discomfort and injury to animals will be limited to that which is unavoidable in the conduct of scientifically valuable research, and that analgesic, anesthetic, and tranquilizing drugs will be used where indicated and appropriate to minimize discomfort and pain to animals.
- (e) A description of any euthanasia method to be used.

Review of Activities Involving Animals

- (1) To approve a proposed activity or proposed significant changes in ongoing activities, the IACUC shall review and determine that the proposed activities are in accordance with this Policy. In making this determination, the IACUC shall confirm that the activity will be conducted in accordance with the Animal Welfare Act (AWA) insofar as it applies to the activity and that the activity is consistent with the National Institutes of Health (NIH) *Guide for the Care and Use of Laboratory Animals* (hereinafter referred to as the NIH *Guide*) and the *Ag Guide* unless acceptable justification for a departure is presented. Furthermore, the IACUC shall determine that the activity conforms with the Institution's Office of Laboratory Animal Welfare (OLAW) Assurance and meets the following requirements:
 - (a) Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design.
 - (b) Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia, or anesthesia, unless the procedure is justified for scientific reasons in writing by the investigator.
 - (c) Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized at the end of the procedure or, if appropriate, during the procedure.
 - (d) The living conditions of animals will be appropriate for their species and contribute to their health and comfort. The housing, feeding, and care of the animals will be reviewed by an attending veterinarian or their designee who must also be a Doctor of Veterinary Medicine experienced in the

proper care, handling, and use of the species being maintained or studied.

- (e) Medical care for animals will be available and provided as necessary by a qualified veterinarian.
- (f) Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.
- (g) Methods of euthanasia used will be consistent with the recommendation of the AVMA Panel on Euthanasia.

(2) Prior to the review, each IACUC member shall be provided with the full protocol which includes the proposed activities to be reviewed. Written descriptions of activities that involve the care and use of animals shall be available to all IACUC members, and any member of the IACUC may obtain, upon request, full committee review of those activities. If full committee review is not requested, at least one member of the IACUC designated by the chairperson and qualified to conduct the review, shall review the activity and have the authority to approve, require modifications in (to secure approval) or request full committee review of the activity. If full committee review is requested, approval of the activity may be granted only after review at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present. No member may participate in the IACUC review or approval of an activity in which the member has a conflicting interest (e.g., is personally involved in the project) except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the constitution of a quorum.

(3) The IACUC may invite consultants to assist in the review of complex issues. Consultants may not approve or withhold approval of an activity or vote with the IACUC unless they are also members of the IACUC.

(4) The IACUC shall notify investigators and the institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval. If the IACUC decides to withhold approval of an activity, it shall include in its written notification a statement of the

reasons for its decision and give the investigator an opportunity to respond in person or in writing.

- (5) The IACUC shall conduct continuing review of approved animal activities covered by this Policy at appropriate intervals as determined by the IACUC, but not less than once every three years.
- (6) The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the AWA, the NIH *Guide*, and the Institution's OLAW Assurance. The IACUC may suspend an activity only after reviewing the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present.
- (7) If the IACUC suspends an activity involving animals, the Institutional Official (IO) in consultation with the IACUC shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation, as consistent with MWU procedures, to the appropriate agencies which may include OLAW; the Association for Assessment and Accreditation of Laboratory Animal Care, International; the United States Department of Agriculture (USDA); and other appropriate funding agencies.
- (8) Applications and proposals that have been approved by the IACUC may be subject to further appropriate review and approval by officials of the Institution. However, those officials may not approve of an activity involving the care and use of animals if it has not been approved by the IACUC.

APPENDIX I

Institutional Animal Care and Use Committee

This Committee is composed of at least five (5) members appointed (according to federal guidelines) by the President and Chief Executive Officer in consultation with the IO. One member is appointed as Chair by the President with the recommendation of the IO. The membership of the Committee includes at least one practicing scientist experienced in research with animals; at least one member not affiliated with the Institution; a veterinarian with training or experience in laboratory animal science and medicine, who has direct or delegated authority and responsibility for activities involving animals at the Institution; and one member who is a nonscientist. Members are selected for this Committee in accordance with the requirements set forth in the AWA (Public Law 89-544, 1966, as amended).

The charge to the IACUC is to:

1. review the Institution's program for humane care and use of animals, using the NIH *Guide* as a basis for evaluation, at least once every six months;
2. inspect the animal facility, at least once every six months using the NIH *Guide* and the *Ag Guide* as a basis for evaluation, at least once every six months;
3. prepare reports of the IACUC evaluations conducted as required by points 1 and 2 above and submit the reports to the IO. The reports shall be updated at least once every six months upon completion of the required semiannual evaluations and shall be maintained by the Office of Research and Sponsored Programs and made available to the NIH, OLAW, and other regulatory agencies upon request. The reports must contain a description of the nature and extent of the institution's adherence to the NIH *Guide*, the *PHS Policy*, the *Ag Guide*, and the AWA, and must identify specifically any departures from the provisions of the NIH *Guide* and the *PHS Policy* and must state the reasons for each departure. The reports must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, consistent with this policy, and, in the judgment of the IACUC and the IO, is or may be a threat to the health or safety of the animals. If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule for correcting each deficiency.
4. review concerns involving the care and use of animals at the Institution;
5. make recommendations to the IO regarding any aspect of the Institution's animal program, facilities, or personnel training;
6. review and approve, require modifications in (to secure approval) or withhold approval of those components of all activities related to the care and use of animals for testing, training, or research at MWU;

7. review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing testing, training, or research activities;
8. monitoring of animal care and use is required by the PHS *Policy* and the AWA. This is achieved by laboratory inspections (either semiannual regular facility inspections, or additional), veterinary or IACUC observation of selected procedures; observation of animals by animal care, veterinary, and IACUC members; and external regulatory inspections and assessments;
9. suspend an activity involving animals if it is determined that the activity is not being conducted in accordance with applicable provisions of the AWA, the NIH *Guide*, the PHS *Policy*, or an approved IACUC protocol.

MIDWESTERN UNIVERSITY

STANDARD POLICY

DIVISION: All University Colleges

CAMPUS: Downers Grove and Glendale

SUBJECT: Policy on Reporting Animal Welfare Concerns	POLICY NO.		
APPROVED BY: <i>Kathleen H. Goetting, PhD</i> President & CEO	ISSUE DATE 4/16/2024	SUPERSEDES 2/5/2015	PAGES 1 of 1

PURPOSE: To define the oversight by which the reporting of animal welfare concerns is accomplished at Midwestern University (MWU).

POLICY: The Institutional Animal Care and Use Committee (IACUC) for the respective MWU campus will define the procedures by which the reporting of animal welfare concerns is accomplished. These standard operating procedures will include reporting misuse, mistreatment or non-compliance of the care and use of animals in research at MWU.

MIDWESTERN UNIVERSITY

STANDARD POLICY

DIVISION: All University Colleges

CAMPUS: Downers Grove and Glendale

SUBJECT: Research Surveys of MWU Students	POLICY NO.		
APPROVED BY: <i>Kathleen A. Gospring, PhD</i>	ISSUE DATE 6/14/23	SUPERSEDES 6/25/2018 1/22/2018	PAGES 3

PURPOSE: To clarify the approval process prior to distribution of internal and external research surveys to Midwestern University (MWU) students.

DEFINITIONS: "Research" is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. (Title 45 CFR 46.102(d)).

"Dean" refers to a college dean or their designee (e.g., an Associate Dean).

"PI" refers to the faculty member serving as the principal investigator.

BACKGROUND: All research involving human subjects must be reviewed and approved by an Institutional Review Board (IRB) before it is initiated, which includes surveys. Researchers must keep in mind that the overall review and approval process often takes a minimum of one month and must plan accordingly. In general, the timeline for a successful survey is as follows: 1) the faculty PI and student(s), when applicable, prepare the survey and justification, 2) the PI seeks approval of the Dean(s) of the college(s) of the survey participants, 3) the Dean(s) provides written approval, 4) the PI submits a completed IRB application and the approval(s) of the Dean(s) to the IRB, 5) the IRB approves the survey, and 6) the PI distributes the survey.

POLICY: This policy applies to human subjects research-related surveys intended for students. This includes use of university emails, email distribution lists, Facebook, Twitter, and other social media methods that utilize MWU's name or resources. It does not apply to non-research institutional surveys or surveys distributed by the Office of Institutional Research and Educational Assessment (OIREA) to assess teaching or faculty performance.

Due to the number of requests for MWU students to participate in surveys, both from internal and external constituencies, MWU may limit the number of surveys sent to students, in order to prioritize federally mandated and other important institutional surveys. **Limiting the active solicitation to participate in surveys allows MWU to prioritize the importance of select surveys that are required or benefit the institution while decreasing survey fatigue among our student body.**

Surveys intended for distribution to MWU students, regardless of the method, will be brought to the attention of the appropriate Dean(s) for their approval.

Faculty Responsibilities: All surveys submitted to an IRB must have a faculty member serving as the PI. It is the responsibility of the PI to:

- Propose the timing for when the survey would ideally be distributed.
- Ensure that the survey has the support of each Dean over the college(s) in which they would like the survey distributed.
 - This requires that faculty send sufficient information to the appropriate Dean(s) such that an informed decision can be made.
 - If students are involved at this stage of the process, provide documentation of the PI's review and approval of the survey before the survey is presented to the Dean(s).
- Send the survey out to students once all necessary approvals have been obtained.
 - The PI should note that students do not have access to MWU e-mail distribution lists.

Dean(s) Responsibilities: The Dean must review and approve surveys when intended for distribution to students in their college. If a Dean elects to appoint a designee to review and approve surveys, the ORSP Research Administrator must be notified of the name of the designee. The approval of the Dean signifies their support of the:

- Research project topic and the questions asked.
- Timing of the survey (i.e., that survey fatigue has been considered and that the survey appears a reasonable use of the student's time).

The Dean is **not** expected to evaluate research methodology or data analysis, but rather should focus on the appropriateness of the survey's focus/questions as it relates to the students in their college and the proposed timing of the questionnaire distribution.

If supportive of the survey, the Dean will provide an email noting their approval to the PI. If not supportive, the Dean may make suggestions to the PI providing a path to move the survey forward, or they may not approve the survey (e.g., if they believe the timing would cause survey fatigue or if they're not supportive of the topic).

If a Dean is also serving as the faculty PI of the research survey, then the CAO of the college should assume the responsibilities of the Dean if there is a request to administer the research survey to students in the PI's college.

Office of Research and Sponsored Programs (ORSP): Once a survey is approved for distribution to the desired college classes by the Dean(s) and the PI wishes to move forward with the approval process, they may submit a completed IRB application along with the approval of Dean(s) to the IRB through the ORSP.

Surveys Denied for Active Distribution

When internal or external survey requests are denied for mass distribution to MWU students, the Dean of Students may approve a link to the survey to be posted through MWU's OIREA. All MWU students will be reminded twice per year by the OIREA of the availability to participate in additional surveys found on their website, but students will not be contacted through specific solicitations and/or additional reminders in any other manner, aside from those sent out by the OIREA.

MIDWESTERN UNIVERSITY

STANDARD POLICY

DIVISION: All University Colleges

AREA: Administrative

SUBJECT: Human Subjects Research	POLICY NO. 0007		
APPROVED BY:  Kathleen H. Goeppinger, Ph.D. President and CEO	ISSUE DATE	SUPERSEDES	PAGES
	4-2-25	12/96	5

PURPOSE: To establish the means by which institutional measures are designed to ensure the safety and welfare of human research subjects.

POLICY: It is the policy of Midwestern University that no research involving human subjects shall be conducted as an activity or in association with any educational program, health care, or other activities under the auspices of MWU until approved by the Institutional Review Board. Approved research projects shall be suspended or terminated by the responsible investigator or upon direction of the chairperson of the Institutional Review Board when a bona fide question is raised concerning unknown or unsuspected risks to human subjects or when departure from research procedures prescribed to protect human subjects occurs until review and action by the committee has been completed.

Research involving human subjects, conducted at Midwestern University and its affiliates, must be reviewed and/or approved by the MWU Institutional Review Board (IRB). This review is required of all such research without qualification as to source of funds. Review by the MWU IRB may also be required of research carried out under the sponsorship of an institution other than MWU but which is performed on the MWU premises, even if the research activities have been approved by the IRB at that institution or elsewhere.

Any individual intending to conduct research involving human subjects, whether or not supported by a grant, contract or fellowship from any public or private agency, must submit a formal application to the IRB. If a grant or contract is involved, this submission should occur sufficiently in advance of the due date of the application in order to allow time for the review process, should it be deemed necessary.

Activities within the scope of the IRB's responsibilities include *research*, development and related activities which would normally be construed as biological, behavioral or psychological investigations involving *human subjects*.

Human subject means a living individual about whom an investigator (whether professional or student) conducting research:

- (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

- (1) Risks to subjects are minimized:
 - (i) By using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and
 - (ii) Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- (2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (*e.g.*, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
- (3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.
- (4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative.
- (5) Informed consent will be appropriately documented or appropriately waived.
- (6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- (7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- (8) For purposes of conducting the limited IRB review, the IRB need not make the determinations at paragraphs (1) through (7) of this section, and shall make the determination that if there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

In all activities involving human subjects research, regardless of the type of review or qualification for an exemption, informed consent must be obtained from each participant prior to engaging in the research activity, unless waived by the IRB. In cases where the participant cannot provide consent (children, incapacitated, mentally incompetent, etc.), consent must be obtained from the individual's parent, guardian, or legally authorized representative and assent must be obtained from the participant unless the participant is incapacitated or otherwise unable to provide assent. For research projects approved through expedited or full board review pathways, investigators must use the MWU-approved informed consent/assent document(s) unless a waiver of documentation of informed consent or a waiver of certain elements of informed consent is granted by the IRB. For exempt research, investigators are required to follow the MWU guidance on study information sheets to convey required information to prospective research participants. According to federal regulations, "informed consent" refers to the knowledgeable agreement of an individual or a legally qualified representative whereby he or she exercises free choice to participate in a study without any undue inducement or any element of force, fraud, deceit, duress, or other kinds of constraint or coercion. An informed consent document must be written in clear, non-technical language and must include appropriate elements as defined in 45 CFR 46.

APPENDIX I

Institutional Review Board

Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.

Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

The charge to the Institutional Review Board (IRB) is to:

- (1) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy, including exempt research activities for which limited IRB review is a condition of exemption.
- (2) An IRB shall require that information given to subjects (or legally authorized representatives, when appropriate) as part of informed consent is in accordance with § 46.116. The IRB may require that information, in addition to that specifically mentioned

in § 46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

- (3) An IRB shall require documentation of informed consent or may waive documentation.
- (4) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.
- (5) An IRB shall conduct continuing review of research requiring review by the convened IRB at intervals appropriate to the degree of risk, not less than once per year, except as described in (5) a.
 - a. Unless an IRB determines otherwise, continuing review of research is not required in the following circumstances:
 - i. Research eligible for expedited review;
 - ii. Research reviewed by the IRB in accordance with the limited IRB review;
 - iii. Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:
 1. Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
 2. Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.
- (6) An IRB shall have authority to observe or have a third party observe the consent process and the research.

MIDWESTERN UNIVERSITY

STANDARD POLICY

DIVISION: All University Colleges

AREA: Administrative

SUBJECT: Clinical Trials	POLICY NO. 0009		
APPROVED BY: Administrative Team	ISSUE DATE 7/97	SUPERSEDES	PAGES 1 of 7

PURPOSE: To establish the means by which Clinical Trials are conducted at Midwestern University

POLICY: Effective July 1, 1997, all clinical trials must be reviewed and approved by appropriate administrative officers and institutional committees at Midwestern University prior to initiation of a study. The budget to be negotiated for the conduct of the clinical trial must provide for reimbursement of Midwestern University for the time and effort of Midwestern University employees involved in completion of the project. Additional approvals or clearances may also be required by administrative staff at clinical sites where the study is conducted.

PROCEDURE:

A. Clinical Trial Agreement, Contract or Subcontract

As soon as it is apparent that initial discussions with representatives from an external sponsor may lead to the conduct of a clinical trial, contact the Office of Research and Sponsored Programs in Downers Grove to establish an approximate time table for completing all institutional clearances. Support staff in the Office of Research and Sponsored Programs will provide a Proposal Approval Form (PAF), sample informed consents, Clinical Trial Budget Summary form, and a Clinical Trial Agreement (CTA) or contract to formalize the agreement between the sponsor and Midwestern University.

B Proposal Approval Form (PAF)

1. Complete a Midwestern University Proposal Approval Form (PAF) which is available from the Office of Research and Sponsored Programs. Clearly indicate any required commitment of additional institutional resources that are not included in the budget provided by the sponsor. If necessary contact the Office of Research and Sponsored Programs for clarification regarding this issue.

MIDWESTERN UNIVERSITY

STANDARD POLICY

DIVISION: All University Colleges

AREA: Administrative

SUBJECT: Clinical Trials	POLICY NO. 0009		
APPROVED BY: Administrative Team	ISSUE DATE 7/97	SUPERSEDES	PAGES 2 of 7

2. Sign and date the PAF in the space indicated for the Principal Investigator and obtain signatures of Section Director, Department Chairman or Program Director, and the COO or designee of the participating medical center or facility where the study will be conducted. In order to expedite review and approval by the MWU Institutional Review Board and administration, forward a copy of the PAF, research protocol and informed consent to the Office of Research and Sponsored Programs. The original PAF must be forwarded to the Office of Research and Sponsored Programs after it has been signed by the COO or designee at the participating medical center or facility.

C. Clinical Trial Agreement (CTA)

1. Normally, preliminary discussions are undertaken by the principal investigator and sponsor prior to formalization of the study through a CTA or Contract. If the Sponsor has provided a contract, please forward a copy of the unsigned contract to the Office of Research and Sponsored Programs, along with the Budget Summary and PAF. If the Sponsor does not have a standard contract or clinical trial agreement, it will be necessary to complete a Midwestern University Clinical Trial Agreement (CTA) before the study can be initiated. A sample CTA, with instructions for completion, is available from the Office of Research and Sponsored Programs. Principal investigators are not authorized to sign a contract or a CTA in the name of the University
2. The Midwestern University CTA includes clauses that provide for indemnification of MWU, its officers, administrators and the principal investigator in the event of research injury to participating human subjects that is the result of the drug or device being studied. If the sponsor's contract is to be submitted to the Office of Research and Sponsored Programs for review, it must contain an indemnification clause identical to the clause in the Midwestern University CTA. As a separate issue, MWU requires that sponsors of these studies describe the extent of care and

MIDWESTERN UNIVERSITY

STANDARD POLICY

DIVISION: All University Colleges

AREA: Administrative

SUBJECT: Clinical Trials	POLICY NO. 0009		
APPROVED BY: Administrative Team	ISSUE DATE 7/97	SUPERSEDES	PAGES 3 of 7

possible compensation for research injury that the sponsor provides to participants in the event of research injury. The sponsor's "Statement on Compensation for Research Injury" must be included in the informed consent document.

3. Prepare a complete budget using a Clinical Trial Budget Summary form which describes the payments from the sponsor for physician or staff services, hospital based laboratory work (radiology, pathology lab tests, cardiology procedures), etc. as outlined in the research protocol submitted for IRB review. The total budget must include the Midwestern University Indirect Cost Rate of 15 % of the direct costs requested from the sponsor for the clinical trial.

Contract Administration

A. Procedures for Account Establishment

1. Upon receipt of a completed Clinical Trial Budget Summary form and CTA or contract signed by the sponsor and the Director, Office of Research and Sponsored Programs, the Controller will establish a restricted account for the funds provided by the sponsor. All account attributes, including source and purpose of revenues, beginning and ending dates, names and signatures of account administrators, and the Office of Research and Sponsored Programs file number will be noted on the **Request for Establishment of a Restricted Account (RERA)** form provided by the Business Office. The Business Office will assign an account number which will be noted on the RERA form returned to the investigator.
2. The budget amount will be entered in the financial system and be reflected on the general ledger as funds are received by the University. Note that expenditures are allowed prior to the receipt of funds, with the prior approval of the Business Office. However, the funds cannot be reflected as earned (budgeted) until the principal investigator has provided deliverables

MIDWESTERN UNIVERSITY

STANDARD POLICY

DIVISION: All University Colleges

AREA: Administrative

SUBJECT: Clinical Trials	POLICY NO. 0009		
APPROVED BY: Administrative Team	ISSUE DATE 7/97	SUPERSEDES	PAGES 4 of 7

(normally patient data) acceptable to the sponsor and payment has been received by the University.

B. Contract Amendments and Extensions

1. If the principal investigator or sponsor want to amend or extend a CTA or Contract, the Office of Research and Sponsored Programs must be contacted. Amendments and extensions to contracts will be processed in accordance with the terms and conditions of the original contract. Principal investigators are not authorized to sign an amendment to a contract or CTA in the name of the University.

C. Billing and Recognition of Revenue

1. Accounts Receivable
Accounts receivable are defined as the amounts due the University from sponsors for clinical trials approved by the University. Clinical investigators will be responsible for submitting reports or cost claims to sponsors, along with the University EIN number and a request to forward checks to the Controller's office in Downers Grove.
2. Advances
Advance payments are generally recognized as funds received prior to the contractually agreed upon start date of the clinical study or payments received at an interim period agreed upon and incorporated in the executed contract.
 - a. Payment Received at Interim Period
Advance payments received based upon contract terms will be credited to the restricted account as a cash advance. A budget equal to the amount of the advance will be posted to the restricted account for use by the investigator.

MIDWESTERN UNIVERSITY

STANDARD POLICY

DIVISION: All University Colleges

AREA: Administrative

SUBJECT: Clinical Trials	POLICY NO. 0009		
APPROVED BY: Administrative Team	ISSUE DATE 7/97	SUPERSEDES	PAGES 5 of 7

b. Cash Reimbursements or Advances

All checks shall be made payable to Midwestern University. The federal EIN number assigned to the University is # 36-3377698. Payments should be mailed to the address below :

C/O Grant Accountant
Business Affairs Office
Midwestern University
555 31st Street
Downers Grove, IL 60515

D. Charges to accounts

Costs to clinical research projects are comprised of allowable direct and indirect costs. For costs to be allowable they must be reasonable, allocable to the project, and appropriate to the circumstances. Charges should be made within a reasonable time frame, normally during the period of time that the trial is conducted and reporting requirements are fulfilled.

1. Direct costs are those costs which can be directly identified with a particular project. This would include such items as:
 - a. Salaries and wages or fees for MWU employees working on the project
 - b. Physicians fees for services
 - c. Fringe benefits
 - d. Equipment
 - e. Travel
 - f. Supplies
 - g. Services (may include services provided by hospital and clinics)
 - h. Patient care (may include services provided by hospital and clinics)
 - i. Consultants and subcontractors
 - j. Other direct costs

MIDWESTERN UNIVERSITY

STANDARD POLICY

DIVISION: All University Colleges

AREA: Administrative

SUBJECT: Clinical Trials	POLICY NO. 0009		
APPROVED BY: Administrative Team	ISSUE DATE 7/97	SUPERSEDES	PAGES 6 of 7

2. Indirect Costs

Indirect costs are those University costs which cannot be directly identified with a particular project. These costs are recovered through the assessment of an indirect cost rate of 15% of direct costs (i.e., Total Cost= Direct Cost plus Indirect Cost of 15 % of Direct Cost).

3. Hospital and Clinic Charges

The Columbia Olympia Fields Osteopathic Hospital and Medical Center supports biomedical research conducted by Midwestern University faculty and has provided reduced rates for hospital services such as x-ray, EKG, EEG, etc that are charged to grants. Effective July 1, 1996, all hospital services are charged at 35 % of the standard rate, and all laboratory services are charged at the ELS or "reference" laboratory rate. These discounted rates are subject to change and should be discussed with appropriate administrators at the OFOHMC.

Predetermined discounted rates for clinical services have not been negotiated at other medical centers. If an investigator uses services at another medical center, it is the investigator's responsibility to discuss the rate structure for clinical services that may be charged to a clinical trial budget.

E. Reports to the Sponsor

The Principal Investigator is responsible for the timely preparation and submission to the sponsor of all technical reports required as a condition of the contract. Financial reports to the sponsor, if required, will be prepared by the Business Office.

MIDWESTERN UNIVERSITY

STANDARD POLICY

DIVISION: All University Colleges

AREA: Administrative

SUBJECT: Clinical Trials	POLICY NO. 0009		
APPROVED BY: Administrative Team	ISSUE DATE 7/97	SUPERSEDES	PAGES 7 of 7

F. Account Closing Procedures: Termination and Disposition of Balances

1. At the completion of the clinical trial, the principal investigator must request the termination of a clinical trial account. The Business Affairs Office will request that the principal investigator certify that all funds due the University have been received. This will be done in the form of a certification that will accompany the account closeout documents. Departments will be informed as a part of normal internal audit procedures, that the University will, on a random basis, confirm with sponsors that all funds due were paid to the University.
2. Any balance left at the end of the clinical trial after all budget expenses have been accounted for shall be transferred to a restricted account to support educational, research, or service programs that are consistent with the mission of Midwestern University. The funds may be used for instructional or other academic activities subject to the approval of the appropriate College Dean. The use of these funds for research activities is subject to the approval of the Director, Office of Research and Sponsored Programs. If these funds are to be used to support clinical faculty services, they must also be approved by the CFO. The CFO must be informed of the projected use of funds in these restricted accounts on an annual basis by the fund administrator to minimize any cash/flow impact on the University.

MIDWESTERN UNIVERSITY
STANDARD POLICY

Subject: Remuneration for Research Participants		Policy No: 405
Issue Date: 11/24/2019	Supercedes: 11-14-17	Pages: 4
Division: All University		
Campus: All University		
Approved By: Kathleen H. Goeppinger, Ph.D. President and CEO		

PURPOSE

To provide guidance relating to processes to be followed when Midwestern University (the University) compensates human research subjects for their participation in a research study.

DEFINITION

Human Subject – a living individual about whom an investigator (whether professional or student) conducting research obtains:

- a. Data through intervention or interaction with the individual, or
- b. identifiable private information.

This person may or may not have an affiliation with the University.

Institutional Review Board (IRB) – The IRB is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated. The IRB has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction as specified by both the federal regulations and local institutional policy. Research that has been reviewed and approved by the IRB is subject to review and disapproval by officials of the Institution. However, those officials may not approve research if it has been disapproved by the IRB.

Research – a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalized knowledge.

Subject Payments – cash and non-cash payments to individuals (subjects) for their participation and time commitment in a clinical trial, social science survey, or other research.

POLICY

This policy and procedure establishes the payment process that the University faculty and staff must

use to ensure compliance with subject privacy and IRS regulations when making payments related to human subjects who take part in University research studies. The Internal Revenue Service (IRS) requires human subject payments aggregating \$600.00 (subject to change in IRS rules) or more paid to an individual during a calendar year be reported on Form 1099-MISC, Miscellaneous Income.

Research relating to individuals and groups may involve the collection and storage of information that, if disclosed to third parties, could cause harm or distress to the subject. Investigators must take reasonable steps when possible to protect the confidentiality of such information, e.g., by omitting information that might lead to the identification of the individual subjects, limiting access to the information, anonymizing data, or other means. During the process of obtaining informed consent, the investigator will tell the prospective subjects about the precautions that the investigator will take to protect confidentiality. Oversight of these areas is the responsibility of the Institutional Review Board (IRB).

An investigator must inform prospective subjects of the limits to the ability of the investigator to ensure strict confidentiality and of the foreseeable adverse social consequences of breaches of confidentiality, in a manner that is balanced with the potential risk to the research subject. For example, some jurisdictions require the reporting to appropriate agencies of certain communicable diseases or evidence of child abuse or neglect. Food and Drug Administration authorities and other federal agencies have the right to inspect clinical-trial records of drug or device studies. A sponsor's clinical-compliance audit staff may require and obtain access to confidential data. MWU's Information Technologies Services (ITS) and/or Business Services personnel may see payment records as a part of the University's oversight of research conducted by University faculty. These and similar limits to the ability to maintain confidentiality must be anticipated and disclosed to prospective subjects.

The principal investigator will inform prospective human subject participants that the University's ITS and financial personnel could see payment records. Business Services and ITS recognize that confidentiality and regulations apply to human subjects research, and they will use reasonable practices to ensure the confidentiality of information, while meeting IRS reporting requirements and conforming to the University's standard accounting and payment practices. When human subjects' payments are requested, the University IRB will approve the language that must be included in the informed consent document.

If subjects get paid for participation in a project, faculty providing compensation also need to be sensitive to concerns that the form of payment may contain information that would indicate to a third party a subject's participation in a research project. For example, there may be information on a request for payment that could constitute a confidentiality breach, because it could be apparent to the person processing the payment that the recipient of a check is a research subject. While the possibility is remote, if the research is of a sensitive nature, this could lead to personal embarrassment, loss of employment and/or insurability.

The value of the compensation paid to the human subjects should not exceed the value of the time and effort provided by the human subjects in order to avoid the appearance of undue influence on the human subjects.

POLICY

Individuals who take part in University research studies may receive payment for their participating as human subjects. The University and the investigator will take steps to maintain the confidentiality of human subjects when making payments to third parties that provide research-related services and/or products. To the extent possible under the law, and while meeting IRS reporting requirements and conforming to the University's standard accounting and payment practices, effort will be made to ensure research subject confidentiality is reasonably maintained in the University payment process.

Even though the investigator may adhere to confidentiality safeguards in the conduct of a study, a risk of breach of confidentiality may still exist when payments to subjects are involved. Therefore, the IRB requires that for payment purposes:

- a. Only the minimum necessary information is included on the payment request (i.e. when payment is in the form of a check). Where possible, provide the necessary information in a generic manner. For example, a check may say "Research participation" followed by the date of participation;
- b. Other than researchers (including students who are researchers) on the IRB-approved study protocol, only designated staff within the department sponsoring the study will have access to identifying information;
- c. payments made to human subjects who are also employees or students of the University will be treated the same as non-affiliated subjects.

PROCEDURE FOR POLICY

Prior to payment. Confirm the individual receiving payment meets the definition of a human subject at the time of the research participation and that IRB approval was current at the time of subject contact.

Determine form of compensation and the correct form to use. The form(s) needed to process the payment depends on what type of compensation is being issued or needed. Use the list below as a general guide. When making payments directly to human subjects chose one of the available options:

- a. **Paying the subject with a gift card**
 - i. Gift cards are to be from a single source such that Target, Starbucks and Amazon are the three approved gift cards allowed (American Express/Visa multi-vendor gifts cards are not allowed).
 - ii. The value of the compensation paid to the human subjects will be approved by the IRB and should not exceed the value of the time and effort provided by the human subjects in order to avoid the appearance of undue influence on the human subjects. A credit for unused gift cards will be issued when the gift cards are returned to Business Services.

- b. **Paying the subject by check** Complete a check request and submit to Business Services. If a subject payment is to be for \$50.00 or more, it will be processed via check request rather than a gift card, unless an exception is made by the IRB.

Other Procedures

- a. Gift cards must be purchased via the University purchasing department.
- b. Gift cards can be kept in Business Services or kept with the principal investigator and will be charged to the appropriate general ledger code when disbursed to the requesting principal investigator.
- c. The maximum value of gift cards to be distributed to the requesting principal investigator at one time is \$250.00. Exceptions to this rule require approval from the Director of Research and Sponsored Programs.
- d. As checks and gift cards are disbursed to human subjects, the principal investigator is responsible for adding the following information to a secure site on the University universal drive: name, date, type of payment (check or gift card) and amount of payment. Home address will be needed for mailing when the payment is by check. This information will be kept in an ITS folder as described below (f).
- e. If there is a possibility that a research participant will receive more than \$600.00 in compensation, the subject must provide Midwestern University with a form W-9 for tax reporting. The form W-9 is the Request of Taxpayer Identification Number and Certification.
- f. It is required that the confidentiality of the study and the human subject(s) be maintained. The only explanation that is required on the payment document should match the ITS folder label with the dollar amount. The ITS folder will be labeled by the PI's last name, followed by "approved study", followed by the date of approval (i.e. for PI Jane Doe it would say "Doe approved study 5-12-19) rather than "Doe's Merck Autism Study." When paying the subject directly with a University check, the payee's home address will need to be provided, in addition to all the other elements of a check request.

MIDWESTERN UNIVERSITY

STANDARD POLICY

DIVISION: All University Colleges

AREA: Administrative

SUBJECT: Human Subjects Research – IRB Review	POLICY NO. 0008		
APPROVED BY: Joshua Baker, O.D., M.S., President & CEO 	ISSUE 9/15/25	SUPERSEDES 12/98	PAGE 5

PURPOSE: To establish the means by which review is conducted by the Institutional Review Board for all human subjects' research.

POLICY:

Submission of Proposals or Protocols

Investigators proposing to conduct research studies involving human subjects must submit a completed Form A along with appropriate institutional forms via InfoEd to the Office of Research and Sponsored Programs.

Form A (available within InfoEd) must be submitted for review by the Office of Research and Sponsored Programs and the Institutional Review Board (IRB) within InfoEd. The information collected in Form A allows for a determination of the level of review for research involving human subjects of research. As noted below, the IRB has adopted three levels of review that are consistent with federal guidelines: Exempt, Expedited, and Full Review. Additional forms may also be required by potential extramural sponsors of these studies. Proposals must be submitted well in advance of any deadlines (program requirements, external sponsors, etc.) to allow time for the IRB to review the proposals.

Review of Research Proposals

The IRB shall review and have the authority to approve, require modification in, or disapprove all research involving human research subjects. In order to initially approve or provide continuous approval of non-exempt research, the IRB shall review all study-related documents to determine that the following criteria are satisfied:

1. Risks to participants are minimized.
2. Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the expected results.
3. Selection of participants is equitable.
4. Informed consent will be sought from each prospective participant or the participant's legally authorized representative, in accordance with, and to the extent required by, 45 CFR 46.116.
5. Informed consent will be appropriately documented or appropriately waived in accordance with 45 CFR 46.117.

6. When appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of participants.
7. When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.

Since MWU does not currently consider the broad consent process, the elements of approval related to broad consent listed in 45 CFR 46.111(a)(8) are omitted here.

For Exempt research, the same criteria will be used with the exception of Criterion 5. Research that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, MWU officials may not approve human subjects research if it has not been approved by the IRB.

Types of Review

Research studies reviewed by the IRB shall be categorized based upon DHHS regulations 45 CFR 46.101 (revised as of 18 June 1991) and reviewed as follows:

Exempt Review

Research activities in which the only involvement of human subjects will be in one or more of the exempt categories may be reviewed and approved by the IRB Chair or a designated member reviewer, provided that such approval is reported to the IRB at the next convened meeting. Exempt categories are defined within 45 CFR 46.104.

Expedited Review

Research activities involving no more than minimal risk to human subjects in which the only involvement of human subjects will be in one or more of the expedited categories may be reviewed and approved by the IRB Chair or, by one or more experienced members of the IRB designated by the Chair. All human subjects studies reviewed by the expedited review mechanism must be reported to the IRB at the next convened meeting. Expedited categories are defined within 45 CFR 46.110.

Full Board Review

All other research involving more than minimal risk to human subjects shall be reviewed by the IRB at regular convened meetings at which a majority of the members are present, including at least one member whose primary concerns are in non-scientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

Emergency Exemption from Prospective IRB Approval

Emergency use is defined as the use of an investigational drug or biologic product (not device) with a human subject in a life-threatening situation in which no standard acceptable treatment is available and there is not sufficient time to obtain IRB approval. The emergency use provision in

the FDA regulations [(21 CFR 56.104(c))] is an exemption from prior review and approval by the IRB.

"Emergency use" means the use of a test article on a human subject in a life-threatening situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain IRB approval. FDA regulations require that any subsequent use of the investigational product at the institution have prospective IRB review and approval. (FDA acknowledges, however, that it would be inappropriate to deny emergency treatment to a second individual if the only obstacle is that the IRB has not had sufficient time to convene a meeting to review the issue).

Notification is required to allow IRB tracking to ensure that the investigator files a report describing such use within the five-day timeframe required by 21 CFR 56.104(c). The IRB must either convene and give "full board" approval prior to use of the drug, or if the conditions described above are met and it is not possible to convene a quorum with the time frame available, the use may proceed without any IRB approval.

Even for emergency use, the investigator is required to obtain informed consent of the subject or the subject's legally authorized representative unless both the investigator and a physician who is not otherwise participating in the clinical investigation certify in writing all of the following:

1. The subject is confronted by a life-threatening situation necessitating the use of the test article.
2. Informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from, the subject.
3. Time is not sufficient to obtain consent from the subject's legal representative.
4. No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the subject's life.

If in the investigator's opinion, immediate use of the test article is required to preserve the subject's life, and if time is not sufficient to obtain an independent physician's determination that the four conditions above apply, the clinical investigator should make the determination and, within 5 working days after the use of the test article, have the determination reviewed and evaluated in writing by a physician who is not participating in the clinical investigation. The investigator must notify the IRB within 5 working days after the use of the test article.

Post Approval Submissions and Reports

Continuing Review

The IRB shall conduct continuing review of research requiring review by the convened IRB at intervals appropriate to the degree of risk, not less than once per year, except as described below.

1. Unless an IRB determines otherwise, continuing review of research is not required in the following circumstances:
 - a. Research eligible for expedited review.
 - b. Research reviewed by the IRB in accordance with the limited IRB review.
 - c. Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:
 - i. Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
 - ii. Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

The principal investigator shall submit, via InfoEd, a completed Continuing Review (if required by the IRB) prior to the current expiration date of the project. A copy of the consent form in use must also be reviewed. Continuing Reviews are reviewed differently depending on the review level of the initial study (Expedited and Full Board).

Protocol Deviation / Adverse Event Report

In IRB-approved research, a protocol deviation refers to any departure from the procedures or plans outlined and approved by the IRB. This deviation can be intentional or unintentional, but in either case, it represents a non-adherence to the IRB-approved protocol.

An adverse event refers to any incident, experience, or outcome that meets all three of the following criteria listed below. **Only the IRB can categorize an event as an adverse event.** It is the research PI's responsibility to submit reportable events for IRB assessment.

- Is unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
- Is related or possibly related to an individual's participation in the research; AND
- Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, social, economic, legal, or informational harm) than was previously known.

The PI must report the protocol deviation or adverse event to the IRB utilizing the Protocol Deviation / Adverse Event Report form via InfoEd as soon as it is recognized.

Protocol Deviation / Adverse Event Report forms are reviewed differently depending on the review level of the initial study (Exempt, Expedited, and Full Board) and the content of the Protocol Deviation / Adverse Event Report.

Amendment

The IRB requires that all changes to an approved study be documented through an Amendment Form. PIs are required to submit the Amendment Form through InfoEd and also incorporate the changes being made to the study into the main body of Form A. Amendments are reviewed

differently depending on the review level of the initial study (Exempt, Expedited, and Full Board) and the content of the Amendment.

Closure

The IRB requires submission of a Closure form through InfoEd upon completion of a study. Closures are reviewed differently depending on the review level of the initial study (Exempt, Expedited, and Full Board).

Suspension of Research

The IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head.

Research activities may be suspended by the IRB if a Continuing Review is more than thirty (30) days overdue.

The principal investigator may request a hearing with the IRB for justification of the suspension.

Resumption of a project may be allowed if:

1. The original research proposal is still applicable and the reason for the suspension no longer exists.
2. A revised research proposal (Amendment) is submitted to and approved by the IRB.