



Study Research Misconduct - SYSTEM

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Approvals

- Signature: Jorge Hernandez, Vice President, Administrative Services and CCO signed on 3/28/2025, 6:17:16 AM
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Purpose

The purpose of this Policy is to describe the responsibilities of Northside Hospital, Inc. and its affiliates (collectively, “Northside”) personnel in reporting, investigating and resolving any alleged instances of Research Misconduct to promote and maintain high ethical standards in the conduct of Research at Northside and the integrity of the scientific enterprise at large.

Policy

It is the policy of Northside to foster a research environment that promotes responsible conduct of Research, discourages Research Misconduct and deals promptly with allegations or Evidence of possible Research Misconduct. It is the policy of Northside to inquire into and, if necessary, to investigate and resolve promptly and fairly all instances of alleged misconduct. Additionally, it is the policy of Northside to comply in a timely manner with applicable Federal requirements for reporting on cases of possible misconduct when sponsored project funds are involved, and to provide full and continuing cooperation with granting agencies under this Policy and applicable Federal regulations. This Policy applies to all individuals employed by or contracted with Northside and who are engaged in Research. This Policy sets forth procedures to address allegations of Research Misconduct properly and to promote ethical standards in the conduct of Research and the investigation of alleged misconduct. This Policy applies to all Research conducted at Northside, regardless of the sponsor or otherwise. Reporting requirements to the Office of Research Integrity apply only to Research funding obtained or applied for under the United States Public Health Service Act; however, other reporting requirements may apply when Research is funded by other agencies or sponsors.

Definitions

For purpose of this Policy, the following definitions shall apply:

- (A) “Accepted Practices of the Relevant Research Community” means those practices established by 42 CFR part 93 and by PHS funding components, as well as commonly accepted professional codes or norms within the overarching community of researchers and institutions that apply for and receive PHS awards.
- (B) “Allegation” means a disclosure of possible Research Misconduct through any means of communication and brought directly to the attention of Northside or an HHS official. The disclosure may be by written or oral statement or other communication to a Northside official.
- (C) “Assessment” means a consideration of whether an Allegation of Research Misconduct appears to fall within the definition of Research Misconduct; appears to involve PHS-supported biomedical or behavioral

research, biomedical or behavioral research training, or activities related to that research or research training; and is sufficiently credible and specific so that potential Evidence of Research Misconduct may be identified. The Assessment only involves the review of readily accessible information relevant to the Allegation.

(D) “Complainant” means the person who in Good Faith makes an Allegation of Research Misconduct.

(E) “Evidence” means anything offered or obtained during a Research Misconduct Proceeding that tends to prove or disprove the existence of an alleged fact. Evidence includes documents, whether in hard copy or electronic form, information, tangible items, and testimony.

(F) “Fabrication” means making up data or results and recording or reporting them. It may also include misrepresentation of a researcher’s qualifications or ability to perform the Research.

(G) “Falsification” means manipulating Research materials, equipment, or processes, or changing or omitting data or results such that the Research is not accurately represented in the Research Record.

(H) “Good Faith” as applied to a Complainant or witness means having an honest belief in the truth of one’s Allegation or testimony, based on the information known to the Complainant or witness at the time. An Allegation or cooperation with a Research Misconduct Proceeding is not in Good Faith if made with knowledge or reckless disregard for the information that would negate the Allegation or testimony. “Good Faith” as applied to an institutional or committee member means cooperating with the Research Misconduct Proceeding by impartially carrying out the duties assigned for the purpose of helping an institution meet its responsibilities under applicable regulations. An institutional or committee member does not act in good faith if their acts or omissions during the Research Misconduct Proceedings are dishonest or influenced by personal, professional, or financial conflicts of interest with those involved in the Research Misconduct Proceeding.

(I) “HHS” or “Health and Human Services” means the United States Department of Health and Human Services.

(J) “Inquiry” means preliminary information gathering and preliminary fact-finding to determine whether an Allegation or apparent instance of Research Misconduct has substance and if an Investigation is warranted.

(K) “Intentionally” means to act with the aim of carrying out the act.

(L) “Institutional Certifying Official” means the official responsible for assuring on behalf of Northside that Northside has written policies and procedures for addressing allegations of Research Misconduct, in compliance with applicable regulations and complies with Northside’s policies and procedures and regulatory requirements. The Institutional Certifying Official is responsible for certifying the content of Northside’s annual report and ensuring the report is submitted to the Office of Research Integrity (ORI), as required. The Chief Compliance Officer is the Institutional Certifying Official.

(M) “Institutional Deciding Official” means the institutional official who makes final determinations on Allegations of Research Misconduct and any institutional actions. The same individual cannot serve as the Institutional Deciding Official and the Research Integrity Officer. The Institutional Deciding Official’s final determination of Research Misconduct findings must be in a written decision that includes whether Northside found Research Misconduct and if so, who committed the misconduct, and a description of relevant actions taken, or to be taken by Northside. The Chief Compliance Officer is the Institutional Deciding Official.

(N) “Institutional Record” means:

1. records Northside compiled or generated during the Research Misconduct Proceeding, except those Northside did not rely upon, including but not limited to: (i) documentation of an Assessment; (ii) the inquiry report and any supporting records (including but not limited to, Research Records and transcripts of transcribed interviews conducted during the inquiry, information the Respondent provided to Northside, and documentation of any decision not to investigate; (iii) the Investigation report and supporting records (other than drafts of the report) considered or relied upon during the

Investigation (included but not limited to, Research Records, transcripts of interviews conducted, and information the Respondent provided to Northside); (iv) decisions by the Institutional Deciding Official; and (v) the complete record of any institutional appeal.

2. a single index listing all Research Records and Evidence Northside compiled during the Research Misconduct Proceeding except those not considered or relied on.
3. a general description of the records that were sequestered but not considered or relied on.

(O) “Investigation” means the formal development of a factual record and the examination of that record that meets the criteria and follows the procedures of §§ 93.310 through 93.317, *The Institutional Investigation*.

(P) “Knowingly” means to act with awareness of the act.

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

(R) “Preponderance of the Evidence” means proof by Evidence that, compared with Evidence opposing it, leads to the conclusion that the fact at issue is more likely true than not.

(S) “PHS” or “Public Health Service” means the United States Public Health Service, an operating component of HHS.

(T) “Recklessly” means to propose, perform, or review Research, or report Research results, with indifference to a known risk of fabrication, falsification, or plagiarism.

(U) “Research” means a systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) relating broadly to public health by establishing, discovering, developing, elucidating or confirming information about, or the underlying mechanism relating to, biological causes, function or effects, diseases, treatments or related matters to be studied.

(V) “Research Integrity Officer” or “RIO” means the institutional official responsible for administering the institution’s written policies and procedures for addressing Allegations of Research Misconduct. The Research Program Director is the RIO.

(W) “Research Misconduct” means Fabrication, Falsification or Plagiarism in proposing, performing or reviewing Research, or in reporting Research results. Research Misconduct does not include honest error or honest differences of opinion.

(X) “Research Misconduct Proceeding” means any actions related to alleged Research Misconduct, including but not limited to Allegation assessments, Inquiries, Investigations, Office of Research Integrity oversight reviews, and appeals.

(Y) “Research Record” means the record of data or results that embody the facts resulting from scientific inquiry, both physical and electronic, including but not limited to, Research proposals, raw data, processed data, clinical research records, laboratory records, study records, laboratory notebooks, progress reports, manuscripts, abstracts, theses, records of oral presentations, online content, lab meeting reports, and journal articles.

(Z) “Respondent” means the person against whom an Allegation of Research Misconduct is directed or who is the subject of a Research Misconduct proceeding.

(AA) “Retaliation” means an adverse action taken against a Complainant, witness or committee member by Northside or one of its employees or agents in response to (a) a Good Faith Allegation of Research Misconduct;

or (b) Good Faith cooperation with a Research Misconduct Proceeding.

Procedure

1.0 Reporting Allegations

1.1 Northside employees and contractors shall report observed, suspected or apparent allegations of Research Misconduct to the Central Research Department, the Research Program Director, the Chief Compliance Officer and/or the compliance hotline. This information shall be forwarded to the Chief Compliance Officer who is responsible for taking appropriate action. The Complainant is responsible for maintaining confidentiality and cooperating with the Chief Compliance Officer and the Research Program Director and their designees with the Inquiry and any Investigation.

1.2 The Chief Compliance Officer will be responsible for ensuring that any review of Allegations or apparent instances of Research Misconduct, including any Inquiry or Investigation, is conducted in a timely, objective, thorough, fair, confidential and competent manner. The Research Program Director is responsible for appointing and assisting the Inquiry committee, ensuring that necessary and appropriate expertise is secured and avoiding bias or personal, professional or financial conflicts on the part of the individuals involved in the process. In the event that the Research Program Director cannot participate in the Inquiry due to a conflict of interest, the Chief Compliance Officer (or his/her designee) will assume the function of the Research Program Director.

1.3 Disclosure of the identity of Respondents and Complainants and witnesses while conducting Research Misconduct Proceedings must be limited, to the extent possible, to those who need to know as determined by Northside, consistent with thorough, competent, objective and fair Research Misconduct Proceedings and as allowed by law. Those who need to know and whom Northside may notify, may include: IRBs, journals, editors, publishers, co-authors, and collaborating institutions. Such disclosure no longer applies when Northside has made its final determination of Research Misconduct findings. Northside must, however, disclose identities of Respondents, Complainants, or other relevant persons to the Office of Research Integrity for review of Research Misconduct Proceedings. In addition, except as otherwise required by law, confidentiality of Research subjects' identities must be maintained and disclosure should be limited to those who have a need to know to carry out the Research Misconduct Proceeding. Northside may continue to manage published data and acknowledge that data may be unreliable.

1.4 The Program Director is responsible for promptly taking all reasonable and practical efforts to obtain and secure custody of all the Research Records and evidence needed to conduct Research Misconduct Proceedings, including such records that become known or relevant during the Research Misconduct Proceedings; inventory such records; and sequester the records in a secure manner. Where the Research Records or Evidence are located on or encompass scientific instruments shared by multiple users, Northside can obtain copies of the data from the instruments, so long as the copies are substantially equivalent in evidentiary value. A dated receipt should be signed by the Research Program Director (or his/her designee) and the person from whom the Research Record or Evidence is obtained, and a copy of the receipt should be given to the person. The Research Record and Evidence shall be locked and secured. Reasonable accommodations for access to data or copies of secured records will be made when necessary and appropriate. When possible, Northside will obtain the Research Records or Evidence before notifying the Respondent of allegations, and whenever additional items become known or relevant to the Inquiry or Investigation.

- a. When there are additional Respondents identified during an Inquiry or Investigation, Northside need not conduct a separate Inquiry for the new Respondent(s). Each additional Respondent will be provided with notice and an opportunity to respond to the Allegation(s).
- b. When an Allegation(s) involves Research conducted at multiple institutions, and a joint Research Misconduct Proceeding is conducted, one Institution must be designated the

lead Institution. The lead institution will obtain Research Records and other Evidence pertinent to the proceeding, including witness testimony from other relevant institutions. With mutual agreement, the joint Research Misconduct Proceeding may include committee members from involved institutions. Determinations regarding further Inquiry or Investigation is needed, and/or whether Research Misconduct occurred and any actions to be taken can be made jointly by the institutions involved, or by the lead institution.

1.5 A preliminary and informational Assessment of each Allegation of Research Misconduct will be made by the Research Program Director to determine if the Allegation merits a formal Inquiry. Upon receiving an allegation of Research Misconduct, the Research Program Director will promptly assess whether the Allegation (a) falls under the definition of Research Misconduct; (b) is within the applicability criteria §93.102, and (c) is sufficiently credible so that potential Evidence of Research Misconduct may be identified. While assessing the merits of the Allegation, the Research Program Director may consult in confidence with others as appropriate. If the Research Program Director determines no sufficiently credible and specific evidence supports the Allegation of Research Misconduct, and the Chief Compliance Officer concurs, the Allegation will be dismissed. A written report sufficiently detailing the Assessment, including the reasons for the dismissal, shall be maintained in a secure manner for at least seven (7) years. The Complainant may be notified of the dismissal and may appeal a decision for dismissal directly to the Chief Compliance Officer.

1.6 If, after the Assessment, the Research Program Director believes an Allegation meets the criteria listed in Section 1.5 and thus describes an instance of Research Misconduct and is sufficiently credible and specific so that potential Evidence of Research Misconduct may be identified, the issue will move to the Inquiry process (regardless of the funding source for the Research project). Northside will document the Assessment and promptly sequester all Research Records and other Evidence, and promptly initiate the Inquiry.

2.0 Inquiry

2.1 The purpose of an Inquiry is to determine whether an Allegation or apparent instance of Research Misconduct warrants a full Investigation or requires that special action be taken pending resolution of the Allegation or apparent Research Misconduct. The Inquiry will determine whether the Allegation of Research Misconduct appears to be well founded, the seriousness of the alleged misconduct, the scope of the alleged incident, and the relevance of any other information that is available. Because an Inquiry is an initial review, it does not require a full review of all of the Evidence related to the Allegation. An Inquiry, including preparation of the final Inquiry report and the final decision of the Chief Compliance Officer, must be completed within 90 calendar days of initiating the Inquiry. If the Inquiry takes longer than 90 days to complete, the Inquiry report must document the reason for exceeding the 90-day period.

2.2 To the extent possible, Inquiries (and resultant Investigations) will be conducted in a confidential manner so as to protect the affected parties. Although a person participating directly in the conduct of an Inquiry or Investigation must be qualified to evaluate the situation, no such person may have unresolved personal, professional or financial conflicts of interest with the Complainant, Respondent or witnesses.

2.3 If an Inquiry is made, the Research Program Director, in consultation with other Northside officials as appropriate, will appoint an ad hoc committee and committee chair within 10 business days of the initiation of the Inquiry. The committee shall consist of at least 3 individuals who do not have real or apparent unresolved personal, professional or financial conflicts of interest in the case, are unbiased, and have the necessary expertise to evaluate the issues related to the case. These individuals may be subject matter experts, administrators, lawyers, or other qualified persons and may

be from outside Northside. Additionally, the Chief Compliance Officer shall serve as a non-voting staff member of the Inquiry committee.

2.4 At the time of or before beginning the Inquiry, the Research Program Director will notify the Respondent in writing of the Allegation(s). If the Inquiry subsequently identifies additional Respondents, the Research Program Director will notify those individuals as well. A copy of the notice will also be provided to the Chief Compliance Officer, Vice President of Legal, Risk Management and Ancillary Services and other appropriate Northside officials. The notice should include:

- (a) the need to maintain confidentiality by all parties;
- (b) a summary of the Allegation(s) of Research Misconduct;
- (c) a description of the Inquiry process;
- (d) identification of the Inquiry committee;
- (e) a copy of applicable Northside policies and procedures;
- (f) a copy of Federal regulations and policies, if applicable; and
- (g) admonition against Retaliation.

2.5 To the extent not already completed at the Assessment/Allegation stage, the Research Program Director shall ensure for appropriate custody and maintenance of all the Research Records and evidence needed to conduct the Research Misconduct proceeding in accordance with Section 1.4 above. The Respondent shall assist with the location and identification of such records and evidence.

2.6 The Inquiry committee will review the merits of the Allegation(s) and recommend a course of action to the Chief Compliance Officer, including whether a full Investigation should be conducted. An Investigation is warranted if there is a reasonable basis for concluding that the Allegation(s) falls within the definition of Research Misconduct and preliminary information-gathering and fact-finding indicates that the Allegation(s) may have substance. The Inquiry committee may have access to Research Records and other documents relating to the alleged misconduct and may interview the Complainant, Respondent and any relevant witnesses. It shall not, however, attempt to reach a decision on the merits of the Allegation(s). An Inquiry does not require full review of all the Evidence related to the Allegation. The Inquiry committee shall prepare a written Inquiry report that includes:

- (a) the names, professional aliases, and positions of the Respondent and Complainant;
- (b) a description of the Allegation(s) of Research Misconduct;
- (c) PHS support, including, for example, grant numbers, grant applications, contracts and publications listing PHS support, if applicable;
- (d) a composition of the Inquiry committee, if used (e.g., name, position, subject matter expertise);
- (e) an inventory of sequestered Research Records and other Evidence reviewed and how sequestration was conducted;
- (f) transcripts of any transcribed interviews;
- (g) a timeline and procedural history;

- (h) any scientific or forensic analysis conducted;
- (i) the basis for recommending the Allegation(s) warrants an Investigation;
- (j) the basis on which any Allegation(s) do not merit an Investigation;
- (k) comments on the Inquiry report by the Respondent or Complainant; and
- (l) transcripts of any transcribed interviews;

2.7 The Inquiry committee shall provide a draft copy of the report to the Respondent, who may review and comment within ten (10) days of receipt. After receiving the comments of the Respondent, the committee will forward a final copy of its report, including comments from the Respondent, along with its recommendations, to the Research Program Director. If there is potential evidence of honest error or a difference of opinion, it will be noted in the Inquiry report

2.8 The Research Program Director shall review the final Inquiry report and ensure that it meets the requirements of Section 2.6 and that it contains: Director of Central Research Office/IRB shall review the final Inquiry report and ensure that it contains:

- (a) the name and position of the Respondent;
- (b) a description of the Allegation(s) of Research Misconduct;
- (c) PHS support, including, for example, grant numbers, grant applications, contracts and publications listing PHS support, if applicable;
- (d) the basis for recommending that the Allegation(s) warrants an Investigation; and
- (e) any comments on the Inquiry Report by the Respondent of Complainant.

2.9 The Research Program Director shall provide the Chief Compliance Officer the final Inquiry report. The Chief Compliance Officer shall review the report and determine in writing whether an Investigation is warranted. After this decision has been rendered, the Inquiry process is deemed complete.

2.10 The Research Program Director shall promptly notify the Respondent of the final Inquiry decision. If it is decided that an Investigation will be conducted, the Respondent must be notified of the decision before the Investigation begins. A copy of the notice of the final Inquiry decision will also be provided to the Chief Compliance Officer, Vice President of Legal, Risk Management and Ancillary Services and other appropriate Northside officials. The notice to all parties must include:

- (a) a copy of the Inquiry report;
- (b) the need to maintain confidentiality by all parties;
- (c) a description of the Investigation process if the case will proceed to an Investigation;
- (d) a copy of applicable Northside policies and procedures;
- (e) a copy of Federal regulations and policies, if applicable; and
- (f) admonition against Retaliation.

Additionally, if any Allegations of Research Misconduct not addressed in the Inquiry will be addressed during the Investigation, the Respondent must be notified in writing of these Allegations within a reasonable amount of time of the decision being made to pursue such Allegations.

2.11 If the Complainant disagrees with an Inquiry decision to dismiss the case, the Complainant may appeal to the Chief Compliance Officer. A notice of appeal should also be provided to the Respondent. The Chief Compliance Officer will review the case and make a final determination as to appropriate action.

2.12 If a decision not to conduct an Investigation is made, all the information assembled in the course of the Inquiry will be maintained in confidence for at least seven (7) years to permit a later assessment of the reason for determining that an Investigation was not warranted. See also Section 4.0 of this Policy for certain notification requirements that may be applicable.

2.13 If the Inquiry decision concludes that a formal Investigation will be initiated and the matter involves PHS supported Research or an application for PHS support for Research, the Office of Research Integrity must be notified in the time and manner required by Federal regulations (see 42 C.F.R. §§ 93.309 and 93.310(b)). Northside must notify, with the accompanying Inquiry report (see Section 2.6), the Office of Research Integrity of its decision to initiate an Investigation on or before the date the Investigation begins.

3.0 Investigation

3.1 The purpose of an Investigation is to examine thoroughly, in an unbiased and impartial manner, an Allegation of Research Misconduct and to determine whether such misconduct has taken place and if so, by whom and to what extent. A finding of Research Misconduct requires that there be a significant departure from Accepted Practices of the Relevant Research Community, that the misconduct be committed Intentionally, Knowingly, or Recklessly and that the Allegation be proven by a Preponderance of the Evidence. An Investigation shall begin within 30 days after the Inquiry decision determining that an Investigation is warranted and all aspects of the Investigation shall be completed within 180 days of beginning the Investigation, including conducting the Investigation, preparing the report of findings, providing a draft report for comment to the Respondent and sending the final report to the Office of Research Integrity. If Northside is unable to complete an Investigation of PHS supported Research within 180 days, the Chief Compliance Officer must request an extension in writing that includes the circumstances or issues warranting the additional time from the Office of Research Integrity. If the investigation takes longer than 180 days to complete, Northside will include the reasons for exceeding 180 days in the Investigation report.

Evidentiary standards:

(a) Burden of Proof: Northside has the burden of proof for making a finding of Research Misconduct. The Respondent has the burden of proof as to any affirmative defenses and mitigating factors. However, destruction of Research Records or Respondent's failure to furnish Research Records adequately documenting the questioned Research establishes a rebuttable presumption of Research Misconduct that may be relied upon by Northside.

(b) Standard of Proof: A determination that Research Misconduct has occurred must be established by a Preponderance of the Evidence.

3.2 If an Investigation is conducted, the Chief Compliance Officer, in consultation with other Northside officials as appropriate, will appoint an ad hoc committee and committee chair within ten (10) business days of the initiation of the Investigation. The committee shall consist of at least three (3) individuals who do not have real or apparent unresolved personal, professional or financial conflicts of interest in the case, are unbiased and have the necessary expertise to evaluate the issues related to the case. These individuals may be subject matter experts, administrators, lawyers or other qualified persons and may be from outside Northside. Additionally, the Chief Compliance Officer shall serve as a non-voting staff member of the Investigation committee

3.3 Upon formation of the Investigation committee and before the Investigation begins, the Chief Compliance Officer will notify the Respondent in writing of the Allegation(s) and any new Allegations of Research Misconduct not addressed during the Inquiry or initial notice of Investigation within a reasonable time of deciding to pursue the Allegation(s). If additional Respondents are identified during the Investigation, Northside may, but is not required to, conduct a separate Inquiry for each new Respondent. Identified Respondents must be notified of the Allegation(s), in accordance with Section 2.4 of this Policy, and provided with an opportunity to respond. Separate Investigation reports and Research Misconduct determinations are required for each Respondent.

3.4 To the extent not already completed at the Allegation and Inquiry stages, the Chief Compliance Officer shall ensure for appropriate sequestration, custody and maintenance of all Research Records and Evidence needed to conduct the Research Misconduct Proceedings in accordance with Section 1.4 above. The Respondent shall assist with the location and identification of such records and Evidence.

3.5 The Investigation committee will review the merits of the Allegation(s) and recommend a course of action to the Chief Compliance Officer, including any sanctions or administrative actions proposed to be taken. The Investigation will include a thorough examination of all Research Records and Evidence relevant to reaching a decision on the merits of the Allegation(s), including but not limited to, review of grant or contract files, reports, scholarly publications, manuscripts, and other documents; inspection of laboratory or clinical facilities and/or materials; and interviewing of each Respondent, Complainant and any other available party who has been reasonably identified as having an involvement in or knowledge about relevant aspects of the Investigation. The Investigation committee shall sufficiently document the Investigation, including recording and transcribing each interview and providing a copy of such recording or transcription to the interviewee for correction. Any exhibits shown during an interview must be numbered and referred to by that number in the interview. The Respondent must not be present during witnesses' interviews but must be provided a transcript of the interview. The Investigation committee shall diligently pursue all significant issues and leads discovered that are determined relevant to the Investigation, including any evidence of additional instances of possible Research Misconduct, and continue the Investigation to completion. Northside will consider whether additional researchers are responsible for the alleged Research Misconduct. If multiple institutions are involved, the investigation will be conducted in accordance with Section 1.4(b). The Investigation committee will prepare a written report that shall include:

- (a) a description of the nature of the Allegation(s) of Research Misconduct, including additional Allegation(s) addressed during the Research Misconduct Proceeding, if any;
- (b) a description and documentation of PHS support, if any;
- (c) a description of the specific Allegation(s) of Research Misconduct for consideration in the Investigation;
- (d) the Northside policies and procedures under which the Investigation was conducted;
- (e) Composition of the Investigation committee, including names, positions, and subject matter expertise;
- (f) Inventory of sequestered Research Records and other Evidence, except for records Northside did not consider or rely on; and a description of how any sequestering was conducted during the Investigation. The inventory will include manuscripts and funding proposals that were considered or relied on during Northside's Investigation;
- (g) Transcripts, with any corrections and numbered exhibits. of all interviews conducted, which must be recorded and transcribed;

- (h) Identification of the specific published papers, manuscripts submitted but not accepted for publication (including online publication), PHS funding applications, progress reports, presentations, posters, or other Research Records allegedly containing Falsified, Fabricated, or Plagiarized material;
- (i) Any scientific or forensic analyses conducted;
- (j) for each separate Allegation of Research Misconduct identified during the Investigation a statement of whether the Investigation committee recommends a finding of Research Misconduct and:
 - i. If the Investigation committee recommends a finding of Research Misconduct, the Investigation report must, for that allegation:
 - 1. identify whether the Research Misconduct was Falsification, Fabrication or Plagiarism, and if it was Intentional, knowing or in reckless disregard;
 - 2. state whether the other requirements for a finding of Research Misconduct were met;
 - 3. summarize the facts and analysis that support the conclusion and consider the merits of any reasonable explanation by the Respondent;
 - 4. identify specific PHS support, if any;
 - 5. identify whether any publications need correction or retraction; and
 - 6. identify the person(s) responsible for the Research Misconduct.
 - ii. If the Investigation committee does not recommend a finding of Research Misconduct, the Investigation report must include a detailed rationale.
 - iii. List any current support or known applications or proposals for support that the Respondent has pending with non-PHS Federal agencies.
- (k) A description of any recommended sanctions or other administrative action may be included.

3.6 The Investigation committee shall provide a copy of the report to the Respondent, who may review and comment within 30 days of receipt. At the same time, the Respondent must be provided a copy of, or supervised access to, the Evidence on which the report is based. The Investigation committee may also provide a copy of the report or relevant portions of the report to the Complainant, who may review and comment within 30 days of receipt. Upon receipt of any comments, the Investigation committee will compile the final report, which shall include and consider any comments of the Respondent and Complainant and will transmit it to the Chief Compliance Officer.

3.7 The report of the Investigation committee and its attachments will be forwarded to the Chief Compliance Officer for review and a written disposition. If the Chief Compliance Officer finds that the Respondent has not engaged in Research Misconduct, the Chief Compliance Officer will dismiss the complaint. If the Chief Compliance Officer finds that the Respondent has engaged in Research Misconduct, the Chief Compliance Officer may order appropriate sanctions and may initiate Northside procedures leading to possible additional sanctions and administrative action. The Chief Compliance Officer will notify the Respondent in writing, the Complainant, the Research Program Director, the Vice President of Legal, Risk Management and Ancillary Services and other appropriate Northside officials of the decision.

3.8 If the Complainant disagrees with an Investigation decision to dismiss the case, the Complainant may appeal to the Chief Compliance Officer. A notice of appeal should also be provided to the Respondent. The Chief Compliance Officer will review the case and make a final determination as to appropriate action.

3.9 All information assembled in the course of the Investigation will be maintained in confidence for at least seven (7) years to permit a later assessment. See also Section 4.0 of this Policy for certain notification requirements that may be applicable.

3.10 If the matter involves PHS supported Research or an application for PHS support for research, the Office for Research Integrity must be notified in the time and manner required by Federal regulations. Northside will promptly notify the Office of Research Integrity when a Respondent appeals Northside's findings on Research Misconduct or institutional actions. Northside, after the Chief Compliance Officer makes the final determination of Research Misconduct findings, will transmit the Institutional Record to the Office of Research Integrity, which must be logically organized. However, if the Institutional Record has not been transmitted prior to an appeal, Northside will wait until the appeal is concluded before transmission and will include the complete record of the appeal in the Institutional Record.

4.0 Adjudication

4.1 As required by applicable laws, regulations and other guidance, at the conclusion of the Investigation, or at any other time required by an involved granting agency, the Chief Compliance Officer will notify the granting agency of the facts of the case, the conclusions rendered, and the disposition of the matter, including actions taken by Northside, which will be documented in written decision. The Chief Compliance Officer will notify other outside parties as may be appropriate, including publishers or institutions with whom the party found to have committed Research Misconduct is now or has been professionally affiliated.

4.2 For PHS supported Research, the Research Program Director and the Chief Compliance Officer must carry Inquiries and Investigations through to completion and pursue diligently all significant issues. The Chief Compliance Officer must notify the Office of Research Integrity in advance if Northside plans to close a case at the Inquiry, Investigation, or appeal stage on the basis that the Respondent has admitted to committing Research Misconduct, or a settlement with the Respondent has been reached. The Chief Compliance Officer need not report to the Office of Research Integrity the closing of a case at the Inquiry stage on the basis that an Investigation is not warranted.

4.3 If the alleged misconduct is not substantiated by the Investigation, diligent efforts will be made to restore fully the position and reputation of the Respondent and to counter potential or actual Retaliation against the Respondent. In addition, all reasonable and practical efforts will be made to protect or restore the position and reputation of any Complainant, witness or committee member and to counter potential or actual Retaliation against them. However, if it is further demonstrated that the charges were brought under malicious or dishonest circumstances, Northside may bring appropriate action against the Complainant or others involved.

4.4 A permanent record, including the Institutional Record, of all Research Misconduct Proceedings, including but not limited to sequestered Evidence, including physical objects, committee reports, exhibits, minutes of meetings, and other materials, will be kept in a secure manner by the Research Program Director for seven (7) years after the completion of any proceeding involving the Research Misconduct Allegation(s). These records will be protected from release if release would compromise the conduct of an Inquiry or Investigation, constitute unwarranted invasion of privacy, or reveal the content of communications or recommendations of action to be taken. In the case of sponsored projects, the Research Program Director is responsible for determining and complying with reporting requirements; representing Northside in all negotiations with the sponsor; and implementing any administrative actions that may be directed by the sponsor.

4.5 At any time during a Research Misconduct Proceeding, the Chief Compliance Officer must act and notify the Office of Research Integrity without prior hearing or review should the Chief Compliance Officer have reason to believe that any of the following conditions exist:

- (a) The health or safety of the public is at risk, including an immediate need to protect human or animal subjects;
- (b) HHS resources or interests are threatened;
- (c) Research activities should be suspended;
- (d) There is a reasonable indication of possible violation of civil or criminal law;
- (e) Federal action is required to protect the interest of those involved in the Research Misconduct Proceeding;
- (f) The Chief Compliance Officer believes the Research Misconduct Proceeding may be made public prematurely so that HHS may take appropriate steps to safeguard evidence and protect the rights of those involved; or
- (g) The research community or public should be informed.

5.0 Time Limitation and Exceptions. This Policy generally applies to alleged Research Misconduct that happened within six (6) years from when Northside or HHS received an Allegation of Research Misconduct.

5.1 Exceptions. The six (6) year limitation does not apply when there is either a “subsequent use” or if the Office of Research Integrity or Northside in consultation with the Office of Research Integrity determines the alleged Research Misconduct could have a substantial adverse impact on the health and safety of the public. The “subsequent use” exception continues or renews an incident of alleged Research Misconduct that occurred before the six (6) year limitation through the Respondent’s use of, republication of, or citation to the portion(s) of the Research Record alleged to have been Fabricated, Falsified, or Plagiarized for the benefit of a Respondent. This also applies when a Respondent uses, republishes, or cites to the portion(s) of the same Research Record in published manuscripts, submitted PHS grant applications, progress reports submitted to PHS funding components, posters, presentations, or other research records within six (6) years of when the Allegations were received by HHS or an institution. When Research Misconduct appears subject to the subsequent use exception, Northside must document any determination that a subsequent use exception does not apply, records of which must be maintained according to this Policy.

References

	Reference Type	Title	Notes
Document ID	27920	Document Status	Official
Policy Manual	Corporate Compliance - System-Wide	Policy Manual Department Manager	Hernandez, Jorge
Document Owner	Hernandez, Jorge	Next Review Date	03/28/2027
Original Effective Date	02/28/2012		
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Reviewed	[09/24/2018 Rev. 1], [01/09/2020 Rev. 1], [10/11/2021 Rev. 2], [12/18/2024 Rev. 3]		

Attachments:

(REFERENCED BY THIS DOCUMENT)

Other Documents:

(WHICH REFERENCE THIS DOCUMENT)

The policies and procedures in this manual are guidelines only. They are not intended to reflect the legal standard of care. They are not a substitute for professional judgment or individualized care.

This policy contains confidential and proprietary business information that reflects Northside Hospital's business practices and models which it has developed over time. The disclosure of this information would cause significant harm to Northside Hospital's business interests. Therefore, this policy must be maintained in a strictly confidential manner and should not be disclosed or disseminated to third parties without the express written authorization of Northside Hospital administration.

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[https://www.lucidoc.com/cgi/doc-gw.pl?ref=nhatl:27920\\$4](https://www.lucidoc.com/cgi/doc-gw.pl?ref=nhatl:27920$4).